Common Market for Eastern and Southern Africa (COMESA)

Draft Policy Statements and Guidelines

for:

- **Commercial Planting of GMOs**
- **Trade in GMOs**
- **Emergency Food Aid with GMO Content**

June, 2010

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INTRODUCTION

The Common Market for Eastern and Southern Africa (COMESA), the largest trading economic bloc on the continent, has 19 member states, a population of over 389 million people, an annual import bill of around US$ 32 billion and export bill of US$ 82 billion. Agriculture plays a big role in the economies of COMESA countries in terms of livelihood, employment and international trade. Agricultural commodities are major drivers for growth in intra-COMESA trade. COMESA trade statistics indicate that total intra-COMESA trade during 2008 amounted to some US$6.3 billion. Of this, food and agricultural raw materials constituted US$2.1 billion. However, cyclical droughts and abiotic stresses in the region predispose these countries to food security problems, while biotic challenges such as disease pathogens and pests affect productivity of most staple crops. This has prompted the need to explore all available tools and options that would make a contribution in raising productivity, incomes and improving environmental quality.

In recognition of the importance of regional integration and trade, Article 4 of the COMESA treaty calls for member states to among others to: establish a customs union; and simplify and harmonize their trade documents and procedures. It is against this background that COMESA Ministers of Agriculture have consistently called for a regional approach to expanding opportunities for agricultural production, enhancing regional food security, increased regional trade and market access through research, value addition and trade facilitation. In response, key priorities for COMESA in consolidating its strategic objectives include implementing major programs in infrastructure, trade and agriculture. In the agricultural sector, the focus is on implementing the Comprehensive Africa Agricultural Development Programme (CAADP), a programme of the African Union whose implementation mandate in the region rests with COMESA. CAADP was established by the African Union's New Partnership for Africa's Development (AU/NEPAD) in July 2003 as the highest policy level framework for the coordinated development of agriculture in Africa. The overall goal of CAADP is to "Help African countries reach a higher path of economic growth through agriculture-led development, which eliminates hunger, reduces poverty and food insecurity, and enables expansion of exports."

Agricultural biotechnology, among the diverse options available, has been recognized as a viable tool that would make a significant contribution for improving crop yields, household incomes, and the nutritional quality of staple foods in an environmentally sustainable way. Indeed, the African Union (AU) Member States are seeking to develop strategies for addressing the challenges surrounding development and safe deployment of modern biotechnology for addressing poverty, hunger and malnutrition on the continent. Members have over the years been encouraged to develop functional biosafety systems and also domesticate the internationally legally binding instrument – the Cartagena Protocol on Biosafety. The aim of the Protocol, which entered into force on September 11, 2003, is to ensure an adequate level of protection in the field of safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account human health and the environment and specifically focusing on transboundary movements (Secretariat of the Convention on Biological Diversity, 2000).

The importance of regional cooperation in harnessing the technology safely and responsibly and handling of other GMO related issues is evident from the experience of other global regional blocs. In cognizance of this reality, COMESA endorsed the implementation of the initiative - ***Regional Approach to Biotechnology and Biosafety Policy in Eastern and Southern Africa*** (RABESA) in 2003.

RABESA was initiated by COMESA Ministers of Agriculture with the broad objective of supporting harmonization of biosafety policies among its member states. Since inception, the RABESA initiative has been implemented in close collaboration with the COMESA Secretariat, the Policy Analysis and Advocacy Program (PAAP) of ASARECA, ISAAA Africenter and the Program for Biosafety Systems (PBS). At the end of 2009, the Alliance for Commodity Trade in Eastern and Southern Africa (ACTESA) was created and endorsed as a specialized agency of COMESA by the Council of Ministers and the Heads of State. The main goal of ACTESA is to increase farmer productivity and incomes in the COMESA region through trade in staple crops. In cognizance of the potential of biotechnology in enhancing the quality and productivity of staple crops, a biotechnology and biosafety unit has been created within ACTESA. ACTESA will now be responsible for spearheading the biotechnology agenda of the COMESA region.

A number of consultative meetings and studies were conducted during the first phase of the RABESA initiative and afterwards a COMESA regional workshop was held in May 2006 in Nairobi, Kenya. The meeting made three recommendations for regional policy on GMO-related areas:

1. Adoption of a centralized regional risk assessment so as to create standardized and more transparent, cost-effective procedures; enable the sharing of resources, information and expertise.
2. Establishment of a central regional clearing-house to provide advice/guidance to member states on commercial trade in GM products
3. Development of guidelines on procurement of GM food aid at a regional level, which guidelines would then be used by each country to make decisions on case–by-case basis.

Other general policy recommendations included:

a. Development of regional centers of excellence in biotechnology and biosafety;
b. Establishment of a panel of experts to provide technical advice on issues pertaining to the development, handling and management of GMOs in the region;
c. Intensified efforts to increase public awareness of GMOs at the national level;
d. Capacity building in all aspects of biotechnology and biosafety; and
e. Proactive action by the COMESA secretariat on issues of collaboration and co-operation with the African Union, other regional economic communities, international organizations and other relevant entities in raising the region's capacity in the area of biotechnology and biosafety.

The need for regional cooperation was further reiterated at the AU workshop held in October 2006 in Addis Ababa and attended by experts representing diverse interests. A High-Level Africa Panel of Experts on Biotechnology (APB) was established to advise the AU on matters of biotechnology and biosafety and an African position on biotechnology developed and approved by the AU. The main message from the APB was:

"...regional economic integration in Africa should embody the building and accumulation of capacities to harness and govern modern biotechnology. Regional economic integration can be an institutional vehicle for mobilizing, sharing and using existing scientific and technology capacities,

including human and financial resources as well as physical infrastructure for biotechnology, R&D and innovation" (African Union, 2006).[1]

The African Union Commission's purpose is to guide modern biotechnology developments at national, sub-regional and regional (Africa-wide) levels. It aims to harmonise, coordinate and enhance capacity in a cost effective way. The idea is to create and strengthen regional centres of excellence in modern biotechnology and biosafety that would undertake a broad range of risk analysis issues. Its strategy includes policy and legal frameworks as one of four pillars under the Comprehensive Africa Agriculture Development Programme (CAADP). The AU position therefore, includes *inter alia* the establishment of a mechanism to facilitate the harmonisation of regulatory systems.

The implementation of the second phase of the RABESA initiative was endorsed at the 4th meeting of the COMESA Ministers of Agriculture held in Khartoum in March 2007. This phase focused on the development of harmonised regional policies concerning different aspects of GMO governance.

The main issues to be addressed in the policy statements and guidelines were summarized as follows:

Areas of focus	**Appropriate option /recommendation**	**Reasons advanced**
1. Commercial planting of GMOs	Centralized regional assessment, national decision making	• Standardized and more transparent • Cost effective • Sharing of resources, information and expertise
2. Commercial trade policy in GM produce	Advice/information from a central regional clearing house, national decision making	• Regional level assessment is cost effective • Cooperation in assessing issues • Assures national commitment • Information sharing • Capacity building
3. Emergency food aid policy	Guidelines developed at regional level, decision to be taken at the country level on case by case basis	• Facilitates transit of food aid to neighbouring states • Facilitates provision of food to the needy

[1] **Juma, C. and Serageldin, I.** (Lead Authors) 'Freedom to Innovate: Biotechnology in Africa's Development'. A report of the High Level African Panel of Experts on Modern Biotechnology. African Union (AU) and the New Partnership for Africa's Development (NEPAD), Addis Ababa and Pretoria.

