Food and Agriculture Organization
of the United Nations

FAO Technical summary report

Strengthening the capacity on Genetically Modified (GM) food safety assessment and communication in Kenya, Uganda and Zambia

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Abstract

Recently the Common Market for Eastern and Southern Africa (COMESA) Secretariat has requested support from FAO as the main implementation partner in a programme aimed at facilitating intra-regional trade through harmonization of food safety regulations. The need has been particularly highlighted to implement a programme of trainings focusing on building an understanding of the scientific issues underlying current divergences on regulatory approaches used by COMESA Members in relation to commodities that are important to intra-regional trade.

In the last decade, the development has allowed some of the COMESA countries to be engaged in a) research, 2) import or 3) production of Genetically Modified (GM) food products while the level of capacity in evaluating the relevant applications of GM foods are not uniformly conducted among different countries due to the different laws/regulations, procedures/protocols, and/or available expertise/experts. While environmental and socio-economic parameters can differ between countries, GM food safety assessment can be universally identical, following the same procedures of the relevant Codex Alimentarius Guidelines. In 2017 and 2018, Kenya, Uganda and Zambia have worked with FAO to take an approach to assess the *status quo* and to jointly develop capacity in terms of knowledge and resources.

Each of the participating countries was found to be at a different level of proficiency for GM food safety assessment and risk communication, however several common areas for improvement have been identified across all countries visited. During the project, relevant trainings have been provided and they have successfully addressed some of these shortcomings. Further work needs have been identified by the respective participants and national roadmaps were developed for all three countries as one of the concrete outputs of this project. The project achieved a number of other outputs including significant commitment from all three countries to work together to strengthen GM food safety assessment through regional strategy, having the first GM food safety assessment result shared by Kenya to the FAO GM Foods Platform, and mutual exchange of policy documents which are in line with Codex Alimentarius. The outputs from each country were shared among all three countries and the project results have led to the development of a group/regional initiative that would take place in the future, with flexibility to welcome more countries from the region and the continent.

Keywords: food safety, GMO, LMO, biosafety, biotechnology, risk analysis, risk assessment, risk management, risk communication, GM food safety assessment, Africa, Kenya, Uganda, Zambia, COMESA, EAC, Codex Alimentarius, FAO, capacity development

Contents

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Abbreviations and Acronyms

ABNE	African Biosafety Network of Expertise
ACTESA	Alliance for Commodity Trade in East and Southern Africa
BCH	Biosafety Clearing House
COMESA	Common Market for Eastern and Southern Africa
FAO	Food and Agricultural Organization of the United Nations
GM	Genetically Modified
GMO	Genetically Modified Organism
NBA	National Biosafety Authority (Kenya, Zambia)
NBC	National Biosafety Committee (Uganda)
SAC	Scientific Advisory Committee (Zambia)
SOP	Standard Operating Procedure
UBIC	Uganda Biosciences Information Centre
UNCST	Uganda National Council of Science and Technology

1. Introduction

1.1. Background

Recently the Common Market for Eastern and Southern Africa (COMESA) Secretariat has requested support from FAO as the main implementation partner in a programme aimed at facilitating intra-regional trade through harmonization of food safety regulations. The harmonization process is based on scientific principles and risk assessment. The need has been particularly highlighted to implement a programme of trainings focusing on building an understanding of the scientific issues underlying current divergences on regulatory approaches used by COMESA Members in relation to commodities that are important to intra-regional trade. The engagement of COMESA and the COMESA Secretariat would promote high-level political support for the harmonization process and facilitate regional collaboration in building on scientific approaches to food safety regulation.

In 2016, FAO held a GM food safety assessment regional workshop in Kenya with participants drawn from selected COMESA countries (Kenya, Uganda, Tanzania, Zambia and Zimbabwe) and the workshop trained the participants on how to set up structures for Genetically Modified (GM) food safety assessment and the general principles and approaches to take into consideration. During the intensive discussion sessions of the workshop, all participants agreed that the regional approach would strategically address many shortcomings each country is currently facing in conducting scientific analyses in a timely and effective manner. However, in order to establish such regional initiatives to function effectively, the key needs are actually at the country level - participants stressed that their high-level policy makers need to recognize the topic's importance and demonstrate their willingness and preparedness to further develop the country's technical capacity so that significant contributions can be made to the to-be-established regional initiatives.

Subsequently upon individual requests, FAO worked with the competent authorities in Kenya, Uganda and Zambia to discuss further on key challenges/difficulties regarding GM food safety assessment. The community of the FAO GM Foods Platform[1] has been used as the first entry point to identify concrete needs. After the focused discussion sessions, each country has established a clear national plan of actions which can be proposed to the high-level officials and also can be aligned to the regional initiatives.

In the COMESA Treaty, 19 member countries agree to permit the free movement of products, including food and agricultural products, across their borders. In the last decade, the development has allowed some of the member countries to be engaged in a) research, 2) import or 3) production of GM food products while the level of capacity in evaluating the relevant applications of GM foods are not uniformly conducted among different countries due to the different laws/regulations, procedures/protocols, and/or available expertise/experts. While environmental and socio-economic parameters can differ between countries, GM food safety assessment can be universally identical, following the same procedures of the relevant Codex Alimentarius Guidelines. Confirming the conclusions of the 2016 regional workshop, participating countries have agreed to take an approach to evaluate the *status quo* and to develop capacity in terms of knowledge and resources, starting with the three countries Kenya, Zambia and Uganda with flexibility to welcome more countries from the region and the continent.

[1] FAO GM Foods Platform (http://www.fao.org/gm-platform) is an online platform to share information on GM food safety assessment in accordance with the Codex "Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants (CAC/GL 45-2003, annex III adopted in 2008)". This Platform also facilitates the effective utilization of GM food safety assessment in situations of Low Level Presence (LLP) of r-DNA plant materials in food. The database can aid countries receiving GMO applications by referring to GM food safety assessments conducted by various countries on the same application.

1.2. Project objectives

The overall objectives of the project were to identify specific needs, challenges and difficulties regarding GM food safety assessment at the national level so that some common regional approaches can be suggested to the group of countries to implement in a collaborative manner. The project also aims to build first level capacity for each country and develop further on the existing frameworks and strengths.

The specific objectives were to:

- Review and assess the *status quo* of the countries on regulatory frameworks, policy, processes and protocols of risk assessment and communication;
- Identify key stakeholders and their roles in the area of biosafety;
- With a strong focus on GM food safety, agree on the way forward at the country level and develop a national roadmap;
- Strengthen mechanisms for implementation of international biosafety obligations and internationally accepted principles and guidelines on GM food safety assessment (Codex Alimentarius);
- Share global experiences on GM food safety assessment and relevant risk communication; and
- Agree together with the participating countries on possible regional approaches with resource-friendly solutions of challenges identified at the national level.

1.3. Methodologies

The project employed a tiered approach with three phases as shown in Figure 1.

Figure 1. Project approach

First, to assess the capacity development needs for each country at country-level, a series of workshops were held in Kenya, Zambia and Uganda. Target groups of these workshops were biosafety and food safety competent authorities, risk managers, risk assessors and risk communicators. While the workshops primarily aimed at identifying the individual needs of each country, they were also designed to strengthen the capacity on GM food safety assessment and communication though trainings provided by relevant FAO officers and experts. Prior to the workshop, various documents and websites of the competent authorities were analyzed. Assessment also included the review of various data available in the international databases including the FAO GM Foods Platform. A series of teleconferences with the national biosafety officials were organized prior to the workshops to address questions arising from the analysis of each of the countries' webpages and databases.

The agendas of workshops were designed to have an overview on the current practices of risk assessment, risk communication and risk management, and stakeholder analysis on each part of the necessary process. The sessions also covered information on the existing policy and guidance

documents as well as documents that need to be developed/improved in each of the countries, and the importance of functional separation of risk assessment from risk management. The workshops also identified which GMOs had gone through the national risk assessment schemes, and at which step of the process and on which data were provided for international databases including the FAO GM Foods Platform. During and after the meetings, national challenges, needs and gaps were identified and concrete areas were identified for potential collaboration with a regional approach. The entire process has resulted in a number of recommendations for a way forward in GM food safety assessment and relevant risk communication in the region.

2. Country report: Kenya

2.1. Overview

In 1997, the Government of Kenya initiated the process for developing a National Biosafety Framework. The National Council for Science and Technology (NCST) produced the first set of regulations and guidelines for safe applications of modern biotechnology, which provided a basis for the establishment of the National Biosafety Committee (NBC) to serve as the technical arm of the Council in overseeing the coordination and implementation of biosafety issues. Kenya made history by being the first country to sign the Cartagena Protocol on Biosafety in 2000 and its subsequent ratification in 2003. In 2006 the Cabinet approved the National Policy on Biotechnology demonstrating the Kenya government's vision and commitment towards promotion and application of biotechnology. The policy articulated the need to institute adequate biosafety measures that will ensure maximization on benefits of the technology while minimizing the risks. The National Biotechnology Policy led to the drafting of the Biosafety Act which was passed into law by the Kenyan parliament in December 2008. It received Presidential Assent on 12 February 2009. The Act established the National Biosafety Authority (NBA) to regulate all activities involving genetically modified organisms (GMOs) in food, feed, research, industry, trade and environmental release with the aim of ensuring safety of human and animal health and providing adequate protection of the environment. Four Regulations and supporting guidelines and checklists have been developed that implement the Biosafety Act.

On November 8, 2012 the Kenyan Cabinet through a Presidential decree issued a ban on GM imports. The ban was largely influenced by the discredited Seralini study that wrongly linked tumors in rats to the consumption of GM foods. The ban undermined Kenya's legal and regulatory system for agricultural biotechnology codified in its National Biosafety Act of 2009. Prior to the ban the country had imported GM food aid shipments either destined for the country or on transit to other neighboring nations. The Kenyan National Assembly Agriculture Committee recommended in 2016 that the import ban on GM products should be upheld according to the Biosafety Act of 2009. Although the government is moving forward with the recommendation, as of July 2018, the import ban is still in place. Beyond the ban on import of GM products, technical officers of the National Biosafety Authority have identified additional challenges with respect to the different steps in the risk analysis process. In an attempt to overcome such challenges, a key initiative that has been undertaken is capacity building on Biosafety Communication for different stakeholder groups.

