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REPUBLIC OF KENYA



THE NATIONAL ASSEMBLY

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ELEVENTH PARLIAMENT – FOURTH SESSION - 2016

THE DEPARTMENTAL COMMITTEE

ON

AGRICULTURE, LIVESTOCK AND COOPERATIVES

# REPORT

# ON

# THE GENETICALLY MODIFIED (ENGINEERED) FOODS/PRODUCTS (GMOs)

DIRECTORATE OF COMMITTEE SERVICES
CLERK'S CHAMBERS
PARLIAMENT BUILDINGS
NAIROBI.

NOVEMBER, 2016

## ABBREVIATIONS AND ACRONYMS

| | | |
|---|---|---|
| CAC | – | Codex Alimentarius Commission. |
| DVS | – | Department of Veterinary Service. |
| EFSA | – | European Food Safety Authority. |
| FAO | – | Food and Agricultural Organisation of the United Nations. |
| GOK | – | Government of Kenya. |
| GM | – | Genetically Modified. |
| GMO | – | Genetically Modified Organism. |
| ILRI | – | International Livestock Research Institute. |
| KARI | – | Kenya Agricultural Research Institute. |
| KEBS | – | Kenya Bureau of Standards. |
| KEPHIS | – | Kenya Plant Health Inspectorate Institute. |
| KIPI | – | Kenya Intellectual Property Institute. |
| KU | – | Kenyatta University. |
| KWS | – | Kenya Wild Service. |
| NBA | – | National Biosafety Authority. |
| NEMA | – | National Environment Management Authority. |
| PCPB | – | Pest Control Products Board. |
| TOR | – | Terms of Reference. |
| WHA | – | World Health Assembly. |

## CHAIRPERSON'S FOREWARD

The Committee, in considering the banning of GMO foods in Kenya by the then Cabinet Minister for Health, Hon. Beth Mugo, through an informed decision of the Cabinet on 21st November 2012, as a precautionary measure on its harmful effects resolved to take up the matter due to the Public debate and controversies surrounding GMO food products. The Committee compiled this report arising from the findings of the activities undertaken and its engagement with several stakeholders. This included the following;

i. Benchmarking USA tour (appendix I)
ii. Minutes of the Departmental Committee on Agriculture, Livestock and Cooperatives (appendix II
iii. Submissions by the Cabinet Secretary Health and the taskforce on GMO (appendix III)
iv. Submissions by the National Bio-safety Authority (appendix IV).
v. Report on the Position of the Ministry of Agriculture, Livestock and Fisheries on the Ban of Genetically Modified Foods in Kenya (appendix V).
vi. Submissions from the Kenya University Biotechnology Consortium (appendix VI).
vii. A taskforce set up by the Cabinet Secretary, Ministry of Health on 11th October, 2013 - gazetted through legal notice number13607, toreviewmattersrelatingto genetically modified foodsandfood safety.

On my own behalf, I wish to commend Members of the Committee for their patience, endurance and hard work during the long sitting hours under tight schedules, which enabled us to complete the tasks within the stipulated period.

Furthermore, the assistance received from the offices of the Speaker and the Clerk of the National Assembly was invaluable. The Committee acknowledges the contribution of witnesses in the preparation of this report by way of submissions and presentations.

Finally, it is my pleasant duty, on behalf of the Departmental Committee on Agriculture, Livestock and Cooperatives, to table this report on the floor of the House.

**Hon. Adan Mohamed Nooru, MBS, CBS, MP**

## EXECUTIVE SUMMARY

On 8th November, 2012, in the 16th meeting of the then Cabinet, the Minister of Public Health and Sanitation was directed to use the existing legal framework for public health to ban GM food imports and the ban to remain in force until a review and evaluation of scientific information on safety of GM foods on human health is undertaken. The ban is not permanent but dependent on thorough assessment of Food safety and subject to an informed policy decision.

The Committee resolved to take up the matter surrounding the controversies on GMO food products due to the Public debate. The Committee carried out investigations through Public Participation with various Stake Holders. The main controversy arose out of the fact that Governments of countries with emerging economies like Kenya have to evaluate the balance between widespread hunger in the population (food Security) and the ambiguity surrounding the GM food crop evaluation (food safety).

The Committee in its undertakings through the benchmarking visit to USA, and Public Participation submissions from Stakeholders, Cabinet Secretary for Health, Cabinet Secretary Agriculture, Livestock and Fisheries, National Biosafety Authority, Kenya University Biotechnology Consortium including studying the report by the Taskforce to review matters relating to GMO'sgazettedon 11th October, 2013 through legal notice number 13607, to review matters relating to genetically modified foods and food safety with full TORs.

The taskforce studied and made comparisons on selected agricultural crops in Kenya and found out that generally the production have been below consumption levels. These re maize, wheat, rice, sorghum, millet, beans, cowpeas, Irish potatoes and sweet potatoes. National Meat consumption has been increasing since 2006 enough for domestic demand form cattle, goats, sheep, pigs and chicken. Fish and Milk has steadily increased with production. It should be noted that the modern biotechnological advancement has the potential to solve many

agricultural, technological, nutritional and environmental issues that face humanity. However, the principles of ***"primum non nocere"*** (First Do Not Harm) need to be applied as the guiding principle since the majority of GM plants that are commercially available worldwide have been designed to express proteins that confer either insect resistance, herbicide tolerance, or both.