An assessment of the status of biotechnology and biosafety policies and frameworks within Member States concluded that the COMESA countries are at different levels of development in terms of biotechnology and biosafety policy and legislative frameworks and would thus greatly benefit from a regional approach to development and implementation of biotechnology and biosafety policies and legal frameworks.[2]

The 5th meeting of the COMESA Ministers of Agriculture held in Seychelles in 2008 endorsed the drafting of regional biosafety guidelines & policies for:

a. Handling commercial planting of GMOs,
b. Trade in GMOs &
c. Procurement of emergency food aid with GM content

The development of regional policies and guidelines is a direct response to the resolution by the COMESA Ministers of Agriculture.

It is within the foregoing context that these policy statements and guidelines for handling commercial planting of GMOs, Trade in GMOs and Emergency Food Aid with GM content have been developed to respond to the COMESA Ministers of Agriculture resolutions and directives. The policies and guidelines duly recognize national sovereignty and existence of national biosafety laws and policies. A Panel of Experts (PoE) has been established as a permanent policy guiding committee within COMESA on matters related to biotechnology and biosafety and will direct implementation of the policies and guidelines.

ARTICLE 1.0 DEFINITIONS AND ACRONYMS

Applicant means a person or legal entity that notifies the legal authority by means of an official notification according to prescribed requirements of his intent to plant GMOs for commercial purposes.

Biosafety- protection of human health and the environment from the possible adverse effects of the products of modern biotechnology.

Biosafety Clearing House (BCH)- the term "clearing-house" refers to a mechanism or institution that brings together seekers and providers of goods, services or information, thus matching demand with supply. The Cartagena Protocol on Biosafety established a BCH in order to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and to assist Parties to implement the Protocol.

Commercial planting also referred to as "*general release"* and *"placing on the market" means* the introduction of genetically modified organisms into the environment for commercial purposes.

COMESA Panel of Experts on Biotechnology (also referred to as the Committee or Panel in this document) is a body of eminent scientists and other experts in Biotechnology established by

COMESA for the purposes of guiding it on policy and regulatory matters relating to development and application of modern biotechnology.

Emergency- life threatening man-induced situations or natural calamities that require humanitarian assistance and rapid response to save lives

Emergency food aid- provision of food and related assistance by humanitarian agencies to tackle hunger in emergency situations including cases of war or natural disasters.

Sub-Committee(s) (also *see* Risk Assessors) is a team of risk assessors constituted by the PoE from its membership, members of the RoRE and any other identified expertise for purposes of conducting specific risk assessments.

Genetically modified (GM) foods are foods made from genetically modified organisms (GMO) that have had their DNA altered through genetic engineering

Genetically Modified Organism (GMO) for the purposes of this document, means an organism that has been transformed by the insertion of one or more transgenes.

GM crop plant means a cultivated plant in which the genetic material has been changed through *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles.

Opinion is the final position of the Panel derived from consideration of reports of the risk assessors or the Sub-Committee(s) that is ultimately the position of COMESA on a given application as communicated to the Member State by the Secretary General.

Risk Assessors (also referred as Sub-Committees or GRASCOMs) means a group of experts constituted by ACTESA/COMESA for the purposes of conducting risk assessment of a given application according to the disciplines and fields of expertise required for that assessment.

Protocol means Cartagena Protocol on Biosafety to the Convention on Biological Diversity

Risk assessment policy means documented guidelines on the choice of options and associated judgments for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process is maintained.

Risk assessment for the purposes of this document refers to the process of auditing scientific data submitted to the centralized risk assessment desk of COMESA by the GRASCOMs in the process of generating information that will guide in the formation of an Opinion. The process involves reviewing scientific data generated from studies conducted by the applicant or his agents in order to evaluate risks associated with certain potential hazards, in this case GMO destined for commercial planting.

Risk Assessment is a specialized field of applied science that involves reviewing scientific data and studies in order to evaluate risks associated with certain hazards (EFSA description). In this policy and guidelines, the risk assessment shall involve using standard and internationally acceptable procedures to review applications received by COMESA from Member States and shall mainly

involve auditing the validity and reliability of the data submitted after which an Opinion shall be issued to submitting Member State.

Risk assessor in the case of the centralized risk assessment body is a scientist responsible for auditing data and information, consider the results of all studies and derive an independent opinion.

Roster of Reference Experts means a list of names of experts received to open calls for experts by the COMESA secretariat which clearly stipulate the requirements candidates must meet, and describing the selection criteria and process. The applications for rosters are reviewed by a selection panel appointed by the COMESA secretariat. These experts are bound to the rules governing conduct such as conduct of confidentiality and declaration of interests.

Seed is any plant propagating material

***Submitting Member State* (*also referred to as Applying Member State*)** is any member of the 19 Countries that constitute the COMESA regional bloc that submits an application for GMO commercial planting to COMESA Secretariat for consideration for risk assessment under the centralized regional risk assessment regime.

ABP	Africa Biotechnology Panel
ACTESA	Alliance for Commodity Trade in Eastern and Southern Africa
AU	African Union
CBI	Confidential Business InformationCBID COMESA Biotechnology and Biosafety Information Desk
COMESA	Common Market for Eastern and Southern Africa
CPB	Cartagena Protocol on Biosafety
FAO	Food and Agriculture Organization of the United Nations
GM	Genetically Modified
GMO(s)	Genetically Modified Organism(s)
GRASCOMs	GMO Risk Assessment Sub-Committees of COMESA
LMO	Living Modified Organism
LMO-FFP	Living Modified Organism for Food, Feed or Processing
NCA	National Competent Authority
OECD	Organization for Economic Cooperation and Development
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
PoE	COMESA Panel of Experts on Biotechnology
RABESA	Regional Approach to Biotechnology and Biosafety Policy in Eastern and Southern Africa
RoRE	Roster of Reference Experts
WHO	World Health Organization of the United Nations

ARTICLE 2.0 PREAMBLE

Cognizant of the fact that we COMESA Member States share common borders across which goods and services move for the benefit of our people, we recognize that we face the same developmental challenges including porous borders and transboundary movement of GMOs is inevitable. We

acknowledge that food insecurity is a formidable challenge that can partly be mitigated by commercial adoption of GM crops and food aid which may have GM content;

Cognizant of the fact that there is abundant trade amongst the COMESA countries and that COMESA countries are dependent on imports from other COMESA countries and non-COMESA countries and that the introduction of GM produce in one country is therefore likely to impact on other member countries through trade;

Cognizant of the fact that the potential benefits of a centralized regional policy for Member States in the COMESA region are enormous but giving due consideration to the independence and sovereignty of Member States and national regulatory systems to take final decisions;

Giving reference to the resolutions of the proceedings of the Council of Ministers held in Kampala in 2002 and the COMESA Ministers of Agriculture meeting held in Khartoum in 2007, we hereby undertake the following:

1. To institute and recognize a COMESA-regional level risk assessment mechanism for GMOs destined for commercial planting on a case-by-case basis and upon receipt of a request by Member States' national competent authorities,
2. To develop a regional system of approval after review of the risk assessment to regulate all instances in which GMOs are to be traded as food, feed or for processing in the COMESA countries,
3. To define a policy statement and operational guidelines to apply to food aid imports whose GM content has not been declared safe and released for public consumption in a COMESA member country by a competent authority designated to do so,
4. To endeavour to abide by the provisions of this policy and guidelines and to use them as appropriate in developing national policies and regulations to ensure safe development of agro-biotechnology in the COMESA region.
5. To direct the COMESA secretariat to formally inform every Member State of its obligation to recognize the guidelines and to submit and subject all applications for commercial planting of GMOs in its environment to the centralized regional risk assessment procedures. Member countries are also encouraged to await COMESA's Opinion on the application before taking national decision, given the fact that once commercially planted, a GMO may not be realistically restricted to only one Member State's territory.
6. To use the established centralized biosafety risk assessment mechanism and structures, including the COMESA Biotechnology/Biosafety Information Unit and Communication strategy *inter alia* to enhance information exchange and increase public participation and awareness on matters relating to biosafety and commercial planting of GMOs and their subsequent use for the overall benefit of COMESA citizens;
7. To recognize the decisions and actions taken by Member States basing on the fact that they also belong to other regional trading blocs that may have similar or different biosafety regulatory mechanisms, but give due and quick attention to any Member State that may be impacted by the actions of another Member State operating under a regulatory system of a different trading bloc. In such a scenario, the provisions of the Cartagena Protocol on Biosafety to which all COMESA members are signatories will apply.