2.2. Key stakeholders

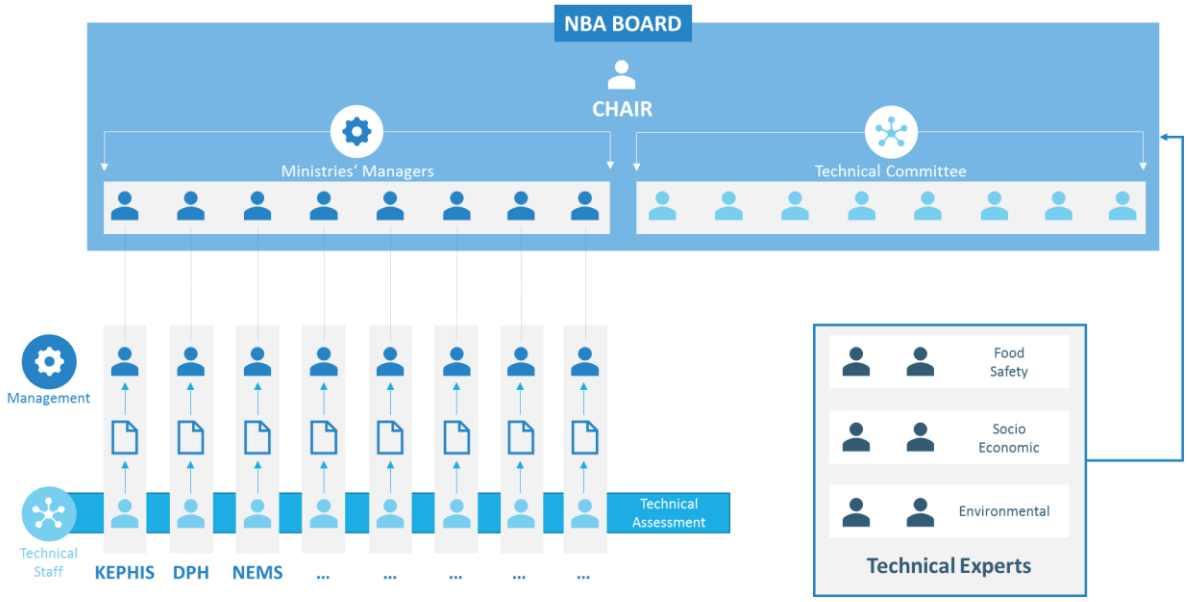
Kenya is a signatory to the Cartagena Protocol on Biosafety. The objective of this protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology. Each signatory country to the protocol is required to designate a national focal point as well as one or several competent national authorities which can perform the administrative functions required by the protocol. In Kenya, the National Biosafety Act of 2009 describes the roles and involvements of the individual stakeholders in the process. It clearly differentiates the role of risk assessment, which is performed by the external expert reviewers (technical experts on food safety, environment and socio economics and technical staff for other relevant government regulatory agencies), from risk management, which is performed at the level of the NBA Board (Figure 2).

In Kenya, the competent authority on the topic of biosafety is NBA and a number of stakeholders are involved in the GM food safety assessment, risk communication and approval process. Primary roles have been assigned to the Department of Health, being responsible for food safety assessment, the Kenya Plant Health Inspectorate (KEPHIS) and the National Environment Management Authority (NEMS), all of which were present during the workshop. High-level policy makers play a key role in the final decision making and approval process, but were not present at the meetings.

The National Biosafety Act lists the stakeholders to be involved in the process, which include at the Board level:

- A chairperson appointed by the Minister;
- The Permanent Secretary in the Ministry for science and technology;
- The Permanent Secretary in the ministry for finance;
- The Permanent Secretary of the Ministry for agriculture;
- The Director-General of the National Environment Management Authority;
- The Managing Director of the Kenya Bureau of Standards;
- The Managing Director of the Kenya Plant Health Inspectorate Services;
- The Director of the Department of Veterinary Services;
- The Secretary of the National Council for Science and Technology; and
- The Chief Public Health Officer.

Figure 2. Kenya biosafety management structure



Six other persons appointed by the Minister, of whom at least two shall be of either gender. Among those 16 persons, 8 form the technical sub-committee at the Board level. The technical sub-committee and the external expert reviewers are responsible for the risk assessment, which is addressing the following areas:

- GM food and feed safety
- Environmental impact
- Social-economic impact

Besides the technical sub-committee, six external experts are invited to review the GMO application, two in each of the aforementioned three areas. Depending on the commodities (plants, animals or microorganisms) of GMO application received, relevant agencies are selected to be involved in the review. For an application of a GM plant, typically the department of public health (DPH), the national environment management authority (NEMA) and Kenya Plant Health Inspectorate Service (KEPHIS) are involved.

Kenya in the past had already submitted risk assessment data to the Biosafety Clearing House (BCH) of the Convention of Bio-Diversity (CBD), and registered 1) a list of biosafety experts, 2) a list of

capacity building needs, 3) information on the competent national authority and 4) decision documents on contained field trials.

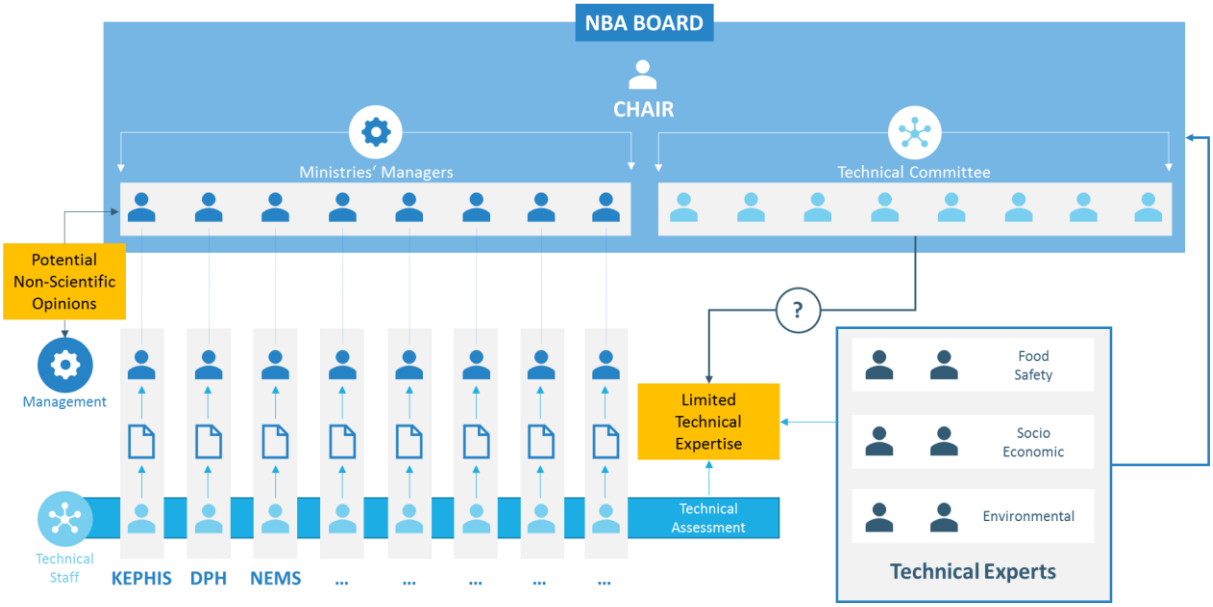
Prior to the present project, Kenya had not shared any data to the FAO GM foods Platform. As a result of the current FAO project, Kenya has become the first African country that contributed the official GM food safety assessment results to the FAO GM Foods Platform. Kenya's contribution to the FAO GM Foods Platform has stimulated South Africa to add 25 entries on their GM food safety assessment results. As of July 2018, Kenya and South Africa remain the only two countries from the Africa region which have shared data on the Platform.

2.3. Technical observations

2.3.1. Risk management

During the intensive discussion sessions, it was noted that, while the structures for a science-based risk assessment and risk management are in place, the current approach is not always consistent (See Figure 3).

Figure 3. Potential inconsistencies on decision-making process



For example, the results and recommendations based on the risk assessment conducted by the agencies' technical staff might not always be identical to the views voiced by the representatives of the agency at the Board level. An example is the view of a Board member that environmental release could be done without performing National Performance Trials, while the agencies' official option was that such trials are needed before environmental release.

2.3.2. Risk assessment

The technical committee at NBA Board level sees, on some occasions, the need to revisit the already performed risk assessment by the agencies' technical staff. This may be due to the fact that at the technical level in the agencies, no dedicated staff is available to perform the review. Some of the staff including NBA secretariat staff, may not have previously performed GM food safety assessment, and may not have had any formal training how to perform this.

While the risk management involves also non-technical experts at board level which participate in the decision-making process, the results of the GM food safety assessment need to be strictly science-based and should not be altered by the non-technical, potentially politically influential,

Board members. An additional reason why the technical committee at NBA Board level may see the need to re-assess the application at their level may be the fact that for the external experts, formal training may have not been given and no evaluation of the understanding of the experts is performed.

2.3.3. Risk communication

The relevant authorities have confirmed that while a good level of alignment between technical officers and policy makers is observed, it is not always true that policy makers are fully informed of the actual process of GM food safety assessment including the Codex-aligned fundamental principles such as comparative approach and substantial equivalence in GM food safety assessment. Therefore, a series of intensive and continuing risk communication for policy makers on the subject matter would be effective. As described earlier, the 2016 technical report has identified the risk communication challenges as below:

- Need for tailoring information/communication for different stakeholder groups
- Challenges with the languages – as different communities in the country use different languages
- The level of openness is different among different stakeholders during the survey administered in 2016
- Communication regarding GMOs and GM food safety is not considered a national priority
- Limited human and financial resources
- Different mind-sets: NBA officials consider themselves as gate-keepers to ensure safety of GM food, but other stakeholder consider NBA as GMO promoters

2.4. Identified challenges

Kenya currently faces major challenges at three levels: 1) scientific level; 2) Political level; and 3) Geographical level and they include the followings:

- Currently, despite the clear separation of risk assessment and risk management stated in the relevant guidelines and regulations, the GM food safety assessment in reality is performed at multiple different levels, including risk managers.
- Risk assessment results are currently put in a mix, with different scientific issues (food safety and environment) and various non-scientific issues (socio-economical) as the risk assessors can comment on any parts of the dossier, rather than only specifically and according to their expertise, to the relevant parts in the document.
- There are currently no fixed, assigned staff capacities to specifically handle GM food safety assessment at the NBA secretariat level. Staff is assigned on ad-hoc basis and some staff may need to learn by doing. This, in some cases, may lead to the NBA Board members to request a re-review of the GM food safety assessment during the decision-making process, which is not desirable. The observation that the lack of core staff for GM food safety assessment at NBA secretariat level can present a challenge was already described elsewhere as "*matching institutional organization for handling and processing requests and permits to their testing and release. Equally important are the capacities of the organization set in place for conducting science-based risk assessment to inform decision making*"[2].
- External experts who are not necessarily familiar with the GM food safety assessment procedures do not receive regularly structured trainings or instructions prior to them performing the actual GM food safety assessment. NBA has suggested that a potentially effective approach to resolving these issues can be the establishment of biosafety-desks at each agency with fixed, trained core staff and external experts. For this training, the FAO

[2] Nang'ayo et al. Regulatory challenges from GM crops in developing economies: the African experience. Transgenic Research. 2014. DOI 10.1007/s11248-014-9905-0

training tool entitled FAO GM Food Safety Assessment Tools for Trainers (http://www.fao.org/docrep/012/i0110e/i0110e00.htm) has been identified as very useful.