The taskforce then gave an outline history and background to GM production giving examples of commercially approved GM crops worldwide and list of major GM events destined for human consumption as shown in page 13 and 14 respectively in their report.On standards for assessing the safety of GM crops, standards provide universal tools for guiding applicants on the suitability, adequacy and credibility of data that must be provided to facilitate assessment for GM food safety and approval of GM food imports. **Note that this can also be used to facilitate regulations. They gave an example of The Codex Alimentarius Commission Guidelines for GM Food – an intergovernmental body established in 1961-3 by conference resolutions of the FAO and WHA to protect consumer's health while ensuring fair practices in the food trade.**

The taskforce look onto the guiding principles on food safety assessment of GM crops, regulating food safety, the food safety assessment procedure for GM food/feed and safety assessment for products that are developed from within the country.As stipulated by the Kenya Law and under the Cartagena protocol on biosafety, it's the responsibility of the NBA (National Biosafety Authority of Kenya) to regulate research and commercial activities involving GMO's with a view of ensuring the safety of human and animal health as well as protection of the environment. (NBA has procedures as shown in page 23 with subsequent food/feed safety assessment flowchart.)

The GoK has put in place control measures for all GM activities or products approved in Kenya are safe. In 2006, the CS approved the National Biotechnology Development Policy; in 2008 Parliament passed the Biosafety Bill, which became law in 2009 – the Biosafety Act. Various regulations to implement the act have been done. **It should be noted that the current**

**safety regulations of Kenya make no reference whatsoever to the safe consumption of GM foods.**

The taskforce then undertook the GM Maize case study, various research papers on safety assessment of GM foods.

Then, they look onto the legal framework and systems of biotechnology on GM foods in Kenya, institutional capacities and coordination of the regulatory agencies; particularly the NBA which works in collaborations with Public Health, DVS, KEBS, KEPHIS, NEMA, PCPB, KWS and KIPI. Also included is Institutional Research on GMO's (KARI, ILRI and PTL at KU as well as Institutional Biosafety Committee.The Taskforce did analysis of food security in Kenya and found that none of the GM food crops currently on the international market can answer the key challenges facing the food insecurity problems in Kenya.

They also undertook on analysis of possible reasons and underlying factors for the ban of GMO importation, cultivation and trade by some countries – which included absent or inadequate national policies or regulatory systems to deal with safety requirement for approving general use of GMO's. It is noted that most countries have either banned or put restrictions to GMO's. Those who allows has put in place for no commercial cultivation but rather processed products.During the Public Participation Forum, the first group that called for lifting of the ban is associated with the GM industry, academicians and some farmers. The second group called for maintenance of the ban is from civil society organizations. Third group from legal, medical, academic professions, some civil society and consumer groups called for lifting of the ban provided that certain conditions are met. The last group stated that the GMO should be applied on case by case basis depending on the assessment of the benefits, risks and safety of each GM products.

The Committee deliberated on this matter and made their observations and recommendations appropriately.

## 1.0MANDATE OF THE COMMITTEE

01. The Departmental Committee on Agriculture, Livestock and Co-operatives is established pursuant to provisions of Standing Order 216 (5). Under the provisions of Standing Order 216 (5) the Committee is mandated to:-

*(a). investigate, inquire into, and report on all matters relating to the mandate, management, activities, administration, operations and estimates of the assigned Ministries and departments;*

*(b). study the Programme and policy objectives of the Ministries and departments and the effectiveness of the implementation;*

*(c). study and review all legislation referred to it;*

*(d). study, assess and analyse the relative success of the Ministries and departments as measured by the results obtained as compared with their stated objectives;*

*(e). investigate and inquire into all matters relating to the assigned Ministries and departments as they may deem necessary, and as may be referred to them by the House;*

*(f). vet and report on all appointments where the Constitution or any other law requires the National Assembly to approve, except those under Standing Order 204* ***(Committee on Appointments)****; and*

*(g). make reports and recommendations to the House as often as possible, including recommendation of proposed legislation.*

02. The Committee is also mandated to scrutinize the budget of line Ministries and Departments as provided under Standing Order No. 235 which states that:-

*(i) Upon being laid before the House, the Estimates shall be deemed to have been committed to each Departmental Committee without question put, for each such committee to deliberate upon according to their respective mandates.*

*(ii) Each Departmental Committee shall consider, discuss and review the Estimates according to its mandate and submit its report and recommendations to the Budget*

*and Appropriations Committee within twenty-one days, after being laid before the House.*

*(iii)The Budget and Appropriations Committee shall discuss and review the Estimates and make recommendations to the National Assembly, taking into account the recommendations of the Departmental Committees, the views of the Cabinet Secretary and the public.*

03. Section 124 of the Constitution of Kenya (2010) also provide for the establishment of the Committees by Parliament.

04. The Departmental Committee on Agriculture, Livestock and Co-operatives oversees the performance of the following Ministries and Government department:-

(i) Agriculture,
(ii) Livestock,
(iii) Irrigation,
(iv) Fisheries development,
(v) Co-operatives development, and
(vi) Production and marketing.