SECTION 2.1 APPLICABLE CONVENTIONS AND ORGANISATIONS

A number of international conventions, codes and organisations are important reference points in

the development and reading of this Policy. These include:

- The ***World Health Organization*** and the ***United Nations Food and Agriculture Organization,*** which have been at the forefront in championing standards applicable to food trade through a joint programme and these apply to GM food trade as well. Their work through the Codex Alimentarius, also known as the food code, seeks to protect the health of consumers and to ensure fair practices in the food trade. It is a global reference point for consumers, producers and national food regulatory agencies which facilitate the formulation, harmonisation and implementation of food standards.

- The ***International Agreement for the Creation of an Office International des Epizooties (OIE)*** whose objective is to publish health standards for international trade in animal and animal products. The OIE Terrestrial and Aquatic Animal Health Codes contain standards, guidelines and recommendations designed to prevent the introduction of infectious agents and diseases pathogenic to animals and humans in the importing countries during trade in animals, animal genetic material and animal products.

- The ***International Plant Protection Convention (IPPC)*** which is the main international phytosanitary instrument. The IPPC uses a certification process to ensure exported plants, plant products and other regulated articles and consignments are in conformity with set standards. The IPPC guidelines for pest risk assessment provide a scientific means for governments to evaluate risks from imports.

- The ***Convention on Biological Diversity*** whose main objectives are the conservation of biological diversity, sustainable use of its components and the fair and equitable sharing of benefits arising out of utilization of genetic resources.

- The ***Cartagena Protocol on Biosafety*** whose main objective is to contribute to ensuring protection in the 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 and human health.

- ***World Trade Organization's*** (WTO) - The main aim of WTO Agreement on Sanitary and Phytosanitary Standards (SPS) is to ensure food safety and prevent the spread of diseases among plants and animals, encourage the adoption of scientific principles in the application of standards and promote SPS measures based on international guidelines and common risk assessment techniques. It designates Codex, OIE and IPPC in its preamble as standard setting bodies for food safety, animal and plant health. All COMESA countries are bound by these standards.

Consequently, any commercial trade of GMOs intended for food, feed or processing must meet the following standards:

- Food safety requirements in the recipient country;
- Export and import requirements of the country of origin and recipient countries;
- Relevant international food safety standards; and,
- Appropriate handling, packaging and documentation procedures and regulations.

ARTICLE 3.0 COMMERCIAL PLANTING OF GMOs

Introduction

Commercial planting of GMOs offers important opportunities for poor African farmers and consumers. The adoption of GM crops holds enormous potential in reducing problems associated with food insecurity, meagre household incomes and vulnerability resulting from climate change. Regional biosafety policies and guidelines on commercial planting of GMOs would thus be required to provide guidance on how to manage the inevitable transboundary movement of GMOs across the porous borders safely, responsibly and sustainably. A centralised regional risk assessment policy would allow COMESA countries to apply a harmonized approach to planting of GM crops and facilitate trade while respecting the national sovereignty of member states.

(a) Objectives

1. To provide COMESA Member States with a mechanism for centralized regional assessment of GMOs destined for commercial planting.

2. To provide an approach for conducting sustainable science-based risk assessments of international quality, on GMOs intended for commercial planting.

3. To promote harmonized risk assessment requirements according to internationally developed guidelines for GMOs.

4. To build the capacity of COMESA member states to conduct science-based risk assessment and management

5. To establish a regional information sharing mechanism on biotechnology and biosafety issues in the COMESA region.

(b) Scope

1. Policies and guidelines for operationalization of the regional GMO risk assessment subcommittees of COMESA (GRASCOMs) for centralized risk assessment

2. Policies and guidelines for risk assessment conducted by GRASCOMs

3. Risk assessment for the purpose of the policy and guidelines entails the assessment of GMOs or GM crop plants for possible risk to human health and the environment.

4. Policies and guidelines on socio-economic, cultural and other related considerations will be handled in accordance with the national biosafety frameworks.

SECTION 3.1 GUIDELINES FOR COMMERCIAL PLANTING OF GMOS

The proceeding section describe in details the standard operating procedures or guidelines to be followed as one of a number of important activities in the process of ensuring safety of GMOs destined for commercial planting in the COMESA region.

SECTION 3.2 ESTABLISHMENT OF COMESA BIOSAFETY AND CENTRALIZED GMO RISK ASSESSEMENT DESK

Within the Biotechnology and Biosafety Unit at the ACTESA/COMESA Secretariat, an office (Desk) will be established for administration and management of Biosafety activities including centralized GMO risk assessment. The main responsibilities will be to manage all aspects related to applications for risk assessment of GMOs intended for commercial planting and communicating with Member States on matters related to the centralized regional risk assessment process and outcomes. For purposes of risk assessment, the PoE will be the sole policy guiding body and will develop risk assessment strategies and policies and formulate risk assessment Opinions on applications submitted by Member States. These functions will be executed through ad hoc sub-committees, to be constituted by the PoE on case-by-case basis.

SECTION 3.3 COMESA RISK ASSESSMENT STANDARD OPERATING PROCEDURES (SOPS)

The PoE shall develop Standard Operating Procedures (SOPs) that will be approved by and endorsed by the COMESA Secretariat. These procedures shall guide the risk assessment process including, but not limited to the setting forth administrative procedures of the risk assessment sub-Committee(s). These SOPs shall be reviewed from time to time to ensure primacy and in consonance with rapid developments in agricultural biotechnology.

SECTION 3.4 GUIDANCE ON ESTABLISHMENT AND OPERATIONS OF THE GMO RISK ASSESSMENT SUB-COMMITTEES (GRASCOMS)

Several sub-committees will be constituted on a case-by-case basis to review the applications taking into consideration the standard practice in comparative analytical approach to GMO risk assessment. The sub-Committees to be named GRASCOM (GMO Risk Assessment sub-committee of COMESA) shall be non-permanent and constituted on a case-by-case basis for each application. Preferably, each GRASCOM should comprise of three groups of not less than three experts per group with expertise in the three main categories required of risk assessment i.e. a) molecular characterization, b) food and feed safety, and c) environmental impacts. These experts will be selected from a Roaster of Reference Experts (RoRE) identified by COMESA. The applicant member states shall be represented or shall be involved in the process of constituting GRASCOM(s). Non-members of the PoE or RoRE may be co-opted on the GRASCOMs as the COMESA Secretariat may deem it necessary. A meeting of all PoE members shall prepare the final **OPINION** on peer reviewing of the reports of the GRASCOM(s).

3.4.1 Code of Conduct

All members of the GRASCOM(s) and the PoE shall be bound by rules governing their conduct as citizens of the COMESA region and working on behalf of COMESA. During the execution of their responsibilities, they shall protect information given to them in confidence including Confidential Business Information (CBI) as may have been deemed to befit such a consideration by the submitting Member State. Other codes shall be stipulated in the SOPs and other COMESA operational policy documents.