- Currently, the entire dossier (typically more than 300 pages and in some cases up to 1 000 pages) is distributed to all agencies for review of all parts of it. This is, almost all the times, unnecessary and is a duplication of work. It is desirable for the NBA secretariat to indicate the relevant parts of the dossier to the relevant agencies (e.g. the GM food safety part to the food safety competent authority) so that efficacy is achieved.
- Politicians and the general public may not or only partially understand the subject of GM food safety issues as well as how the safety can be assessed. A gap in understanding the basics at different levels was identified for farmers, general public and, with high-priority, for high-level politicians.
- A limited financial resource in managing GM food safety is always an issue. For the purpose of optimized use of available resources and knowledge, a regional approach can address many short-comings more cost-efficiently.

2.5. Possible short-term, mid-term and long-term actions

2.5.1. Short-term

Based on the identified challenges above, the following steps are considered necessary on a short-term basis:

- Improve in designated capacities and core-staff for GM food safety assessment at each agency. This may require the designation of specific roles at NBA secretariat level.
- Conduct trainings of external experts for GM food safety assessment, possibly followed by a short evaluation of existing and newly acquired skills. This can be performed as online training, or by physical training workshops facilitated through the NBA secretariat.
- Establish informal technical-level communication channels with other countries proficient in GM food safety assessment.
- Conduct risk communication exercises at political and general public level. This can be performed for high-ranking politicians by holding a capacity-building workshop with practical examples, organized by NBA. At general public level, communication and capacity building will have to be performed at regional level through involvement of trusted local leaders.
- Develop a regional strategic proposal, working with other participating countries in Africa under the FAO project to concretize the feasible and resource-friendly strategic actions in collaboration.

2.5.2. Mid-term

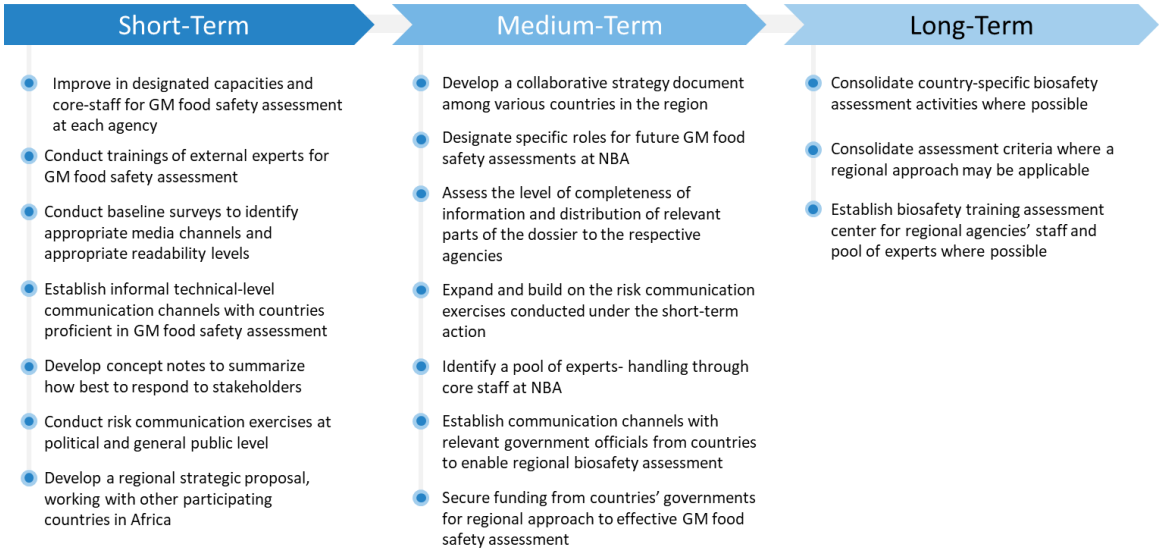
- Develop a collaborative strategy document among various countries in the region, which can serve as blueprint for other countries in the region that consider joining to facilitate and increase efficiency of the process. The document can identify areas which are already similarly implemented, and areas which would benefit from collaboration. For the latter, development of a guidance document may be useful to indicate how collaboration can be effectively achieved.
- Designate specific roles for future GM food safety assessments at NBA (e.g. expert in food safety plus expert in microbiological safety for handling incoming dossiers).
- Assess the level of completeness of information and distribution of relevant parts of the dossier to the respective agencies (e.g. GM food safety assessment part of dossier to Department of Public Health).
- Expand and build on the risk communication exercises conducted under the short-term action.
- Identify a pool of experts- to be administered through core staff at NBA.
- Establish communication channels with relevant government officials from countries to enable regional biosafety assessment.

- Work towards getting a commitment from relevant government officials to accept at least GM food safety assessment from other regional countries.
- Secure funding from countries' governments for regional approach to effective GM food safety assessment.

2.5.3. Long -term:

- Consolidate country-specific GM food safety assessment activities where possible.
- Consolidate assessment criteria where a regional approach may be applicable.
- Establish biosafety training assessment center for regional agencies' staff and pool of experts where possible.

Figure 4. Summary of proposed roadmap for Kenya



3. Country report: Zambia

3.1. Overview

Zambia is a signatory to the Cartagena Protocol and the competent authority for dealing with Genetically Modified Organisms is the National Biosafety Authority (NBA). NBA is a government statutory institution established under the Ministry of Higher Education by the Biosafety Act (2007) No. 10. Through this Act, Zambia has established an institutional framework to perform all three risk analysis components. The NBA Board including chairman is appointed by the Minister of Higher Education. The remit of the NBA is to regulate the import, development, export, research, contained use and release or placing on the market of any genetically modified organism whether intended for release into the environment, use as a pharmaceutical, food, feed, processing or, product of a genetically modified organism. At present the NBA is regulating clinical trials and Malaria research involving gene modification. Neither confined field trials nor national performance trials are not being conducted in Zambia.

The NBA tasks also include the promotion of public awareness and education on the subject matter. The NBA fully considers policy recommendations and guidelines of the Scientific Advisory Committee (SAC). The SAC is, according to the Act, composed of representatives from 12 different disciplines, including breeding and genetics, agronomy, weed science, pathology, molecular biology, food science, toxicology, ecology, entomology, virology, microbiology, and pharmacology. The labelling threshold for foods containing GMOs is set to be 0.9%. Enforcement is performed through the inspection of shipment documentation, not through GMO analysis and quantification in the laboratory. Zambia has approved the importation of several food products made from GM corn varieties for consumption in both humans and animals.

In general, the public has placed a high trust in the Zambian Government concerning GMO's. A "no GM" statement was made in 2002 by the former late President, Levy Patrick Mwanawasa when he decided to reject a shipment from the USA containing grains of GM Corn in a public action. At that time Zambia did not have the capacity to assess the safety of these products thus the action was justified, but there were many unfortunate speculative statements made through various media; which the public perceived as an indication that the GM products are dangerous and can cause adverse health effects. The phrase "GMO causes cancer" was mentioned several times in this context.

3.2. Key stakeholders

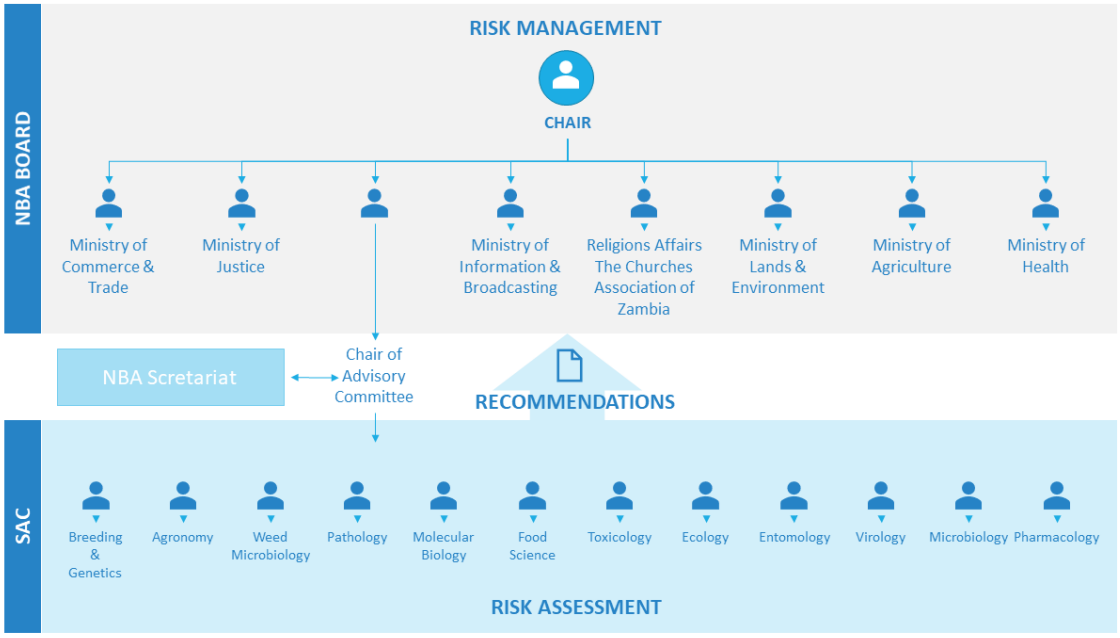
In Zambia, a number of stakeholders are involved in the GM food safety assessment, risk communication and approval process. These include major government agencies. The NBA in its GM food safety assessment primarily interacts with the Ministry of Health and Agriculture. Other important stakeholders are Ministry of Commerce and Trade, Ministry of Lands and Natural Resources, Ministry of Fisheries and Livestock, Zambia Medicines Regulatory Authority, and Zambia Environmental Management Agency.