05. Under the above Ministries, the Committee covers the following subjects;

(i) Agriculture policy;
(ii) Livestock policy
(iii) Fisheries policy
(iv) Cooperative societies

## 1.1 Members of the Committee

**Chairperson** The Hon. Adan M. Nooru, MBS, CBS, MP

**Vice Chairperson** The Hon. KarekeMbiuki, M.P

**Members** The Hon. Daniel Maanzo, MBS,

The Hon. Silas Tiren, M.P

The Hon. MaisonLeshoomo, M.P

The Hon. Mary Wambui, M.P

The Hon. (Dr.) Victor Munyaka, M.P

The Hon. Korei Ole Lemein, M.P

The Hon. John B. Serut, M.P

The Hon. Peter N. Gitau, M.P

The Hon. Florence Mutua, M.P

The Hon. John Kobado, M.P

The Hon. Benjamin Washiali, M.P

The Hon. Patrick Wangamati, M.P

The Hon. James OpiyoWandayi, M.P

The Hon. Raphael Letimalo, M.P

The Hon. AyubSavulaAngatia, M.P.

The Hon. WaitituMunyua, M.P

The Hon. KimaniIchung'wah, M.P

The Hon. Ferdinand Wanyonyi, M.P

The Hon. KabandoWaKabando, M.P

The Hon. Justice Kemei, M.P

The Hon. Benjamin Andayi, M.P

The Hon. Millie Odhiambo - Mabona, M.P

The Hon. Jude Njomo, M.P

The Hon. Fredrick Outa, M.P

The Hon. Aisha Jumwa, M.P

The Hon. Alfred KiptooKeter, M.P

The Hon. Paul SimbaArati, M.P

## 1.2 Committee Secretariat

1. Mr. Benjamin Magut - First Clerk Assistant
2. Ms. Angeline Naserian - Third Clerk Assistant
3. Mr. Ahmad Guliye - Third Clerk Assistant
4. Mr. Noah Too - Research Officer I
5. Mr. David Ngeno - Research Officer III
6. Ms. Lucy Makara - Fiscal Analyst

## 1.3 List of Recommendations

The Committee in its deliberations made the following recommendations:-

1. There is need to involve the local independent scientists within National Institutions using Government funding to research matters relating to GMO's.
2. There is need to kick start Commercialization of Bt-Cotton, however the government should put in place safety nets to ensure the byproducts of non-food GMOs do not find way into the food chain.
3. NBA should have a structured working relationship with other bodies to harmonize the process of developing, testing and regulating GMO products.
4. The Committee recommends that the government to encourage and support the development of this technology while at the same time as for all the other technologies, putting in place safety measure so as to ensure that the GM technology delivers the promises to humanity.
5. Further to the above recommendation Number 4, the Committee recommends that the ban on GM imports remains un-lifted until such a time when the following conditions are met:-

   **i.New Legislation on the Safety of GM Food for Human Consumption be put in place**

   New Legislation/regulations be put in place on the safety of Genetically Modified Foods for human consumption. The Committee noted that no GM product has so far been tested for safety for human consumption by Biosafety Authority. The present Biosafety Act that was passed by Parliament in 2009 has no specific provision for testing GM products for safety for human consumption.

   **ii. Requirement for Acute and Sub-Acute Toxicity Testing laws/regulations has been in place**

   That all GM products must pass a preliminary, independently verified, 90-day animal feeding study, which cover the acute and sub-acute phase of testing for human consumption. The 90- day feeding tests will qualify the GM producer for the issuance of a Class A permit from the Food Safety and Quality Control Unit of the Ministry of Health. This permit should be for a limited period not exceeding two (2) years.

iii. **Requirement for Chronic Toxicity Testing laws/regulationshas been put in place.**That all GM products must pass an independently verified year animal feeding chronic toxicity test. This test will rule out carcinogenicity, teratogenicity, etc. The Chronic toxicity tests will qualify the GM producer for the issuance of a Class B permit from the Food Safety and Quality Control Unit of the Ministry of Health. This permit should be for a period not exceeding five (5) years.

iv. **Requirement for Long-Term and Epidemiological Surveillance Testing laws/regulations has been put in place.**

That the long term tests will involve animal testing for at least three generations to rule out any transgenerational harm. The epidemiological tests will take the form of surveillance by the Ministry of Health on human populations for at least two generations i.e. from childhood to adult hood for the first generation and their offspring. This testing will use the usual epidemiological tools for surveillance. The long term and epidemiological surveillance testing will qualify the GM producer for the issuance of a Class C permit declaring the product safe for human consumption and needing no further tests.