3.4.2 Declaration of interests

Members of any constituted GRASCOM shall disclose any circumstances that could give rise to a potential conflict of interest. In the event of real conflict of interest, such a member or members shall excuse himself/herself from participating in risk assessment of the application in question. This also applies to the members of the PoE whereby a member who may have a conflict of interest shall be required to excuse him/herself from being present when a specific agenda item is being discussed or an Opinion is being taken.

3.4.3 Roster of Reference Experts:

Biosafety regulatory experts in the fields listed below, to be referred as a Roster of Reference Experts (RoRE) shall be available to serve on any sub-committee for the risk assessment as shall from time to time be constituted by the PoE:. The fields are:

1. Molecular biology (this is the crucial subject);
2. Plant breeding/agronomy (agronomic/phenotypic field studies for food, feed and environmental assessment);
3. Animal nutrition (the compositional studies analyzed for fresh materials values);
4. Biochemistry (protein chemistry):
6. Toxicology (toxicology studies);
7. Ecology (entomology, soil science, zoology, botany, microbiology).
8. Any other field of expertise as shall be deemed necessary in consultation with the chairperson of the Committee e.g. a farmer, statistical analysis, veterinary toxicology, human nutrition, food allergens and different branches of science.

3.4.4 Recruitment, Selection and Appointment Criteria

The Roster of Reference Experts shall be developed and updated from time to time by COMESA Secretariat with guidance of the PoE. These experts shall be sourced from Member States through a call for submission of curriculum vitae and motivational documents of relevance to the areas of identified competences. Selected experts will then be formally appointed by the ACTESA Chief Executive Officer. The Roster shall be reviewed by the PoE and updated at least once a year. Modalities of term of service and membership renewal shall be determined by COMESA Secretariat in consultation with the PoE.

3.5 GUIDING PRINCIPLES TO THE COMMITTEES FOR CONDUCT OF GOOD RISK ASSESSMENT

The following risk assessment principles shall be adhered to by GRASCOM(s) and the PoE and shall from time to time be reviewed by ACTESA/COMESA Secretariat in consultation with key stakeholders. These principles are based on international best practices employed by the *CODEX Alimentarius Commission* in assessment of human health risks associated with GMOs.

Transparency: The overarching principle for scientific risk assessment both for food and feed and for the environment shall be transparency in all aspects in reaching the final Opinion. Transparency in the procedures followed by GRASCOMs, formulation of the Opinion expert body- the PoE in execution of their responsibilities as well as the scientific assessment of data and information shall be maintained at all stages of risk assessment. All other procedural policies which may include the recruitment and selection of experts, risk assessment procedures as well as constitution of the GRASCOMs shall be as transparent as possible.

Independence: A functional separation of responsibilities between risk assessment at GRASCOM, PoE and national levels shall be maintained. To preserve independence between the three levels, an efficient and transparent mechanism of interaction shall be developed by COMESA Secretariat.

Participation: It is envisaged that stakeholder participation would mainly occur at Member State level. Guiding principles for scientifically substantiated contribution from stakeholders in both submitting and non-submitting Member States shall be developed.

Excellence: To enable centralized risk assessment gain respect, maintain credibility and trustworthiness, competency and efficiency at the RoRE, GRASCOM and the COMESA Biosafety and Centralised GMO Risk Assessment Desk shall be strictly observed. To further strengthen this system, a credible peer reviewing mechanism of GRASCOMs' or risk assessors' reports shall be standard practice.

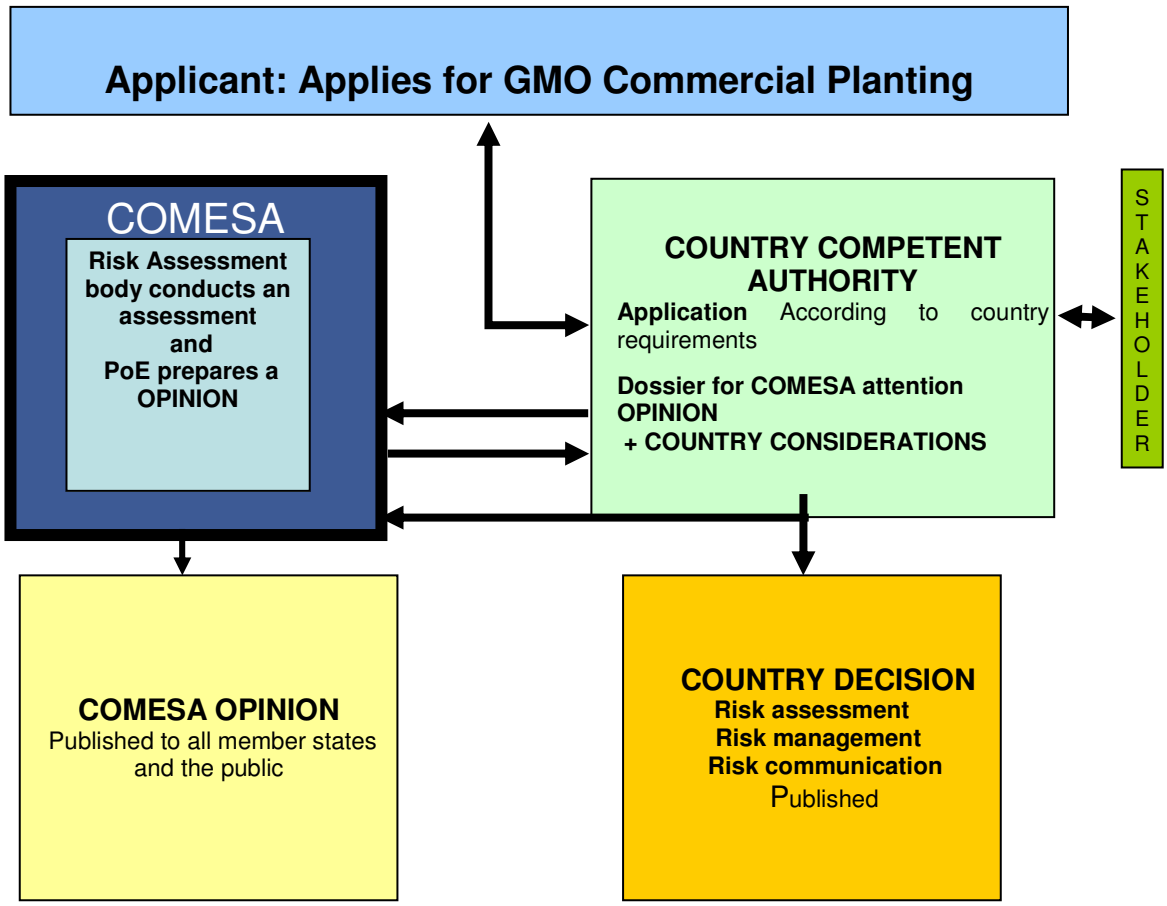
3.6 NOTIFICATION PROCEDURES

This section gives guidance on the procedures through which requests will be submitted to the ACTESA/COMESA Biosafety and Centralized GMO Risk Assessment Desk, how risk assessment shall be conducted and Opinions made and issued to the submitting Member State. A summary of these procedures is given below.