In accordance with the Biosafety Act, the handling of the submitted applications as well as the collation of responses is performed by the technical staff of the NBA. Risk assessment is performed by members of SAC. Representatives of SAC come exclusively from an academic background, who are employed on a full-time basis by leading universities in the country. Biosecurity is currently not part of the Biosafety Act. The Act is presently undergoing revision. SAC is required to have all 12 positions for the different disciplines mentioned in the Biosafety Act filled (Figure 5). At present four positions are vacant which include a toxicologist, virologist, a pharmacologist and a microbiologist. These assessment tasks are outsourced as the need arises. The chair of the SAC is also part of the Management Board of NBA and relays the findings of the SAC to the Management Board.

The risk management Board has the following representations:

- A chairperson, appointed by Minister of Higher Education
- A representative from the Ministry of Health
- A representative from a Ministry responsible for Lands and Environment
- A representative from Religious affairs-The Churches Association of Zambia
- A representative from the Ministry of Information and Broadcasting
- A representative from the Scientific Advisory Committee
- A representative from the Ministry of Justice
- A representative from Ministry of Commerce and Trade
- A representative from Ministry of Agriculture

Figure 5. Zambia biosafety management structure



While the structures and theories for a science-based risk assessment and risk management are in place, the NBA would require more efforts in closing gaps in performing practical risk assessment.

3.3. Technical observations

NBA currently has only two technical staff allocated for the handling of applications. This is insufficient as the check for completeness of information of a typically 300-1000 pages dossier with information relating to various aspects of risk assessment is likely beyond a single person's expertise. Beyond this, if several dossiers arrive within a short time of each other, the evaluation for completeness of information cannot be performed by a single or even two staff in a reasonable amount of time, given that the entire process of decision making is aimed to be completed in 90-150 days.

At the risk assessment level, several experts in the following knowledge areas are currently missing, virologist, toxicologist, and pharmacologist. However, the NBA has a system to co-opt experts as and when required for risk assessments. Toxicological assessment of GM maize for food use has already been performed. At the Research and Development level, there is some experience with genetic modification of crops at research institutions and universities.

3.3.1. Risk management

The Board members are responsible for risk management, and they are nominated through their ministries and selected/appointed by the Minister responsible for Science and Technology for a period of three years. The Board positions are only renewable once. A key concern is in case all Board members are replaced around the same time, it would leave a significant knowledge and experience gap after six years, when new members join the Board while the old members rotate off. There is need to put in place a Board succession plan for subsequent appointments and formal training and guidelines to be put in place to mitigate the issue.

There is some overlap between risk management and risk assessment in that review of applications are partially re-assessed by some of the Management Board members with a scientific background. The Board members are recommended to focus on decision making and policy guidance.

3.3.2. Risk assessment

Risk assessment has been conducted for 15 crops or events, two pharmaceutical products as well as one modified bacteria for malaria research. Similar to the NBA management Board, SAC members are appointed for a period of three years, renewable once. Replacing all 12 members of the SAC simultaneously does not guarantee the continuity of the work. It may leave a significant knowledge and experience gap if all current members rotate off at the same time while new members with no or little experience in risk assessment may end up joining the committee. Successive appointments or an overlap period could be beneficial. Gaps in risk assessment included the understanding of some terminology used in risk assessments performed by other countries, for which the reference documents can be found on the FAO GM Platfform2. Additionally, there is no formal training that all SAC members had undergone on how to conduct their respective parts of the risk assessments. However, some SOPs are available as draft documents.

3.3.3. Risk communication

Risk communication is currently performed by monitoring media reports for topics related to NBA work, and responding to few telephone callers directly. In addition, some agricultural shows are attended. NBA has a website (http://www.nbazambia.org.zm/) containing information on the activities of NBA with some explanations. However, major parts of the website contain placeholders for information to be filled.

NBA maintains a Twitter account (@NBA_Zambia) since November 2017 that has few tweets and few followers as well as an NBA Facebook account. Announcements for GM products to be approved or previously approved are/were made in at least two newspapers on different days and comments received in a period of 30 days. However the number of comments on the newspaper adverts or announcements is currently very low. This may be due to the formality of language used, lack of interest or knowledge on the subject matter in such announcements or because neither the content nor the impact may be understood by large parts of the population. It was mentioned on several occasions that many citizens are misinformed and think that a product size larger-than-normal is considered a product of modern biotechnology. Similarly, products produced from hybridized plants are considered products of modern biotechnology.

NBA has produced some brochures and print material to explain the NBA's function and the application process. Some of the symbols/signs/pictograms used in the flyers should be revised as they may convey an unintended negative or alarming message to the expected audience. Educational and training activities by NBA are currently achieved through donors and counterpart funding from the Zambian Government. However, at present, very little funding is available to sustain all the programs. It has not been established which communication channels are the best to reach and engage the population, and which Fog Index Level is appropriate for communication with

the public. It's unfortunate that at present, certain groups of the public perceive NBA to promote products of modern biotechnology, rather than being a regulatory or neutral body assessing the safety of products derived from modern biotechnology. At the parliamentary level, there is more reluctance to accept crops of modern biotechnology in the country, as stated by the Vice President of the time, who informed the House in February 2018 that, following a bumper harvest, "Government had no plans to import GMO foods into Zambia".

3.4. Identified challenges

Major challenges identified during the meetings and the individual conversations include the:

- Completeness of information supplied with new GM applications is not consistent
- There is currently no consistent approach for conducting GM of incoming GM applications
- Risk assessment is performed inconsistently
- Subject matter experts for several key areas of risk assessment are missing (including a toxicologist)
- Lack of understanding on science underlying genetic modification by high-level politicians is not yet sufficiently addressed
- Sustainability to perform constant risk assessment and making risk management decisions are not secured if all members of SAC and management board rotate off at the same time

3.5. Possible short-term, mid-term and long-term actions

3.5.1. Short-term

Based on the challenges identified, the following actions are considered necessary:

- Add at least one another staff member to the NBA team to manage the applications. Such staff should ideally have expertise on one of the crucial areas of GM food safety assessment, e.g. molecular biology, toxicology, microbiology.
- Establish informal technical-level communication channels with various other countries technical officials working in GM food safety assessment.
- Conduct baseline surveys to identify appropriate media channels and appropriate readability levels of communication for the general public, media and parliamentarians.
- Develop a strategy document to summarize how best to respond to media, public or parliamentarian enquiries.
- Produce guidelines and templates for announcements of newly approved GM products in newspapers and other media (Facebook, Twitter, TV and radio)
- Complete information on the NBA website.
- Build trust with non-government media outlets in times without crisis through training and information events.

3.5.2. Mid-term

- Conduct risk communication capacity development workshops for media and parliamentarians as well as people (institutions) trusted by the general public (a "multiplier" or training-of-trainers approach).
- Develop a curriculum for biosafety at universities/colleges.
- Establish a formal training for experts performing GM food safety assessment and risk management.
- Establish a mentoring scheme (and possibly an intern scheme) to ensure knowledge transfer and continuity at NBA and SAC level, and potentially another one at Management Board level.
- Consider developing a regional expert roster to compensate for lack of expertise in a single country.
- Form a regional collaborative mechanism for GM food safety assessment with Kenya, Uganda and Zambia (also possibly with other African countries) by looking at the assessment

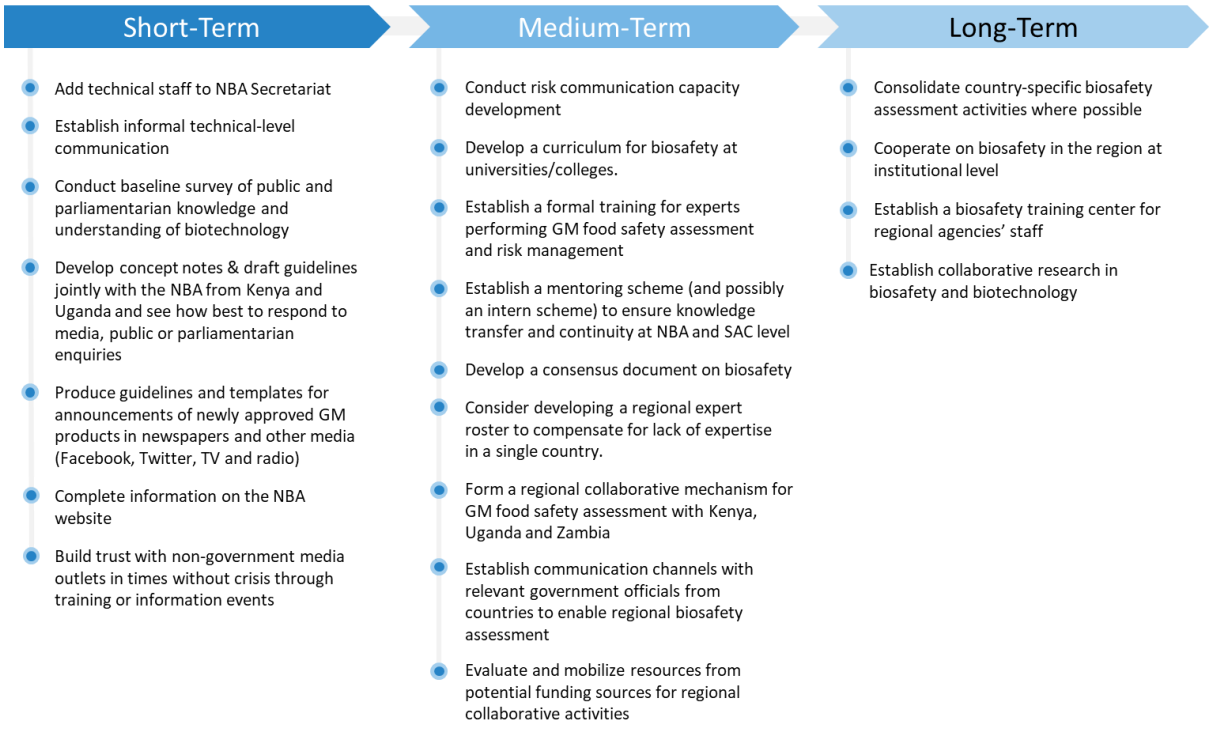
criteria in the categories of GM food safety assessment, socio-economic impact assessment and environmental risk assessment.