v. **Responsibility for Reparation laws/regulationsfor has been put in place.**

That any GM producer whose product causes harm as confirmed by metabolomics, by animal and human testing and or through accepted new technologies involving in silica (computer) modelling will be held fully responsible for making good the harm and for reparation. The issuing authority may withdraw any permit if later testing including chronic testing and surveillance reveals harm.

vi. **Definition of the Role of the Food Safety and Quality Control Unit of the Ministry of Health has been put in place.**

That the specific role of GM food safety evaluation for human consumption is at the State Department of Health. Therefore they should be responsible for issuing the permits after consultation with the appropriate regulatory agencies and the Pharmacies and Poisons Board.But in case of severe famine where there is threat or loss of life, the president on the advice of the Cabinet, may instruct the Food Safety and Quality Control Unit to issue a special permit for the importation of life-saving food for a limited period provided that such cannot be used seed for cultivation and has been declared fit for human consumption.

## 2.0 INTRODUCTION

Improving the productivity of Kenya's agriculture is central to meeting the challenges of feeding the growing population, creating wealth, reducing poverty and managing the degradation of natural resources. A concerted effort has to be made in addressing the country's vulnerability to climate change and its biotic and abiotic impact on agricultural productivity, as well as its policy and institutional reform agenda.

Kenya is committed to exploring various forms of technologies that would ensure food security in the light of emerging climate changes. This is evident the adoption of the National Biotechnology Development Policy in 2006 and the accompanying regulatory framework. The legal and regulatory review was achieved through wide ranging stakeholder consultative processes undertaken at various levels that included several departments and their administrative heads.

The Departmental Committee on Agriculture, Livestock and Cooperatives saw the need to benchmark and a delegation was nominated to tour the USA due to its long standing experience on appropriate agricultural legislation in food security and long history of research and development and, commercialization of Biotech Crops.

## 2.1 Benchmarking Tour to USA

The aim of the tour was: -

i. to share experience on how to strengthen technological competence to acquire, assimilate, further develop and effectively apply the technology for enhanced agricultural production;
ii. to share experience on agricultural sector reforms that have far reaching implications on the agricultural sector, their merits and demerits;
iii. to identify policy and institutional framework that would help make biotechnology and its products accessible to the rural farmers;
iv. to gather information on how to ensure effective but safe transfer of biotechnology

v. to discuss with key industry players that would enable them make informed decisions as the country moves towards commercialization of the Bt Cotton and drought tolerant maize;

vi. to learn best practices in agricultural biotechnology research and GMO fields, biofuels, corn farming, livestock production and feed lot system.

## 2.2Observations of the Delegation

- On the face of it, GMO products grown are as safe as conventionally grown products, since they are well researched and are released for public use basic on scientific evidence.
- Use of GMO has allowed additional income to farmers, has helped to save soil and conserve fertility and can improve yields while using water more sustainably;
- GMOs are consumed in the US and also exported to other countries including Europe where they constitute 70% of livestock feed.

## 3.0 SUBMISSIONS BY STAKEHOLDERS

The Committee sought more information on the issue of GMO and in this regard met various stakeholders in the Country, who included the Cabinet Secretaries for the Ministries of Health, and Agriculture, Livestock and Fisheries; and the National Biosafety Authority.

### 3.1. Submission by the Cabinet Secretary, Ministry of Health and the Taskforce on GMO Regarding Kenya's ban on GM Food Imports

The taskforce on GMO was gazetted on 11th October, 2013 to review matters relating to genetically modified foods. The Cabinet Secretary Health and The Taskforce on GMO on their appearance before the Committee on Agriculture, Livestock and Co-operatives on 1st July 2014, informed the Committee that the ban on GMO foods in Kenya was a precautionary measure due to lack of information on the safety of GMO foods for human consumption.

The ban only applied to food products and not on non-food products such as Bt Cotton. The ban also did not affect advancement of research in Bio-technology which the Kenyan government has continued to support for years. The taskforce informed the Committee that there is still no sufficient information to prove whether GMO foods are safe or not for human consumption and furthermore, the country does not have the proper legislation and mechanism to assess the safety of GMO foods (see Appendix II).

The Cabinet Secretary also informed the Committee that while the report by the Taskforce on GMO was ready, he could not reveal its contents until he had tabled the report to the Cabinet. The Committee had not received the findings of the Taskforce at the time of preparation of this report.

**NB: The issues raised clearly indicate that the Ban on GMO foods still stays.**

#### 3.1.1: Committee Observations

The Committee observed that:-

i. The ban was as a precautionary measure but it is indefinite thus creating a legal vacuum;

ii. There was need to review the National Biosafety Act No. 2 of 2009 to give it more teeth;

iii. Kenya has the potential of applying biotechnology with proper safety measures in place to be able to increase its food basket to be food secure;

iv. It was not sufficient for the precautionary ban to only affect food products and leave out non-food products;

v. By-products of the non-food GM products may be used in food industries e.g the Bt-Cotton thus making it difficult to manage roll out of non-food GMO products.

vi. Despite the ban, there are foods and foods flavours circulating in our supermarket stores e.g the aromat seasoning.