EXPLANATION OF THE FLOWCHART

Step 1: Application or submission of request to of NCA Member State(s)
Applicant (notifier) submits a request (notification) to the Member State's National Competent Authority (NCA) or any other biosafety reference point where the NCA has not been identified according to the country requirements

FLOWCHART OF THE PROCEDURES FOR CENTRALIZED RISK ASSESSMENT



Step 2: Risk assessment by GRASCOM(s) and peer reviewing by the PoE

a. The risk assessors that form the GRASCOM(s) are selected by the PoE Chairperson in collaboration with the COMESA Biosafety and Centralized GMO Risk Assessment Desk from the RoRE and appointed by COMESA Secretariat.
b. The applicant submit a complete dossier (in triplicate) to the Secretariat who then "courier" it to the appointed members of the risk assessment team or GRASCOM(s).
c. If more than one GRASCOMs are formed, they prepare each a report(s) according to the PoE SOPs and COMESA policies and principles. Reports include all questions from each GRASCOM and answers by the applicant. The risk assessors shall be experts in: a) molecular characterization, b) food and feed safety, and c) environmental risk assessment who may operate separately or together as a single GRASCOM.
d. Should additional information or an explanation be required from the applicant, the Desk may put such a request directly to the applicant with consent of the PoE ChairPerson

The three reports of the panels of the risk assessors, country reports as well as stakeholder inputs are peer reviewed by the PoE members for the session.

Step 3: COMESA and Submitting Member State solicit Stakeholder in-put

a. COMESA asks the submitting Member State to solicit stakeholder in-put, on the scientific risk assessment issues before the GRASCOM(s) using national regulations, which is thereafter submitted to COMESA for use in centralized risk assessment and making of the final Opinion.

b. Non-applying Member States may also be invited to make stakeholder in-put on this scientific risk assessment issues before the GRASCOM(s) directly to COMESA through internet/e-mailbased channels and other realistic means

Step 4: Opinion of COMESA on the Application

a. The PoE considers the GRASCOM(s) reports and indicative Opinions in a peer reviewing manner whereby all members of the Panel are involved.
b. Stakeholder in-put on risk assessments from Member States is given due attention in making the Opinion.
c. The PoE Chairperson and Secretary prepare the final Opinion, which is confirmed by members of the Panel, signed by the Chairperson and Secretary.
d. The Opinion then is forwarded to COMESA Secretary General for endorsement and subsequent dissemination or communication to the applying or submitting Member State(s) through their NCA(s)
e. Member States are obligated to communicate to COMESA with justifications, their final definition on whether or not to authorize commercial planting or not.
f. The opinion is published on the COMESA Website, COMESA BCH site and is availed on request in writing to any other Member State than the one in which commercial planting is anticipated to be effected
g. Member states are also obligated to make their decisions public in accordance with Article 23 of the Cartagena Protocol on Biosafety.

REFERENCE TO EXAMPLE APPLICATION

The example is the opinion of EFSA on GM maize TC1507 from Pioneer Hi-Bred. Please refer to the website of AGBIOS for links to different countries for risk assessment reports involving this trait. http://www.agbios.com

3.7 APPLICATION REQUIREMENTS

Any person, company or legal entity intending to commercially plant a GMO(s) in any COMESA state shall apply to the National Competent Authority of recipient Member State. It is mandatory under this policy and guidelines that such an application shall be forwarded to COMESA Secretariat for consideration by the PoE under the centralized regional risk assessment mechanism. Full dossiers and associated documentation shall be submitted together with the request. The submitting Member State will meet costs of submitting the dossiers and any other costs relating to the risk assessment as shall from time to time be determined by COMESA. After the risk assessment has been conducted by GRASCOM(s) and final Opinion made, the PoE, through

COMESA Secretariat shall communicate the Opinion to the submitting Member State. Decision on whether to authorize or not to authorize commercial planting of GM plants rests in the national legal and regulatory systems of the submitting Member State BUT such a decision shall not be taken before receiving the Opinion sought from COMESA.[3] [4] Member States are obligated to communicate to COMESA with justifications, their final decision on whether or not to authorize commercial planting.

COMESA will put in place mechanisms to make information required from the Member States as clear as possible to minimize the need for additional information for the purposes of facilitating timely risk assessment. In the event that more information is needed to finalize the centralized risk assessment, it will be requested by COMESA from the Member State following stipulated guidelines to be developed by COMESA Secretariat in consultation with the PoE.

3.8 GUIDANCE ON RISK ASSESSMENTS AND PREPARATION OF OPINIONS

Risk assessment shall be conducted on a case-by-case basis. The recommended approach is described as "comparative analysis" which includes determining 'substantial equivalency' whereby the GM product is compared in several ways with the nearest iso-line in the case of crop plants. A critical component for assessment is molecular characterization as well as the toxicology assessment of "novel" protein (toxicity and allergenicity). These constitute the identification of the possible hazard to human health. Characterization and exposure assessment are the next steps. For environmental assessment, exposure assessment is very important and data from such studies shall be considered. Application information requirements according to the Cartagena Protocol on Biosafety are given as Annex 1 of this document. International guidelines such as those approved by *Codex Alimentarius Commission* as well as the various documents prepared by the OECD shall also serve as points of reference.

The risk assessors in the subcommittee (GRASCOM) shall be issued with the Risk Assessment Policy and requisite Terms of Reference by COMESA Secretariat. Once the risk assessment is completed, the PoE shall peer review reports of the GRASCOM(s) (the risk assessors), as applicable including their indicative Opinions. The product of the scientifically conducted risk assessments shall be the Opinion formulated by the PoE in a transparent and open[5] way. It shall be endorsed by the Chairperson and Secretary of the PoE and subsequently communicated to the submitting Member State by ACTESA Chief Executive Officer within 60 days from the time of submission of the dossier, which is within the provisions of the 270 days timelines provided for by the Cartagena Protocol on Biosafety. This time excludes the time taken when the submitting Member State is sending additional information, as may be requested by COMESA. The Opinion shall also be sent to the other COMESA Member States and made available in the public domain.

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[3] Any information submitted by the National Competent Authorities to COMESA shall exclude the Confidential Business Information (CBI)[3] unless such information is being submitted for purposes of risk assessment and/or review by GRASCOM.

[4] It does happen from time to time that the experts have additional questions and need more information than submitted. The applicant should have the opportunity to respond, communication of which shall be conducted via the National Competent Authorities.

[5] With "open" is meant that the terminology used be such that regulatory decision makers will understand the meaning expressed. .Details explaining considerations made to arrive at the Opinion will be available at COMESA Secretariat

3.9 PUBLIC PARTICIPATION AND INFORMATION

Stakeholder in-put that could add value in preparation of the final Opinion shall be sought from Member States. The submitting Member State shall have the responsibility of conducting public consultations relating to the risk assessment under consideration by COMESA and submit relevant public views to COMESA for purposes of facilitating the risk assessment process. The public in other Member States may be called upon by COMESA to make in-put into the review process on a case-by-case basis, through e-channels and other appropriate means. Member States are encouraged to solicit comments and inputs from stakeholders at the national and regional levels in a participatory manner.

The risk assessment procedures for commercial planting of a GMO, or the results of other deliberations that may be of significance to general stakeholders, shall be publicized in the form of Public Notifications through and by Member State NCAs, a radio announcement or placement in at least two popular daily newspapers. In addition, all procedures and structures as described in the preceding sections of this document, as deemed appropriate and in accordance with Article 23 of the Cartagena Protocol on Biosafety, shall be made available in the public domain.