- Exchange, at the regional level, documents on GM food safety assessments, performed for same/similar crops to evaluate practical level differences.
- Establish communication channels with relevant government officials in the region or countries to evaluate potentials for regional approaches for GM food safety assessment. Work towards getting a commitment from relevant government officials to accept at least GM food safety assessment of crops of modern biotechnology from other regional countries.
- Evaluate and mobilize resources from potential funding sources for regional collaborative activities (e.g. ABNE and ACTESA /COMESA funding schemes) to support the above-mentioned activities.

3.5.3. Long-term

- Consolidate country-specific activities to consider application of regional approach
- Cooperate on biosafety in the region at institutional. The Regional approach may be able to bridge to other countries such as Tanzania and Malawi.
- Establish a biosafety training center for regional agencies' staff and pool of experts to secure a sufficient level and number of expertise.
- Establish collaborative research in biosafety and biotechnology (e.g. students exchange programmes)

Figure 6. Summary of proposed roadmap for Zambia



4. Country report: Uganda

4.1. Overview

Uganda is a signatory to the Cartagena Protocol. The competent authority for dealing with GMOs in Uganda is the National Council for Science and Technology, a government agency under the Ministry of Science, Technology and Innovation. The national BCH mechanism has also been set up in accordance with the requirements of the Cartagena Protocol. So far several GM crops have been gone through the authorization process, although none of them is currently commercialized in the country. This is due to absence of a succinct biosafety law to provide for commercialization criteria of GMO's. In 2017, the Bill was returned to parliament for further review by the president. Uganda has conducted research on GM crops with over 13 confined field trials. These crops among others include, maize (for drought tolerance and insect resistance), banana (for BXW, Black sigatoka, Nematode resistance and for ProVitamin A enhancement), cassava (Cassava brown streak disease resistance), potato (for disease resistance) and rice (for nitrogen use efficiency).

4.2. Key stakeholders

Risk management is performed by the Uganda National Council for Science and Technology, which is comprised of the following stakeholders:

- Makerere University
- Ministry responsible for agriculture
- Ministry responsible for animal industry and fisheries
- Ministry responsible for defence
- Ministry responsible for education
- Ministry responsible for energy
- Ministry responsible for environment protection
- Ministry responsible for health
- Ministry responsible for housing and urban development
- Ministry responsible for industry and technology
- Ministry responsible for lands and surveys
- Ministry responsible for planning and economic development
- Ministry responsible for transport and communications
- Ministry responsible for water and mineral resources
- Ministry responsible for works
- National Bureau of Standards
- National Curriculum Development Centre
- Uganda Manufacturers Association
- Uganda Small Scale Industry Association
- Uganda Polytechnic, Kyambogo
- Universities other than Makerere University

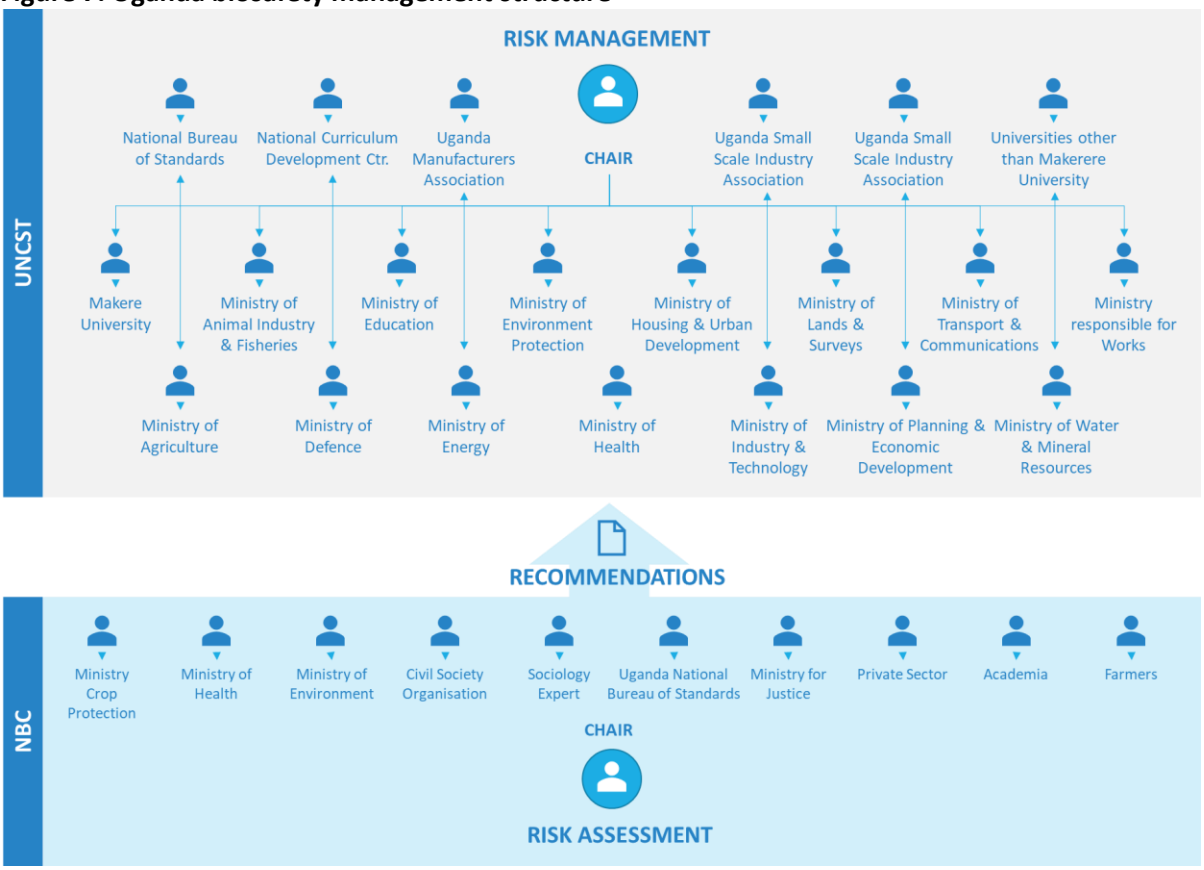
The fields covered by this representation are:
Fields of Science:

- Agriculture and allied sciences
- Computer science, electronics and informatics
- Energy
- Industrial science (engineering and technology)
- Medical science (human and veterinary medicine)
- Natural science (bio- and geo-sciences)
- Physical science
- Social sciences and humanities

Risk assessment activities are performed by the National Biosafety Committee (NBC) and the composition of the biosafety committee by the 2012 Act requires the following representation / expertise:

- one person with at least ten years of experience in plant or animal breeding, genetics, biotechnology or biosafety who shall be the chairperson;
- a representative of the ministry responsible for crop protection with experience and knowledge in phytosanitary matters;
- a representative of the ministry responsible for health with knowledge and experience in public health;
- a representative of the ministry responsible for the environment with experience and knowledge in biodiversity or ecology;
- a representative of civil society organizations involved in biotechnology and biosafety;
- a person with at least 10 years of experience in sociology;
- a representative of the Uganda National Bureau of Standards with experience and knowledge in GMO standards;
- a representative of the ministry responsible for justice;
- a representative of the private sector;
- a representative of the academia or institutions conducting research with knowledge and experience in plant or animal breeding, genetic, entomology, botany ecology, biotechnology or biosafety; and
- a representative of farmers nominated by recognized farmer's umbrella association.

Figure 7. Uganda biosafety management structure



4.3. Technical observations

Uganda is well advanced in the area of research and development for the production of GM plants. Especially Makerere University has a number of experts in this field. While the expertise for the

production of such plants exists, there are several gaps in the risk assessment performed for the produced transgenic products. National Agricultural Research Laboratories in Kawanda have received a license to produce GM banana, resistant against Xanthomonas wilt. Officials in Uganda have expressed their willingness to take an integrated approach together with Kenya and Zambia. The concept/ proposal on the scientific issues by the three countries would then be introduced to possible donors for a funding opportunity.

4.3.1. Risk management

In Uganda, a number of stakeholders are involved in the risk assessment, risk communication and approval process. These include major government agencies: besides the competent authorities, the primary roles have been assigned to the Ministry responsible for health, being responsible for GM food safety assessment, the Ministry responsible for agriculture and the Ministry responsible for industry and technology, all of which were present during the workshop. High-level policy makers play a key role in the final decision making and approval process.

4.3.2. Risk assessment

Risk assessment is expected to be performed by the group of persons listed in Figure 7. However, the exercise conducted as part of the training program revealed that knowledge to perform risk assessment adequately of the risk assessors present is not comprehensive. In addition, parts of the dossier are reviewed by persons whose subject matter expertise has not been demonstrated for this area. Efficacy is also not achieved since the relevant parts of the dossier are not separated out and sent to the subject matter experts. Instead, the entire dossier is sent for assessment.

Bananas are a primary product in Uganda and consumption of banana in Uganda is higher than in other countries in the region. Trials are ongoing on a GM banana in Uganda, however, the relevant result of GM food safety assessment has not been uploaded to the FAO GM Foods Platform or any other international databases.

4.3.3. Risk communication

Risk communication is performed by a number of bodies within the government partner agencies. Coordination and exchange of work performed and action to be taken happens during meetings scheduled two to three times per year or on an as-needed basis. The difficulty here is that NBC is a risk assessment body while NARO is promoting biotechnology development. While coordination of scientific and purely informative message can be amplified using these different channels, one has to bear in mind that it may also lead to confusion with some of the stakeholders if message communicated by NBC are purely scientific or promoting biotechnology.

4.4. Identified challenges

Major challenges identified in Uganda with respect to competent authorities performing risk assessment, risk management and risk communication were:

- There is a limited technical capacity of the currently identified risk assessors and risk managers on risk analysis, particularly on the importance of functional separation of risk assessment and risk management
- Based on the knowledge test administered at the training, the level of knowledge did not reach the required level to properly evaluate applications on GM food safety assessment
- There may be a risk that the experience and institutional continuity may be lost, when assigned reviewers hand over tasks to the new reviewers because the majority of risk assessors and risk managers rotate off after their term ends at the same time
- Quality and consistency of GM food safety assessment may not be fully assured as there is no document (SOP) to illustrate how to conduct GM food safety assessment
- Detection capacity for food inspectors is limited

- There is a sustainability issue for NBC staff (secretariat) to receive and screen incoming GM applications. The assessment of completeness of information of the application (checklist) needs to be conducted by such staff who needs to hold specific background, particularly with molecular biology.
- The level of understanding is not sufficiently high on what types of experts are needed to conduct GM food safety assessment

4.5. Possible short-term, mid-term and long-term actions

4.5.1. Short-term

Officials in Uganda have identified key issues that Uganda is facing and to address such issues, the participants have come up with the following recommendations.