### 3.2 Submission by the National Biosafety Authority (NBA) on GMO

Appearing before the Committee on 10th June, 2014 the National Biosafety Authority made the following submissions:

i. The NBA has established a transparent science-based and predictable risk assessment process to guide decision making on applications for approval of research and commercial activities involving GMOs;

ii. The safety assessment process on GM foods is on a case by case basis. As such, approvals or rejections are for each GMO, based on data generated on their safety;

iii. In the decision making process, the Department of Public Health, among others are involved as they are part of the NBA Board, the organ that makes decisions on all GMO applications;

iv. NBA has attained a critical mass of best talents for regulating and testing of GMOs and their products.

v. In terms of capacity to carry out surveillance, the Authority has opened 4 offices at major entry and exit points namely Mombasa, Busia, Namanga and Jomo Kenyatta International Airport (JKIA);

vi. The Biosafety Inspectors manning the entry points are mandated to scrutinize shipping documents to ensure they are complete and have declared GMO status, monitor and take official samples from consignments entering the country and send them to our collaborating GMO testing laboratories;

vii. Infrastructural capacity to detect GMOs in the country is available in various public institutions and regulatory agencies (KEPHIS and KEBS) research institutes, including KARI's Biotechnology Centre and Public Universities;

viii. NBA works closely with other regulatory agencies, including Kenya Bureau of Standards (KEBS), Pest Control Products Board (PCPB), Kenya Plant Health Inspectorate Service (KEPHIS), National Environmental Management Authority (NEMA), Kenya Wildlife Service (KWS), the Kenya Industrial Property Institute (KIPI) and Department of Public Health;

ix. Within Sub-Saharan Region, NBA has the lead in supporting regional regulatory harmonization at COMESA and East African Community, and number of countries have since benchmarked with NBA as they continue to establish their regulatory framework.

x. It is also important to note that the Authority has adequate mechanisms to assess safety of all GM products before they can be imported and/ or released to the market and that there exists international standards that have been used over the years by regulatory

agencies which provide sufficient data and information that have found no adverse effects of GM foods on human health over the last two decades of their use;

xi. Note that Kenya is a signatory of the International law on application of GM Technology the Cartagena Protocol and also the World Trade Organization (WTO). Under the Cartagena Protocol and WTO, Kenya cannot restrict trans-boundary movement of GM foods without any scientific or socio economic consideration that demonstrates the need for such action;

xii. To recommend and support adequate allocation of resources to enhance GMO detection and testing capacity for the National Biosafety Authority to adequately perform her mandate considering the dynamic nature of modern biotechnology;

#### 3.2.1 Committee Observations

1. Despite the surveillance at entry and exit points by NBA and other bodies, GMO foods are still finding their way into the country. There is a gap in enforcing the ban on GMO foods.

### 3.3 Submissions by the Cabinet Secretary, Ministry of Agriculture, Livestock and Fisheries

In a written brief to the Committee in September, 2014, the Cabinet Secretary made the following submissions:

i. The ministry is awaiting theoutcomeof the work undertaken by the Taskforce on GMO.The Ministry willtakea standbased on theTaskforce'sreport.
ii. Foodsecurityand economicwell-beingofthefarmers,remains apriority objectivefor the Country.
iii. GMOfoodsarenottheonlysolutiontothefoodsecurityissue in Kenya butcompliment other tools.
iv. GMtechnologyisanadditionaltoolinthefarmers'toolbox but NOT the onlyone.It isavalue-additiontechniquenota farmingsystem.

v. The ministry is undertaking other strategies to enhance food security and improve production such as:availing fertilizers, high yield seeds and other inputs, agriculturalmechanization and creating strategic food reserves.

vi. Theministrytakesnoteofvarious**attributes**ofGeneticallyModified(GM) foodsandplants, both positive and negative,asfollows:

a) **Positive attributes**:GM technology promises to produce crops that are Pestresistant, herbicide tolerant anddisease resistant, this will reduce losses to pests, increase production and cut down on production costs. Again, there is potential increase in nutritional contents GM crops such as the 'golden rice' which has been developed andhighcontentofbeta-carotene**(vitamin A).**

b) **Concerns on GM crops**: there has been concern raised over the effects of consumption of products GM plants. It is acknowledged that GM crops may create health problems, it is also feared that there is ariskofintroducing allergens(usuallyglycoproteins)intothefood supply of humansand animals.

vii. KenyahasworkablebiosafetyregulationstoadequatelyoverseeR&D onGMOs.

viii. Kenyahasproperinfrastructuretomonitordevelopment, testinganddistribution ofGMO foods.

ix. KARIisnotsufficientlyfundedforResearchandDevelopmentto keepour scientists withinthecountry for development

x. HighlytrainedKenyanscientistswithtax-payersmoney(andindeed inAfricaasawhole)arenowleadingresearchanddevelopmentin biotechcompaniessuchasMonsanto,henceneedforincentivesto sustain them inthecountry.

xi. Thereisneedtoincludeallotherplayersinthefielde.g.health,legal andotherstakeholderstoaddressanybonafideissuesof concern createdeitherthroughmisinformationorthelowawarenesslevels about biotechnology.

xii. Itistherefore,recommendedthatscientificresearchaimedatrisk analysis, prediction,and prevention,combinedwithadequate monitoringandstewardshipshouldbedonesothatthenegative impactofGMproducts,ifany, may be kept to aminimum.