ARTICLE 4.0 COMMERCIAL TRADE IN GMOS

Introduction

In pursuit of regional integration, the COMESA Heads of State launched the Customs Union (CU) in 2009 to facilitate unrestricted movement of goods, services and people. Simplification and harmonisation of customs legislation and procedures is one of the key elements of the CU. COMESA is also advocating for strategies such as 'maize without borders' to remove trade barriers in the movement of maize across member states. Maize is one of the most widely traded and distributed commodity accounting for 50% of COMESA's total grain imports. And, while the commodities that African countries export to GM sensitive destinations are not yet available in GM form, Egypt, a COMESA member state, has approved commercialisation of GM maize. Further, a number of COMESA member countries belong to the Southern Africa Development Community (SADC) where South Africa, a SADC member grows both yellow and white GM maize on commercial scale. With these developments and the increased field trials currently being undertaken in the region, a Commercial Trade Policy to guide COMESA countries on trade in the region and with other parts of the world with respect to GM crops and their products is necessary. In the absence of such a regionally recognized policy, potential disruption of intra-regional trade would be a major threat.

(a) Objectives

1. To provide centralized guidance on COMESA trade in GMOs ;
2. To provide a harmonized mechanism for decision-making on trade in GMOs among COMESA member countries;
3. To provide guidance on handling of GMOs on transit for sale within the COMESA region.

(b) Scope

This policy and guidelines cover commercial trade of GMOs intended for planting (seed) or for direct use as food, feed or processing within the COMESA region and will apply to trade between COMESA members and among COMESA and non-COMESA members. Where commercial trade involves GM seed originating from a non-COMESA country, it must go through the COMESA Panel of Experts (PoE) on biotechnology who will provide a science-based opinion after a risk assessment review process. At present, the regulatory approach on GM food labelling varies in different countries and areas, and can be broadly classified as voluntary or mandatory. Policies and guidelines on labelling will therefore be handled at the national level in accordance with the Cartagena Protocol provisions and country- specific set of implementing regulations.

SECTION 4.1 GENERAL GUIDELINES

a. For a GMO from a non-member to be traded as food, feed or for processing in COMESA countries, approval thereof must have been granted by the National Competent Authority of one of the countries and/or an Opinion on the risk assessment review conducted by GRASCOM availed.
b. The decision on commercialization of the GMO shall, in addition to being relayed to the Biosafety Clearing House, be shared within COMESA member states through the PoE acting in consonance with the ACTESA/COMESA Biosafety Office for information and to facilitate future decisions on trade with the product among member countries.
c. National sovereignty in decision-making will be respected.

SECTION 4.2 GUIDELINES AND PROCEDURES FOR TRADING IN GM SEED FROM A COMESA COUNTRY

a. For a GM seed approved in a COMESA country which is traded to another COMESA country where the originating and receiving environments are similar, approval should be granted. In the event of a dispute regarding similarity, an opinion will be sought from the PoE through the COMESA Secretariat who will constitute a GRASCOM to provide its opinion. For example, a GM seed approved in Uganda and sought to be traded in Kenya's Western Province would be deemed to be moving within similar environments unless there is an objection.

b. For a GM seed approved in a COMESA country which is traded to another COMESA country where the originating and receiving environments are different, the matter shall be submitted to the PoE through COMESA Secretariat for risk assessment of introducing the GMO into the new environment by a GRASCOM. For example, a GM seed approved in Egypt and sought to be traded in Kenya's Central Province would be deemed to be moving between different environments and its suitability would be subjected to a GRASCOM to conduct a risk assessment for the GMO in the receiving environment and offer an Opinion.

SECTION 4.3 GUIDELINES AND PROCEDURES FOR TRADING IN GMOS FOR FOOD, FEED OR PROCESSING

a. For a GMO approved in a COMESA country which is traded to another COMESA country intended for food, feed or for processing, approval should be given upon application unless tangible evidence of toxicity, allergenicity, digestibility or nutritional changes is raised in the receiving country. Such evidence should be submitted to COMESA Secretariat through the PoE for evaluation by a GRASCOM and provide its opinion of whether it should be traded.
b. GMOs intended for food, feed and for processing must be accompanied by a statement that it is not intended for intentional introduction into the environment.

SECTION 4.4 GMOS IN TRANSIT

a. For a GMO approved in one COMESA country transiting through another COMESA country, automatic approval should be given provided trans-boundary movement guidelines of the Cartagena Protocol are observed.

b. In the event of an objection to transit for a GMO approved in a non-COMESA country transiting through a COMESA country, the matter should be referred to the PoE for a scientific opinion on whether there are any risks of such transfer.

SECTION 4.5 GMOS FROM A NON-COMESA COUNTRY

1. Seed

a. For approved GM seed that has not been approved in a COMESA country, an application shall be made to the importing country. The importing country shall transmit the risk assessment dossier to the PoE who will constitute a GRASCOM to conduct the risk assessment and provide its informed opinion.

b. The importing country shall make a determination on whether to approve or not based on the PoE's (through a GRASCOM) risk assessment opinion and relay that decision to the applicant and the COMESA Biosafety Office.

2. Food, Feed or for Processing

a. For a GMO intended for food, feed or processing and approved in a non-COMESA country which is traded for the first time in a COMESA country an application should be made to the PoE through COMESA Secretariat for a scientific risk assessment by GRASCOM.
b. For a GMO intended for food, feed or processing and approved in a non-COMESA country which has been traded in another COMESA country automatic approval shall be given unless tangible evidence of toxicity, allergenicity, digestibility or nutritional changes is raised in the receiving country. Such evidence should be submitted to the COMESA

Secretariat for evaluation by the PoE through a GRASCOM and its opinion of whether it should be traded.

c. GMOs intended for food, feed and for processing must be accompanied by a statement that it is not intended for intentional introduction into the environment.

SECTION 4.6 ADVENTITIOUS/ LOW LEVEL PRESENCE OF GM

a. Where a consignment of non-GMO food, feed or for processing has low levels or adventitious presence of GMO(s) approved in a COMESA country and which has gone through the PoE's GRASCOM risk assessment process, the consignment will be accompanied by a statement to the effect that it *may contain LMO-FFPS which have been approved in the particular COMESA country concerned and gone through the GRASCOM risk assessment process.* The statement shall have a list of possible unique identifiers for each GM event possibly present in the consignment, and the authorization to export all possible varieties. This might be the case for instance, where a maize consignment from Egypt to Kenya has some unspecified *Bt* maize content.

b. Where a consignment of a non-GMO intended for food, feed or for processing has possible (albeit not definitively known to be present) GM event approved in a non-COMESA country, the consignment will be accompanied by a statement to the effect that it *may contain LMO-FFPS which have been approved in the exporting country.* The statement should have a list of unique identifiers for each GM event possibly present in the consignment, and the authorization to export all possible varieties.

SECTION 4.7 ESTABLISHMENT OF A CENTRAL REGISTRY

a. A web-based register of all GMOs approved for commercial trade in COMESA countries and their identifiers shall be established and regularly updated.

b. Once approved in the country where the application is first made or by a GRASCOM constituted by the PoE, the GMO shall be placed on the web-based register and assigned a number for reference purposes.

ARTICLE 5.0 HANDLING FOOD AID WITH GM CONTENT

Introduction

A number of COMESA member countries are perpetually in need of emergency food aid during human-induced situations or natural calamities (life threatening) that require humanitarian assistance and rapid response to save lives. According to the World Food Programme (WFP), sub-Saharan Africa accounted for 67% of global emergency food aid deliveries in 2007 and about 85% of the deliveries went to COMESA countries. Currently, in the COMESA region, there is no harmonized policy regarding procurement of food aid with GM content and member countries who also belong to multiple trading blocs have adopted a variety of approaches ranging from unconditional acceptance, "milling prior to distribution" guidelines endorsed by SADC countries in Dar es Salaam in 2003, to embracing a total ban milled or otherwise. In a continent beset by

various emergencies and where food production per capita has been declining over the past several decades, total rejection is not a preferred option as it reduces the pool from which humanitarian organisations can draw, complicates emergency operations and ultimately worsens the plight of millions of people.