- For performance of better GM food and feed safety assessment, the regulatory authority should ensure that the NBC is composed, at minimum, of a Microbiologist Nutritionist, Toxicologist, Cell Molecular Biologist, Protein Expert and Geneticist. The appointed authority should additionally note the need to have more microbiologists and nutritionist on the review committee. Also, the re-configuration of the current membership of the NBC could be considered, in order to create specialized environmental risk assessment, food/feed safety assessment and socio-economic teams. However, currently the country may not have sufficient number of qualified experts in each field. Therefore, there is a need to establish a regional roster of experts in food/feed safety assessment to strengthen mechanisms of food/safety assessment in the region.
- Although Uganda has a quite good set of communication materials on the subject, it was suggested for the region to develop a regional communication strategy to address issues related to biosafety and biotechnology.
- Various protocols and broadly captured manuals exist, but participants pointed out that there are no clear guidelines for GM food/feed safety assessment. Thus, the formulation of such guidelines for NBC members would be necessary. To improve the quality of the assessment, participants stressed the need to embrace a regional approach to GM food feed safety assessment for harmony and coherence of the food/feed safety assessment systems between Kenya, Uganda and Zambia through exchange programs, joint reviews and joint scientific conferences.

4.5.2. Mid-term

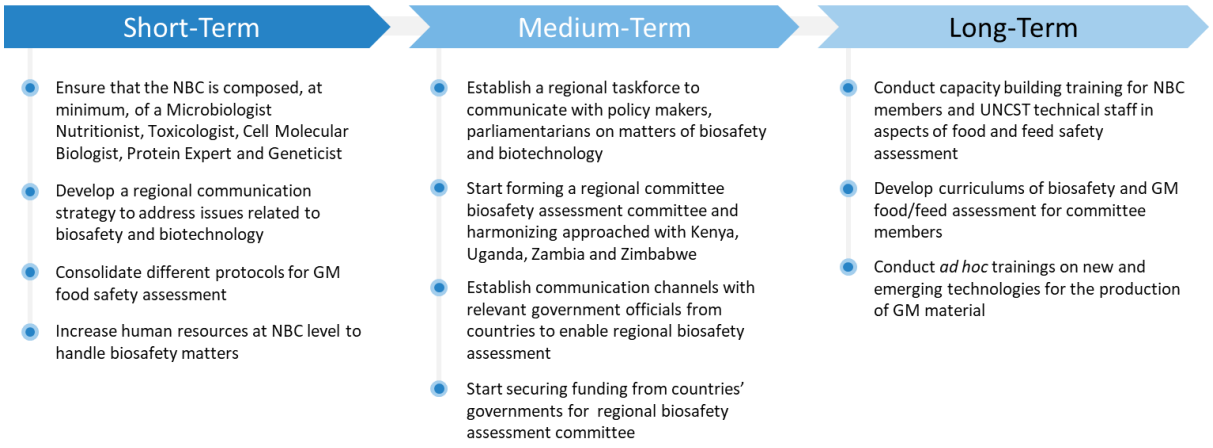
- One of the biggest barriers for the draft biosafety bill to be adopted as a law is the low level of technical understanding of GM food safety issues by many policy makers. The urgency was highlighted by all participants to conduct a high-level regional sensitization and awareness conference in food and feed safety assessment aspects of biotechnology. Related to this point, the establishment of a regional taskforce to communicate with policy makers, parliamentarians on matters of biosafety and biotechnology has been suggested as many participants thought it would be further effective if this type of communication is conducted at the regional or sub-regional level.

4.5.3. Long-term

- Several training and development needs on various related topics have been identified. First, conducting capacity building training for NBC members and UNCST technical staff in aspects of food and feed safety assessment was identified as matter of urgency. Also, development of systematic curriculums of biosafety and GM feed/safety assessment for the committee members and regulators was suggested. In addition, it was suggested that ad hoc trainings should to be planned for new emerging technologies for NBC Members and other scientists involved in the GM application assessments. Areas identified include synthetic biology, gene editing, and gene drives.

- The need to increase human resource personnel at the NBC Secretariat to handle biosafety matters was also highlighted. Currently only one full time person is serving as a Secretariat member, supervised by the head of division; which is insufficient.
- Concerning the data transportability, it was suggested that Uganda should be able to obtain data from similar settings to avoid time and resource wastage. Further discussions and considerations would be useful to work on biosafety issues with possible regional/group approaches.

Figure 8. Summary of proposed roadmap for Uganda



5. Capacity development areas that can benefit from the regional approach

5.1. Identified challenges in 3 countries

5.1.1. Securing sufficient number and types of experts for GM Food safety assessment

There are different types of expertise (e.g. toxicology, allergenicity, molecular biology, entomology, nutrition, statistics and others) required to evaluate each part of the applications for GM food safety assessment, but authorities often find only some are available in their country. Therefore, GM applications have been possibly reviewed by some experts with limited expertise. Also, for the majority of experts serving on the technical committee or invited by tender to perform GM food safety assessment, this is an activity in addition to their current full-time employment thus time commitment by the expert can be insufficient . It is also important to note that such experts usually receive the entire application, without specific instructions on how they can structurally provide their comments. This leads to experts commenting on sections that may not be related to their area of validated expertise and consequently has the potential to dilute the credibility of the assessment performed. In view of the limited resources and the assessment quality required, it is recommended to first clarify the validated expertise for each expert and specifically request to exclusively comment on the information relating to the assessors' field of expertise. However, while there is a good recognition that this is the proper way of conducting GM food safety assessment, countries may not have sufficient number of experts to cover all the required areas. Regional collaboration to tap into different types of expertise from a common pool is suggested and countries confirmed that they would like to positively explore the feasibility.

Challenges also exist to identify appropriate subject matter experts. It was common that the agency/body that is tasked to handle applications is under-resourced, and availability of technical experts is limited. Secretariat staff handling the applications typically had at least a basic scientific background, but without clear procedures on how secretariat staff identifies which kind of expertise is required for each application. The quality of experts selected remains uncertain, and can therefore adversely affect the quality of the assessment. Identifying and establishing a concrete set of criteria in selecting experts would ensure the process to be more transparent and efficient. Documenting which experts are required for a particular application with a short reasoning would significantly improve the credibility and quality of the process.

5.1.2. Structured approach for GM food safety assessment

Currently, GM food safety assessment is largely performed on a learning-by-doing approach in all three countries, and establishing a structured approach would benefit all. Setting up common evaluation criteria will ensure that the assessments to be carried out in a consistent and timely manner. Also optimizing available resources properly in a time and cost-efficient way is helpful to promote sustainability. A regional approach in terms of proficiency, evaluation criteria and processes and efficiency would greatly benefit each country as well as the region.

5.1.3. Risk communication

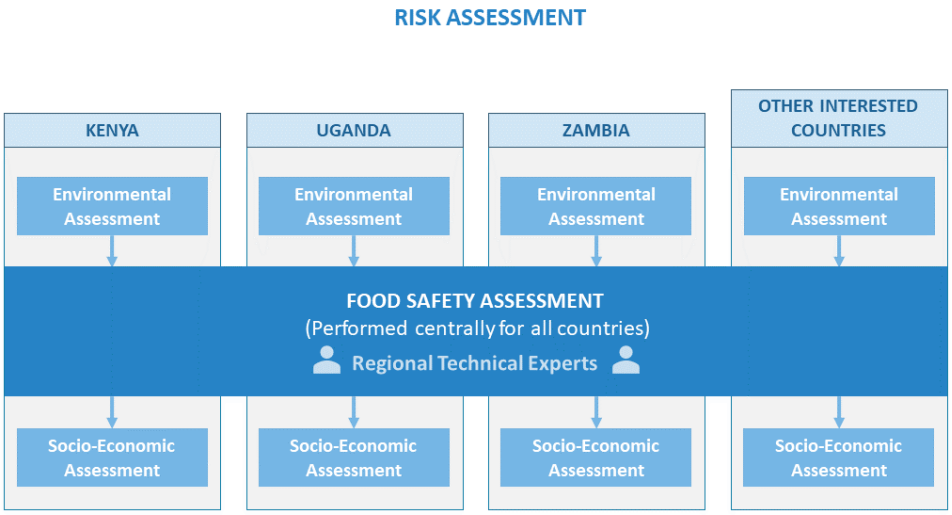
While all the countries had some documents for risk communication in place, the challenge was to explain basic concepts to non-experts (including decision-makers at political levels) such as commonalities and differences of conventional and GM varieties, as well as how the safety of GM food is conducted. It was also observed that some risk managers who are supposed to make the final decision with the results of risk assessment conducted by risk assessors and other legitimate factors tend to question about scientific matters which had previously already assessed by the assessors. This indicates a need to improve risk communication between risk assessors and risk managers to be able to have a common understanding of the structured risk assessment and its results. It should be

made clear that if a risk manager wants to be a part of risk assessment, the person needs to apply to become a risk assessor with validated expertise required for the risk assessment.

5.2. Collaborative approach to address the challenges

Considering the challenges explained in the section 5.1, the following regional collaborative approach has been recommended.

Figure 9. Proposed regional approach



5.2.1. Establish a regional roster of experts

An area of collaboration can be to establish a regional roster of recognized experts with their contact details and validated specific area of expertise. This would allow competent authorities to find experts not available in their own country and also facilitate regional collaboration.

5.2.2. Establish efficient communication channels in the region

A direct communication among experts in the region without intermediates that may delay the process can be established. For example, experts with questions on techniques used in the process of creating the gene construct or transforming the organisms, could contact other experts which may have either already found the answer to that question or have a level of experience which can provide the answer immediately. In addition, an exchange of information between either technical experts or secretariats of the competent authorities in the region on received applications, can help reduce redundancies. This would be feasible when the applicant sends the dossier to multiple countries. If necessary, it may also be useful to develop multilateral agreements for exchange of information under confidentiality.

5.2.3. Develop the common training content

The countries may benefit from having a common set of training materials to conduct in-country or online trainings with the purpose of aligning the programs from the different countries and ensuring consistency of future assessment and decision-making activities. It is important to consider putting a scheme to enable regular evaluation of the training materials to be kept updated and relevant with new scientific developments and needs.

6. Key outputs from the project

The project achieved a number of concrete outputs as followings.