## 3.4 Submissions by the Taskforce on the Genetically Modified (Engineered) Foods/Products (GMOs)

1. On 8th November, 2012, in the 16th meeting of the Cabinet, the Minister of Public Health and Sanitation was directed to use the existing legal framework for public health to ban GM food imports and the ban to remain in force until a review and evaluation of scientific information on safety of GM foods on human health is undertaken.
2. The ban is not permanent but dependent on thorough assessment of Food safety and subject to an informed policy decision.
3. On 11th October, 2013 the Taskforce was gazetted through legal notice number 13607, to review matters relating to genetically modified foods and food safety with full TORs.
4. The main controversy that arises out of this is that Governments of countries with emerging economies like Kenya is careful evaluation of the balance between widespread hunger in the population (food Security and the ambiguity surrounding the GM food crop evaluation (food safety).
5. It should be noted that the modern biotechnological advancement has the potential to solve many agricultural, technological, nutritional and environmental issues that face humanity. However, the principles of ***"primum non nocere"*** (First Do Not Harm) need to be applied as the guiding principle since the majority of GM plants that are commercially available worldwide have been designed to express proteins that confer either insect resistance, herbicide tolerance, or both.
6. The taskforce studied and made comparisons on selected agricultural crops in Kenya and found out that generally the production have been below consumption levels. These re maize, wheat, rice, sorghum, millet, beans, cowpeas, Irish potatoes and sweet potatoes. National Meat consumption has been increasing since 2006 enough for domestic demand form cattle, goats, sheep, pigs and chicken. Fish and Milk has steadily increased with production.
7. The taskforce then gave an outline history and background to GM production giving examples of commercially approved GM crops worldwide and list of major GM events

destined for human consumption as shown in page 13 and 14 respectively in their report.

8. On standards for assessing the safety of GM crops, standards provide universal tools for guiding applicants on the suitability, adequacy and credibility of data that must be provided to facilitate assessment for GM food safety and approval of GM food imports. **Note that this can also be used to facilitate regulations. They gave an example of The Codex Alimentarius Commission Guidelines for GM Food – an intergovernmental body established in 1961-3 by conference resolutions of the FAO and WHA to protect consumer's health while ensuring fair practices in the food trade.**
9. The taskforce look onto the guiding principles on food safety assessment of GM crops, regulating food safety, the food safety assessment procedure for GM food/feed and safety assessment for products that are developed from within the country.
10. As stipulated by the Kenya Law and under the Cartagena protocol on biosafety, it's the responsibility of the NBA (National Biosafety Authority of Kenya) to regulate research and commercial activities involving GMO's with a view of ensuring the safety of human and animal health as well as protection of the environment. (NBA has procedures as shown in page 23 with subsequent food/feed safety assessment flowchart.
11. The GoK has put in place control measures for all GM activities or products approved in Kenya are safe. In 2006, the CS approved the National Biotechnology Development Policy; in 2008 Parliament passed the Biosafety Bill, which became law in 2009 – the Biosafety Act. Various regulations to implement the act have been done. **It should be noted that the current safety regulations of Kenya make no reference whatsoever to the safe consumption of GM foods.**
12. The taskforce then undertook the GM Maize case study, various research papers on safety assessment of GM foods.
13. Then, they look onto the legal framework and systems of biotechnology on GM foods in Kenya, institutional capacities and coordination of the regulatory agencies; particularly the NBA which works in collaborations with Public Health, DVS, KEBS,

KEPHIS, NEMA, PCPB, KWS and KIPI. Also included is Institutional Research on GMO's (KARI, ILRI and PTL at KU as well as Institutional Biosafety Committee.

**14.** The Taskforce did analysis of food security in Kenya and found that none of the GM food crops currently on the international market can answer the key challenges facing the food insecurity problems in Kenya.

**15.** They also undertook on analysis of possible reasons and underlying factors for the ban of GMO importation, cultivation and trade by some countries – which included absent or inadequate national policies or regulatory systems to deal with safety requirement for approving general use of GMO's. Its noted that most countries have either banned or put restrictions to GMO's. Those who allows has put in place for no commercial cultivation but rather processed products.

**16.** During the Public Participation Forum, the first group that called for lifting of the ban are associated with the GM industry, academicians and some farmers. The second group called for maintenance of the ban are from civil society organizations. Third group from legal, medical, academic professions, some civil society and consumer groups called for lifting of the ban provided that certain conditions are met. The last group stated that the GMO should be applied on case by case basis depending on the assessment of the benefits, risks and safety of each GM products.