Considering that all COMESA members have ratified the Cartagena Biosafety Protocol, embracing the distinction the Protocol makes between transboundary movements of LMOs intended for human consumption, feed, or processing, as opposed to those intended for release into the environment for example could suffice without placing excessive burden on humanitarian and donor organizations. When whole kernels of GM maize enter a country as food aid, they can clearly be classified as the former. The Protocol places a minimum regulatory standard on food trade (including aid) of this kind; the exporter must notify importers that the shipment "may contain LMOs" and must notify that the grain is not meant for "intentional introduction into the environment." Beyond this, importers and exporters can treat these LMO shipments in the same way they treat conventional food shipments.

COMESA recommends that its members adopt this basic approach to food aid imports. If such countries wish to go above the COMESA policy by demanding milling or by banning all food aid with GM content, this would be their sovereign right but must be weighed against universal ethical and moral standing of saving lives. As a prerequisite, all food aid, whether it contains GM or not, needs to satisfy international and national food safety requirements including: Food safety requirements of the country where it originates; Food safety requirements of the recipient country; Applicable international standards, guidelines and requirements including those set by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) ; and any additional import requirements if any of the recipient country or transit country as the case may be.

(a) Objectives

1. To provide for harmonised handling procedures of food aid with GM content in the COMESA region.
2. To expedite delivery of food aid with GM content to the needy during emergencies.

(b) Scope

1 The policy statement and operational guidelines will apply to food aid imports whose GM content has not been declared safe and released for public consumption in a COMESA member country by a competent authority designated to do so.

2 The policy and guidelines are not intended to apply to food aid in general and food aid whose GM content had already been declared safe and released in a COMESA member country; or is less than 5%.[6] A signed statement by the applicant that such food aid has already been approved for commercialization and released for public consumption in a COMESA country will suffice.

[6] There is no international consensus on threshold levels for GM foods. This varies from one country to another. A threshold level of 5% is practical and would impose less technicalities on delivery of emergency food aid. This threshold level has been adopted by countries such as Canada and Japan based on regulatory impact assessment studies

SECTION 5.1 GENERAL GUIDELINES

1. With a view to facilitating the transit of food aid to neighbouring states and ultimately ensuring expeditious delivery of food to the needy in the region in the event of an emergency, COMESA hereby adopts this policy and recommends the same for implementation by its member countries.

2. COMESA acknowledges the sovereign rights of its members and the ultimate decision whether or not to accept food aid with GM content will be made by the respective national government or a designated competent authority of the recipient country or transit country as the case may be.

3. A signed statement by the applicant that the GM food aid had already been released for public consumption in a COMESA member will apply when transferring food aid with GM content from one COMESA country to another in a situation where the GM food had already been released for public consumption in a COMESA country.

4. In cases where food aid with GM content has not already been declared safe and released for public consumption in a COMESA member country, such food aid should meet the following conditions:

    a. An application will be submitted to the recipient country consistent with the procedure set forth below and a decision to import the food aid taken by the government of the recipient country;

    b. Should be clearly identified in the manner required by the Cartagena Protocol on Biosafety for LMOs-FFP. Accompanying documentation should clearly indicate that such food aid "may contain LMOs" and is not intended for intentional introduction into the environment.

    c. Decisions on whether or not GM food aid in grain form should be milled or rendered unsuitable for planting prior to distribution shall be made at the importing COMESA Member State level in accordance with its national biosafety regulations and on scientific grounds. All milled GM food aid must meet nutritional requirements, if necessary through fortification or ultimately supplementation, in line with applicable Codex Guidelines.

c. Transit COMESA member states shall facilitate and expedite transportation of emergency food aid. Port-of-entry countries that have not approved imports of GM food aid, or milling is a requirement, should allow the transportation of such consignments without undue delay through their territories to neighbouring land-locked countries. The importer will be expected to comply with biosafety requirements for transportation in the transit and destination countries.

SECTION 5.2 GUIDELINES AND PROCEDURES FOR HANDLING FOOD AID WITH GM CONTENT

(a) General Policy: It is the policy of COMESA that:

1. These policy statement and guidelines should be distributed to all its member countries for the purposes of:

   a) Fostering a harmonized approach to handling food aid with GM content in the COMESA region with the overall objective of delivering such food to the needy in a speedy manner when there is an emergency; and

   b) Serving as a framework for policy, legal and regulatory review and decisions agreeable to each member country.

3. Notwithstanding anything to the contrary contained in the policy statement and these guidelines (e.g. those having dual membership in other regional trading blocs), each COMESA member country retains the right to accept or reject GM food aid within its boundaries.

4. COMESA member countries should regularly alert leading relief agencies including the WFP and inform the BCH of any changes in their national biosafety policy, legal and regulatory systems in relation to the delivery of emergency food aid with GM content. Such communication is important to enable relevant relief agencies make necessary logistical and financial adjustments for timely response during times of humanitarian crisis.

(b) Application: An application to introduce food aid with GM content must:

1. Be made in writing and accompany the applicant's import permit application to the authority designated to handle such applications in the recipient country or, for food aid with GM content in transit, the authority designated to handle import permit applications in the transit country;

2. Contain the name and details of a contact person for further information;

3. Contain certification by the applicant that such GM food aid has been or will be clearly identified as containing LMOs and is not intended for intentional introduction into the environment. This is in addition to food safety requirements that any food aid needs to meet, irrespective of whether it contains GM content or not.

(c) Withdrawal of application or appeal: An applicant may withdraw his/her application or appeal, as the case may be, at any time prior to the issuance of a final decision by the relevant authority.

(d) Review of application: Following receipt of an application to introduce food aid with GM content, the authority designated to handle import permit applications for food in the recipient country must:

a. Inform the applicant in writing of the receipt of the application within ten (10) days;
b. Examine the application for its conformity with the requirements of these guidelines; and,
c. Evaluate potential risks to human health and the environment by the proposed introduction from information filed with the BCH.

(e) Decision:

1. The relevant competent authority must decide on an application to introduce food aid with GM content and communicate such decision to the applicant as soon as possible but no later than 30 days following receipt of the application. The decision should be based on the guidelines stated above (Section 5.0) and the Cartagena Protocol on Biosafety

2. The relevant competent authority must clearly indicate the scope, period of validity and any conditions under which an approval is granted.

3. The relevant competent authority must assign reasons for refusal to approve an application.

4. The authority designated to handle import permit applications for food must make such decision available to the public by whatever means the authority deems appropriate within a period of 15 days after issuing a decision, unless there is an impending appeal. Such communication should not contain information designated as confidential by the applicant or other provider of information.

(f) Appeals:

1. The applicant must be offered the opportunity to appeal a refusal to grant an approval within 15 days of the decision.

2. The relevant competent authority must consider an appeal with due regard to any additional information provided by the applicant and communicate a decision to the applicant within 30 days of receiving the appeal

(g) Variation or revocation of approval:

1. The relevant competent authority may vary or revoke an approval to introduce food aid with GM content where it determines after a post-approval inspection that an applicant had made false statements in the certification or that new information had become available to the relevant competent authority which it considers would pose a risk or damage to humans and/or the environment by introduction of the GM food aid.

2. The relevant competent authority must within a period of 15 days after revoking or varying an approval, make such decision available to the public by whatever means the authority deems appropriate. Such communication must not contain information designated as confidential by the applicant or other provider of information.