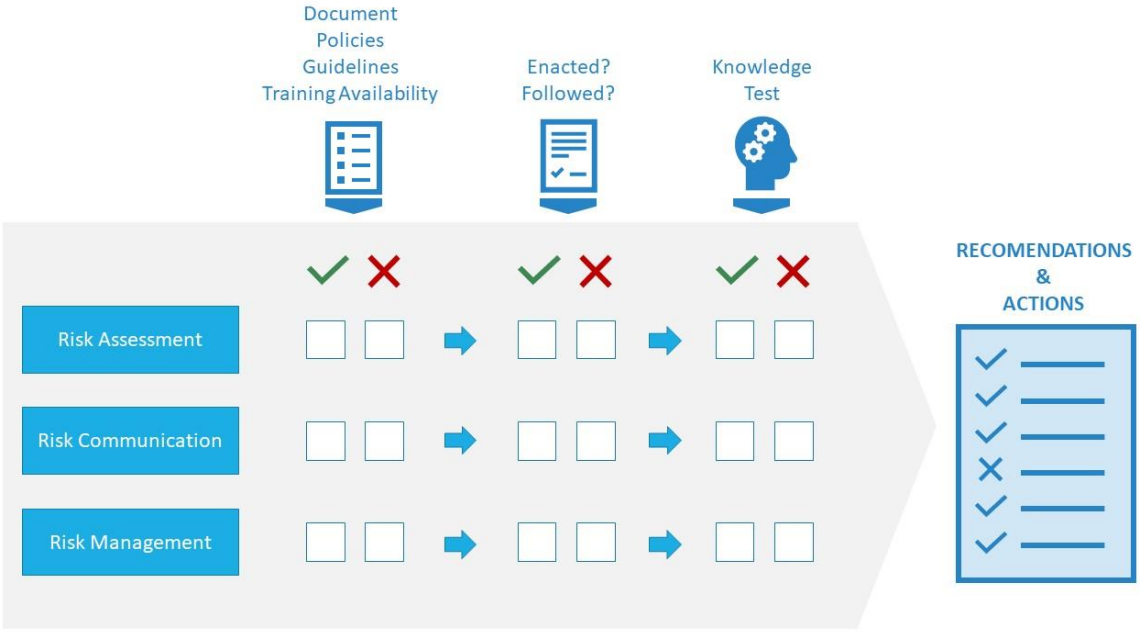
- Joint commitment obtained to work together towards establishment of a regional roster of food safety experts
- Consensus made to form a collaborative group on GM food safety assessment
- Kenya has uploaded the first GM food safety assessment result onto FAO GM Foods Platform
- All relevant risk communication materials shared among 3 countries
- Three countries roadmaps developed for further capacity building at national level
- Agreement reached to jointly develop a mentoring programme on GM food safety assessment for young scientists at competent authorities' institutions and respective universities
- Strong agreement reached to develop a joint project proposal to concretize the regional approach

7. Recommendations

7.1. General recommendation to develop a self-assessment toolbox

The project aimed to conduct stakeholder interviews to understand where the country stands in terms of the capacity in conducting GM food safety assessment to clarify the needs and the areas for improvement. Performing basic assessment in every single country is not efficient and is costly, thus it is recommended that an assessment tool (Figure 10) is developed by FAO to enable countries to conduct their own baseline assessments. Such tool can include questions regarding policies and procedures in place or lacking at risk management, risk communication and risk assessment level. Using an example from the selected COMESA countries, key items, such as the existence of a step-by-step guidance or policy document on how to perform risk assessment, willingness to join the regional collaborative efforts, quick quiz to assess the technical knowledge level for the risk assessors and so forth.

Figure 10. Proposed self-assessment tool for competent authorities



After the assessment has been performed and areas for improvement are identified, practical measures can be suggested and implemented. Advantage of this approach is that cost for first-level assessment are only incurred once and the tool can be used repeatedly for new incoming members of committees. After the assessment has been performed, structured support can be recommended to assist countries to develop its capacity. Another possibility is to create a common repository of guidelines and policy documents from countries willing to share those to which other competent authorities have access to. As such documents are evolving, the challenge of this is to have the most current version in the repository.

7.2. Summary of the recommendations for countries in COMESA and Africa

It is important to note that the outputs from each country's project were shared among all three countries and the project results have led to the development of a group/regional initiative that would take place in the future, with flexibility to welcome more countries from the region and the continent. In particular, the following recommendations have been fully considered and would be actively followed by all countries (Kenya, Uganda and Zambia).

1) Establish a regional roster of experts. This can be achieved by compiling lists by each country with available experts, their contact details and their specific area of expertise. Success of this measure can be a consolidated regional address book shared between the secretariats of competent authorities. It is important that such address book is maintained current and updated to not become obsolete.
2) Establish informal links between the technical experts of the regional scientific experts and between the competent authorities to exchange procedures, guidelines and advice to improve the level of capacity in the region and perform a more proficient and efficient risk assessment.
3) Ensure having and share a step-by-step guidance document for the risk assessment. Having such guidelines and SOPs in place aids conducting the risk assessment in the consistent way in the region.
4) Develop common training materials in the region. This ensures the consistency as well as to establish a structured common GM food safety assessment mechanism for the region.
5) Document the process in identifying the experts with required expertise for each application. This makes the expert selection process more transparent and traceable and allows specifying the required skills and knowledge when inviting external experts.
6) Sensitize decision makers and politicians on the process as well as the subject in the most effective way. A high-level meeting might be an effective way to achieve a goal to help high-level officials to make informed decisions.

Annex 1. Kenya participants

NAME	INSTITUTION/ORGANISATION
Anita N. Kamanda	Ministry of Health (MoH)
Anne Muia	National Biosafety Authority
Cecilia W. Githaiga	National Environment Management Authority (NEMA)
Charles Ochola	Directorate of Veterinary Services (DVS)
David Karani	Ministry of Education, Science and Technology (MOEST)
Diana Imosi	Kenya Plant Health Inspectorate Services (KEPHIS)
Dorington Ogoyi	National Biosafety Authority
Eric K. Korir	National Biosafety Authority
Faith N. Masika	Ministry of Health (MoH)
Felix Bii	National Biosafety Authority
Florence Birya	National Biosafety Authority
George Mondo	National Biosafety Authority
George Ombakho	Ministry of Education/ Board Member
Hellen Kajuju	National Biosafety Authority
Hillary Sang	National Biosafety Authority
Immaculate Kudwoli	Kenya Bureau of Standards (KEBS)
Ivan Obare	Kenya Plant Health Inspectorate Services (KEPHIS)
Jonah Changwony	National Biosafety Authority
Joseph Oduor Odongo	National Biosafety Authority
Josphat Njogo Muchiri	National Biosafety Authority
Julia Njagi	National Biosafety Authority
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Leonard Njagi	Directorate of Veterinary Services (DVS)
Margaret Aleke	Kenya Bureau of Standards (KEBS)/Board Member
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Martin Kimathi	National Biosafety Authority
Nehemiah Ng'etich	National Biosafety Authority
Nicholas M. Kivuvo	Directorate of Veterinary Services (DVS)
Olivia Lorna Olwanda	National Biosafety Authority
Peter Wanjohi	Ministry of Health (MoH)
Reagan Awino	National Environment Management Authority (NEMA)
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Veronica Nabwire	National Biosafety Authority
Warkach K. Tonui	Board Member
Waweru Kabaka	Directorate of Veterinary Services (DVS)

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Christopher Simuntala	National Biosafety Authority
Mutibo Mushenywa	National Biosafety Authority
Sandra Lombe-Mulowa	National Biosafety Authority
Emelda Chalinganga	National Biosafety Authority
Esther Kalukango	National Biosafety Authority
Isaac Bwalya	National Biosafety Authority
SCIENTIFIC ADVISORY COMMITTEE	
Patrick Chikoti	Ministry of Agriculture(ZARI)
Evans Kaimoyo	University of Zambia
K Yambayamba	University of Mulungushi
Stephen Siampungani	Copper belt University
Philip O. Y. Nkunika	University of Zambia
Aron Shibemba	University Teaching Hospital
Nyambe L. Mkadawire	University of Zambia
Martin Chiona	Ministry of Agriculture
EXTERNAL EXPERTS	
Twambo Hachibamba	University of Zambia
Gerald Monga	Ministry of Fisheries and Livestock
Brenda Chileshe	National Industrial & Scientific Research
Hannah Mzyeche	Ministry of Health
NBA BOARD MEMBERS	
Paul Zambezi	
Elizabeth Chizema	Ministry of Health
N. Museba Banda	Ministry of Justice
Marlon Banda	Churches Association of Zambia
Beaton Kaluba	Ministry of Information & Broadcasting
Doreen Chomba	Ministry of Agriculture
Mable M. Simwanza	Seed Certification Institute
Godwin F. Gondwe	Ministry of Lands and Environment
Jane M. Chinkusu	Ministry of Higher Education
Sunday Chikoti	Ministry of Commerce & Trade
Patrick C Chikoti	Ministry of Agriculture Zambia Agriculture Research Institute.