## 4.0 COMMITTEE OBSERVATIONS

1. On the face of it, GMO products grown were as safe as conventionally grown products, since they are well researched and are released for public use basic on scientific evidence.
2. Use of GMO has allowed additional income to farmers, has helped to save soil and conserve fertility and could improve yields while using water more sustainably;
3. GMOs were consumed in the US and also exported to other countries including Europe where they constitute 70% of livestock feed.
4. The ban was as a precautionary measure but it was indefinite thus creating a legal vacuum;
5. Kenya has the potential of applying biotechnology with proper safety measures in place to be able to increase its food basket to be food secure;
6. It was not sufficient for the precautionary ban to only affect food products and leave out non-food products;
7. By-products of the non-food GM products may be used in food industries e.g the Bt-Cotton thus making it difficult to manage roll out of non-food GMO products.
8. Despite the ban, there are foods and foods flavours circulating in our supermarket stores e.g the aromat seasoning.
9. Despite the surveillance at entry and exit points by NBA and other bodies, GMO foods are still finding their way into the country. There is a gap in enforcing the ban on GMO foods
10. There is need for legislation on the safety of Genetically Modified foods for human consumption. Further noting that no GM product has so far been tested for safety for human consumption by Biosafety Authority. The present Biosafety Act that was passed by Parliament in 2009, has no specific provision for testing GM products for safety for human consumption.
11. The ban should not be lifted because GM products must pass a preliminary independently verified study which covers the acute and sub-acute phase of testing for human consumption. The 90-days rodent lab test used in safety assessment of GM products is too short to assure Food and feed safety. Therefore long term multi-

generational laboratory animal studies might be more appropriate for food GM food safety assessment.

12. There is need to involve the local independent scientists within National Institutions using Government funding. To carry out a chronic toxicity testing because all GM products must pass an independently verified 2 year animal feeding chronic toxicity test as the test will rule out Carcinogenicity, Teratogenicity. The chronic toxicity tests will qualify the GM producer for the issuance of a Class B permit from the food safety and Quality control unit. The permit should not exceed a period of 5 years.
13. It is important to seek reassurance on the safety of GM products for human consumption in light that 56% of the European Countries have put various restriction on the imports of GM products especially maize varieties. Most of the GM approvals by the EFSA are restricted to consumption feed and processing but not to cultivation and research. Therefore within European Union there is limited imports and virtually no cultivation of GM crops.

## 5.0 COMMITTEE RECOMMENDATIONS

The Committee at its 58th Meeting on 29th November, 2016deliberated on the report and made the following recommendations:

1. There is need to involve the local independent scientists within National Institutions using Government funding to research matters relating to GMOs.
2. There is need to kick start Commercialization of Bt-Cotton, however the government should put in place safety nets to ensure the byproducts of non-food GMOs do not find way into the food chain.
3. NBA should have a structured working relationship with other bodies to harmonize the process of developing, testing and regulating GMO products.
4. The Committee recommends that the government to encourage and support the development of this technology while at the same time as for all the other technologies, putting in place safety measures so as to ensure that the GM technology delivers the promises to humanity.
5. Further to the above recommendation Number 4, the Committee recommends that the ban on GM imports remains un-lifted until such a time when the following conditions are met:-

   **i.New Legislation on the Safety of GM Food for Human Consumption be put in place**

   New Legislation/regulations be put in place on the safety of Genetically Modified Foods for human consumption. The Committee noted that no GM product has so far been tested for safety for human consumption by Biosafety Authority. The present Biosafety Act that was passed by Parliament in 2009 has no specific provision for testing GM products for safety for human consumption.

   **ii. Requirement for Acute and Sub-Acute Toxicity Testing has been in place**

   That all GM products must pass a preliminary, independently verified, 90-day animal feeding study, which cover the acute and sub-acute phase of testing for human consumption. The 90- day feeding tests will qualify the GM producer for the issuance of a Class A permit from the Food Safety and Quality Control Unit of the Ministry of Health. This permit should be for a limited period not exceeding two (2) years.

**iii. Requirement for Chronic Toxicity Testing has been put in place.**

That all GM products must pass an independently verified year animal feeding chronic toxicity test. This test will rule out carcinogenicity, teratogenicity, etc. The Chronic toxicity tests will qualify the GM producer for the issuance of a Class B permit from the Food Safety and Quality Control Unit of the Ministry of Health. This permit should be for a period not exceeding five (5) years.

**iv. Requirement for Long-Term and Epidemiological Surveillance Testing has been put in place.**

That the long term tests will involve animal testing for at least three generations to rule out any transgenerational harm. The epidemiological tests will take the form of surveillance by the Ministry of Health on human populations for at least two generations i.e. from childhood to adult hood for the first generation and their offspring. This testing will use the usual epidemiological tools for surveillance. The long term and epidemiological surveillance testing will qualify the GM producer for the issuance of a Class C permit declaring the product safe for human consumption and needing no further tests.

**v. Responsibility for Reparation for has been put in place.**

That any GM producer whose product causes harm as confirmed by metabolomics, by animal and human testing and or through accepted new technologies involving in silica (computer) modelling will be held fully responsible for making good the harm and for reparation. The issuing authority may withdraw any permit if later testing including chronic testing and surveillance reveals harm.