ARTICLE 6.0 CAPACITY BUILDING

COMESA shall take the necessary steps and initiatives to mobilize resources for continuous and strategic capacity building of Member States with limited capacity for risk assessment and regulation of GMOs to enable them competently participate in the centralized regional risk assessment framework and to take credible decisions at country-level pertaining to trade in GM produce and in handling food aid with GM contents Member states are encouraged to utilize the COMESA Biosafety Roadmap in their capacity building activities. In addition, members of the PoE and Roster of Reference Experts shall regularly be exposed to regulatory systems in countries where GMOs have been commercially cultivated or traded in order to continuously keep them abreast with diverse practices in GMO risk assessment.

6.1 AWARENESS CREATION

COMESA will work with member states to establish programmes dedicated to creation of awareness on the existence and potential benefits and risks of the various agricultural biotechnology applications among the target farmers and other stakeholders. Localization and implementation of the COMESA Communication Strategy will guide the activities in awareness creation. Capacity building will also include effective communication of biosafety decisions i.e. risk communication skills.

ARTICLE 7.0 COMESA BIOTECHNOLOGY AND BIOSAFETY INFORMATION DESK

The COMESA Secretariat shall establish a Biotechnology and Biosafety Information Desk (CBID) within the Biotechnology and Biosafety Unit to facilitate storage and exchange of information on biotechnology and biosafety both from within and outside the region. The exchange of information shall not be restricted to internet-based distribution only and will encompass other information sharing mechanisms as described in the COMESA Communications Strategy.

The CBID shall be linked to the BCH of the Cartagena Protocol on Biosafety to facilitate information sharing and exchange including access to the roster of experts. It will also be linked to the NEPAD Biosafety Information system under the NEPAD Office of Science and Technology (NOST) handled by the African Biosafety Network of Expertise (ABNE). The CBID will host COMESA's roster of experts, updates of biotechnology and biosafety activities received from Member States' competent authorities, summaries of risk assessment reviews conducted by Member States competent authorities as well as those conducted by the PoE. It will also host any other information that the Member States or the Secretariat shall deem relevant for the benefit of COMESA citizens, importantly related activities from other sub-regional trading blocs chief among them the East African Community (EAC), the Economic Community of West African States (ECOWAS), the Southern Africa Development Community (SADC) and West African Economic and Monetary Union (WAEMU) of which some COMESA members belong. Contact points for Member States without official competent authorities shall be identified and included in the COMESA information system.

ARTICLE 8.0 MONITORING AND SURVEILLANCE

Member States' national competent authorities shall put in place mechanisms for continuous and regular monitoring of commercial plantings, trade and food aid of GMOs authorized under their territories and keeps the COMESA Secretariat updated on any accidents, emergencies or epidemiological findings that may be associated with the authorized events. They may commission scientific investigations to verify such incidents or seek the PoE interventions and update the Secretariat with the findings of such investigations.

ANNEX 1: GUIDANCE ON INFORMATION IN APPLICATION FORMS AND RISK ASSESSMENT AS PER CARTAGENA PROTOCOL ON BIOSAFETY (CPB) ANNEXES I AND II AND III[7]:

CBP ANNEX I: Information Required In Notifications Under Articles 8, 10 And 13 of the Protocol

a) Name, address and contact details of Applicant
b) Name of the Proposed Country where Commercial Planting is to be implemented
c) Country of Export of the GMO, where applicable
d) Name and identify of the GMO, as well as the domestic classification, if any, of the biosafety level of the GMO in the State of export, where applicable
e) Intended date of planting of the GMO crop, if known,
f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or potential organisms related to biosafety
g) Centres of genetic diversity, if known, of the recipient organism and /or the potential organisms and a description of the habitats where the organism may persist or proliferate
h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism related to biosafety
i) Intended use of the GMO or products thereof, namely, processed materials that are of GMO origin, containing novel combinations of replicable genetic material obtained through the use of modern biotechnology
j) Quantity or volume of the living modified organism to be planted
k) Suggested methods for safe handling, storage, transport and use including packaging, labelling, documentation, disposal and contingency procedures, where appropriate
l) Regulatory status of the Genetically Modified Organism within the State of Export, where applicable (for example, whether it is prohibited in the State of Export, whether there are other restrictions, or whether it has been approved for commercial planting), and if the GMO is banned in the State of Export, the reason or reasons for the ban.
m) Result and purpose of any notification by the exporter to other States regarding the GMO to be commercially planted
n) A declaration that the above information given is factual

CPB ANNEX II: Information Required Concerning GMOs Intended for Direct Use as food or Feed, or for Processing

a) The name and contact details of the applicant
b) The name and contact details of the authority responsible for the decision
c) Name and Identity of the GMO to be commercially planted
d) Description of the Genetic Modification, the technique used, and the resulting characteristics of the living modified organism
e) Any unique identification of the GMO
f) Taxonomic Status common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety

[7] *Verbiage* of the a*nnexes is slightly modified, in some parts to fit the purpose and provisions of this Policy and Guidelines*

g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organism may persist and proliferate
h) Taxonomic status, common name, point of collection or acquisition, and the characteristics of the donor organism related to biosafety
i) Approved uses of the GMO
j) A risk assessment report consistent with Annex III of the protocol
k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate

***CPB ANNEX III*: Risk Assessment**

Objective
1. The objective of risk assessment, under the Cartagena Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also account of the risks to human health.

Use of risk assessment
2. Risk assessment is, *inter alia*, used by competent authorities to make informed decisions regarding GMOs.
General principles
3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations
4. Lack of scientific knowledge or scientific consensus should not be necessarily interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.
5. Risks associated with GMOs or products thereof, namely, processed materials that are of GMO origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified receipts or parental organisms in the likely potential receiving environment.
6. Risk associated should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

Methodology

7. The process of risk assessment may on one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process; while on the other hand, information on other subjects may be relevant in some instances.

8. To fulfill its objective, risk assessment entails, as appropriate, the following steps:

a) An identification of any novel genotypic and phenotypic characteristics associated with the GMO that may adverse effects on biological diversity in the likely potential receiving environment, taking also into account of risks to human health;
b) An evaluation of the likelihood of these adverse effects being realized, taking into account of the level and kind of exposure of the likely potential receiving environment to the GMO;
c) An evaluation of the consequences should these adverse effects be realized;

d) An estimation of the overall risk posed by GMO based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;
e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks;
f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or implementing appropriate risk management strategies and/or monitoring the living organism in the receiving environment.

Points to consider

9. Depending on the case, risk assessment takes into account of the relevant technical and scientific details regarding the characteristics of the following subjects:
a) *Recipient organism or parental organisms*. The biological characteristics of the recipient organism or parental organisms, including information on the taxonomic status, common name, origin, centres of origin and centers of genetic diversity, if known and the description of the habitat where the organism may persist or proliferate;
b) *Donor organism or organisms.* Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;
c) *Vector*. Characteristics of the vector, including its identity
d) *Insert or inserts and/or characteristics of the modification*. Genetic characteristics o the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;
e) *Genetically Modified Organism*. Identify the GMO, and the differences between the biological characteristics of the GMO and those of the recipient organisms or parental organism;
f) *Detection and identification of the GMO*. Suggested detection and identification methods and their specificity, sensitivity and reliability;
g) *Information relating the intended use*. Information relating to the intended use of the GMO, including new or changed use compared to the recipient organism or parental organism;
h) *Receiving environment*. Information on the location, geographical, climatic and ecological characteristics, including relevant information on the biological diversity and centers of origin of the likely potential receiving environment**.**