Annex 3. Uganda participants

NAME	INSTITUTION
Maxwell Otim Onapa	Deputy Executive Secretary, Uganda National Council for Science and Technology
Augustine Mwendya	Executive Director. Uganda National Farmers Federation
Charles Mugoya	C.E.O Mugoya Farm
David Hafashimana	Director of Research. Bulindi ZARDI NARO
Harriet Ityang	Principal State Attorney. Ministry of Justice and Constitutional Affairs
John Enyaru	Soroti University
Jacqueline Kwesiga	Head, Microbiology lab. Uganda National Bureau of Standards
Robinah Kaitiritimba	Uganda Health Consumers Organization
Clovice Kankya	Head of Department of Biosecurity, Ecosystems and Veterinary Public Health. Makerere University
Settumba B Mukasa	Assoc. Prof: Department of Agricultural Production. Makerere University
Irene Wanyenya	Head of Food Safety, National Drug Authority
Moses Matovu	Senior Researcher, National Agricultural Research Organization
Phillip Chemonges	Biotechnology Officer, Uganda National Council for Science and Technology
Kwehangana Musa	Biosafety Officer, Uganda National Council for Science and Technology
Grace Ochieng	Coordinator, Biotechnology and Biosafety Consortium
Edward Tujunirwe	Assistant Executive Secretary, Uganda National Council for Science and Technology
Beth Mutumba	Science Officer, Research Management, Uganda National Council for Science and Technology
Barbra Zawedde Mugwanya	Biosafety Officer, National Agricultural Research Organisation

Annex 4. Workshop agenda in Kenya

STAKEHOLDER WORKSHOP ON GENETICALLY MODIFIED (GM) FOOD AND FEED SAFETY ASSESSMENT TOWARDS IMPROVING NATIONAL CAPACITY GM FOOD SAFETY

Kenya School of Monetary Studies (KSMS), Nairobi, Kenya, 27th November 2017

27th November 2017		
Time	**Activity**	**Person In charge**
09.00 – 09.30	Opening addresses	Dorington Ogoyi (NBA) Robert Allport (FAO Kenya)
09.30 – 10.00	Round of introductions	
10.00 – 10.15	Introduction of the FAO project	Masami Takeuchi (FAO)
10.15 – 10.30	Meeting objectives and previous activities in Kenya	Martin Bundi
10.30 – 10.50	Coffee/tea break and photo session	
10.50 – 11.20	General principles of GM food safety assessment, relevant Codex guidelines and FAO training tool, including case studies	Masami Takeuchi
11.20 – 11.35	Discussion	Bert Popping
11.35 – 12.05	Regulatory approval process for Environmental release of GMOs in Kenya	Theophilus Mutui
12.05 – 12.20	Discussion	Josephat Muchiri
12.20 – 12.50	Experiences from other countries on GMO food safety assessment	Bert Popping
12.50 – 13.05	Discussion	Masami Takeuchi
13.05 – 14.00	Lunch	
14.00 – 14.20	Results of the stakeholder analysis and baseline analysis	Martin Bundi
14.20 – 15.20	Discussion on gaps and challenges	Bert Popping
15.20 – 15.45	Discussion on establishment of Biosafety desks	Dorington Ogoyi
15.45 – 16.00	Coffee/tea break	
16.00 – 16.30	Discussion on priority actions and development of a National roadmap	Bert Popping and Dorington Ogoyi
16.30 – 16.45	Conclusions, recommendations and a way forward	Masami Takeuchi
16.45 – 17.00	Closing session	Dorington Ogoyi
End of workshop		

Annex 5. Workshop agenda in Zambia

RISK ASSESSMENT AND RISK COMMUNICATION FOR THE NATIONAL BIOSAFETY AUTHORITY SECRETARIAT, SCIENTIFIC ADVISORY COMMITTEE AND THE BOARD MEMBERS
4-6 April 2018, Lusaka, Zambia

AGENDA
Wednesday, 4 April 2018

Time	Item	Person in charge
08.00 – 09.00	Registration	
Opening session		
09.00 – 09.30	Opening addresses	NBA CEO FAO Zambia
09.30 – 10.00	Round of introductions	
10.00 – 10.15	Objectives of the meeting	Mutibo, NBA
10.15 – 10.30	Background and progress of the project	
10.30 – 11.00	Break	
Risk Assessment		
11.00 – 11.30	General principles of GM food safety assessment, (Framework of Food Safety Assessment) Q and A (5 min)	Masami Takeuchi, FAO
11.30 – 12.00	Overview of the current situation in Kenya Q and A (5 min)	Hellen Kajuju, Kenya NBA
12.00 – 13.00	Lunch	
13.00 – 13.30	Overview of the current situation in Zambia including the process to complete risk assessment (5 cases)	Christopher Sims, NBA
13.30 – 14.00	Discussions on challenges	Bert Popping
14.00 – 14.30	Risk assessment in other countries Q and A (5 min)	Bert Popping
14.30 – 15.00	Discussions on areas for improvement	Masami Takeuchi
15.00 – 15.30	Break	
15.30 – 16.00	FAO GM Foods Platform - Understanding risk assessment results from other countries	Masami Takeuchi, FAO
16.00 – 17.00	Group work on understanding risk assessment results (to be used for the next group work)	

Thursday, 5 April 2018

Time	Item	Person in charge
Risk Communication		
09.00 – 09.30	Principles of risk communication in food safety	Masami Takeuchi, FAO
09.30 – 10.00	Good examples and bad examples of risk communication on GMOs	Bert Popping, FAO Consultant
10.00 – 10.30	Working group on preparing risk communication messages	
10.30 – 11.00	Break	
11.00 – 11.30	Presentations by working groups	
11.30 – 12.00	Risk communication strategy for NBA	Christopher Sims NBA
12.00 – 13.00	Lunch	
Risk Management		
13.00 – 13.30	Stakeholder involvement in Kenya, summary results of the questionnaire in Kenya	Hellen Kajuju, Kenya NBA
13.30 – 14.00	Stakeholder involvement in Zambia, summary results of the questionnaire in Zambia	NBA
14.00 – 15.00	Discussions on similarities/differences between Kenya and Zambia	
15.00 – 15.30	Break	
Institutional capacity and regional collaborations		
15.30 – 16.00	Possible areas for institutional collaboration in the COMESA region	Bert Popping
16.00 – 16.30	Discussions	
16.30 – 16.45	Recommendations	Bert Popping
16.30 – 17.00	Conclusions	Masami Takeuchi, FAO

Friday, 6 April 2018 (with NBA Board members)

Time	Item	Person in charge
Opening session		
09.00 – 09.30	Opening address Round of introductions	NBA All
Workshop summary and recommended actions		
09.30 – 10.00	Background of the project and principles of GM food safety assessment	Masami Takeuchi, FAO
10.00 – 10.30	Summary of the Day 1 and 2	Bert Popping
10.30 – 11.00	Break	
Q and As, a way forward		
11.00 – 12.00	Structured discussions on Zambia's needs, challenges, opportunities, and potential collaborative mechanisms with COMESA countries	Bert Popping, Masami Takeuchi, Hellen Kajuju
12.00	Closure and lunch	

FAO-NBA BOARD MEETING ON GENETICALLY MODIFIED (GM) FOOD AND FEED SAFETY ASSESSMENT TOWARDS IMPROVING NATIONAL CAPACITY GM FOOD SAFETY

Kenya School of Monetary Studies (KSMS)
Nairobi, Kenya, 29th November 2017

AGENDA

29th November 2017

Time	Activity	Person In charge
09.00 – 09.30	Opening addresses	Dorington Ogoyi (NBA) Mary Nyamongo (Chair, NBA Board) Masami Takeuchi (FAO)
09.30 – 09.50	Round of introductions	
09.50 – 10.00	Meeting objectives	Bert Popping
10.00 – 10.15	General principles of GM food safety assessment	Masami Takeuchi
10.15 – 10.30	Key discussion points	Dorington Ogoyi
10.30-10.45	Discussion	Facilitated by Dr. Bert Popping
10.45 – 11.00	Coffee/tea break and photo session	
11.00 – 11.30	Experiences from other countries on GMO food safety assessment	Bert Popping
11.30 – 11.45	Discussion	Masami Takeuchi
11.45 – 12.15	Regulatory approval process for Environmental release of GMOs in Kenya	Theophilus Mutui
12.15-12.30	Discussion	Dorington Ogoyi
12.30 – 12.50	Conclusions, recommendations and a way forward	Masami Takeuchi
12.50 – 13.00	Closing session	Dorington Ogoyi and Mary Nyamongo
Lunch and End of workshop		

Annex 6. Workshop agenda in Uganda

RISK ASSESSMENT AND RISK COMMUNICATION TRAINING IN UGANDA
23-25 May 2018, Kampala, Uganda

AGENDA
Wednesday, 23 May 2018

Time	Item	Resource Person(s)
08.00 – 09.00	Registration	
Opening session		
09.00 – 09.15	Welcome Remarks from UNCST	Deputy Executive Secretary
09.15 – 09.30	Opening Remarks from FAO Uganda	FAO Representative to Uganda
09.30 – 10.00	Round of introductions	All
10.00 – 10.15	Objectives of the meeting	NBC Secretariat
10.15 – 10.30	Background and progress of the project	Masami Takeuchi, FAO
10.30 – 11.00	Break	
Risk Management		
11.00 – 11.30	General principles of food safety assessment and GM food safety assessment	Masami Takeuchi
11.30 – 12.00	Overview of the current situation in Kenya	Hellen Kajuju, Kenya National Biosafety Authority
12.00 – 12.30	Discussions	All
12.30 – 14.00	Lunch	
14.00 – 15.00	Overview of the current situation in Uganda Authorization process Environmental risk assessment Food/feed safety assessment Socio-economic assessment Risk communication	Charles Mugoya Chairperson, National Biosafety Committee
15.00 – 15.30	Break	
15.30 – 17.00	Discussion session for questions from the mission members to the NBC and experts in Uganda	Bert Popping, International expert to facilitate

Thursday, 24 May 2018

Time	Item	Note
Risk Assessment		
09.00 – 09.30	Components of GM food safety assessment and required expertise and experiences	Masami Takeuchi
09.30 – 10.00	Working group 1: finding risk assessment results from other countries (FAO GM Foods Platform)	All (Masami Takeuchi to facilitate)
10.00 – 10.30	Break	
Risk Communication		
10.30 – 11.00	Principles of risk communication in GM food safety – lessons learned from Kenya	Hellen Kajuju
11.00 – 11.30	GMO Risk communication strategy in Uganda	Barbra Zawedde, Uganda
11.30 – 12.00	Working group 2: preparing risk communication messages	All (Masami Takeuchi to facilitate
12.00 – 13.00	Lunch	
13.00 – 13.30	Presentations of the risk communication messages	
Risk Management		
13.30 – 14.00	Stakeholder involvement in Kenya, summary results of the questionnaire in Kenya	Hellen Kajuju
14.00 – 14.30	Stakeholder involvement situations in Uganda	Phillip Chemonges, UNCST
14.30 – 15.00	Possible areas of improvement – structured discussions	Bert Popping to facilitate the discussion
15.00 – 15.30	Break	
Institutional capacity for effective national biosafety framework		
15.30 – 16.00	Structured discussion on Uganda's institutional capacity for effective national biosafety framework	Bert Popping and Masami Takeuchi
16.00 – 16.30	Discussions	
16.30 – 17.00	Consensus building on the list of areas for capacity development needs	Bert Popping to consolidate and present

Friday, 25 May 2018

Time	Item	Note
Regional collaborations		
09.00 – 10.00	A proposal to take a regional approach in GM food/feed safety assessment (Kenya, Zambia, Uganda and any interested COMESA countries)	Bert Popping
10.00 – 10.30	Discussions	All, Bert Popping to facilitate
10.30 – 11.00	Break	
Q and As, a way forward		
11.00 – 12.00	Conclusions on follow-up actions and a way forward	All, Masami Takeuchi to facilitate
12.00	Closure and lunch	