**vi. Definition of the Role of the Food Safety and Quality Control Unit of the Ministry of Health has been put in place.**

vi. Definition of the Role of the Food Safety and Quality Control Unit of the Ministry of Health has been put in place.

That the specific role of GM food safety evaluation for human consumption is at the State Department of Health. Therefore they should be responsible for issuing the permits after consultation with the appropriate regulatory agencies and the Pharmacies and Poisons Board. But in case of severe famine where there is threat or loss of life, the president on the advice of the Cabinet, may instruct the Food Safety and Quality Control Unit to issue a special permit for the importation of life-saving food for a limited period provided that such cannot be used seed for cultivation and has been declared fit for human consumption. Notwithstanding this, every effort will be made to source the food from non-GMO sources failing which emergency GM food may be allowed in.

Signed.....Date...29TH NOV 2016.

**Hon. Adan .M. Nooru, MBS, CBS, M.P**
**Chairperson,**
**Departmental Committee on Agriculture, Livestock and Cooperatives.**

- GMO products grown are as safe as conventionally grown products, since they are well researched and are released for public use basic on scientific evidence.

- There are several GM varieties developed for crops like corn, cotton, soya beans, papaya, canola etc

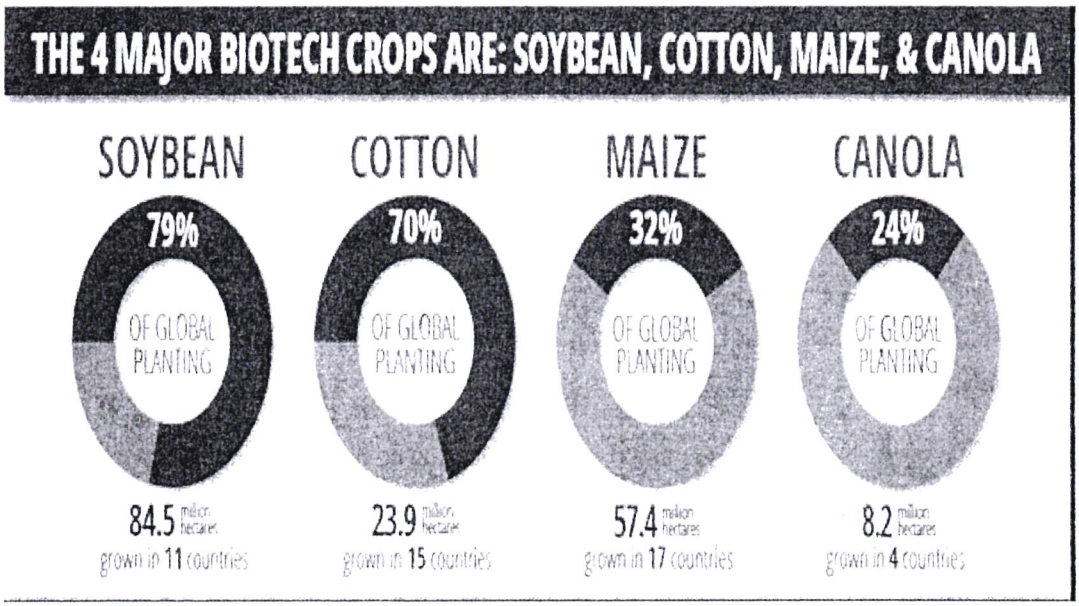


**Fig. 1: Major Biotech Crops in the world**

- The US government managed to save papaya from extinction in Hawaii from viral diseases through GM applications

- Use GM technology can control aflatoxin contamination of grains;

- GE crops are not developed at the expense of others;

- Markets decide which crops to be grown and sold;

- Africa would benefit greatly with application of several GE on food crops;

- Kenya is a regional leader on Science, Technology and Innovation and key in discussions among other African countries;

- US appreciates Kenya's steps in putting measures to harness GMO technology responsibly e.g. adoption of the National Biotechnology Development Policy and passage of the Biosafety Act, 2009 since it will advance crop and agricultural biotechnology in for example cassava which will put Kenya above all other countries in Eastern Africa and Africa at large;

- The ban on GMO food imports into Kenya therefore surprised many because it was not consistent with World Trade Organization rules and other conventions, to which Kenya is contracting Party;

- The Kenya Government should lift the ban the soonest, just like other countries such as Russia did in 2013;

- **The Seralini study** which led to the ban by the Kenyan government on GMO had been retracted from the Journal that had published it. It was recently republished in an anti-GMO journal;

- Rigorous regulatory system is important to ensure consumers, farmers and all other users of GMOs of safety. The US has 3 regulatory agencies– Animal Plant and Health Inspection Service **(APHIS)** which is similar to **KEPHIS and NBA in Kenya**, Food and Drugs Agency **(FDA)** which is similar to **KEBS** and **P&PBin Kenya** and Environmental Protection Agency **(EPA)** which is similar **to NEMA in Kenya. [Kenya's regulatory system apparently mirrors that of the USA];**

- Not everybody supports GE in the US due to political, ideological mindsets and lifestyle issues, very little due to the science itself; and

- 95% of all products in the US supermarkets are GE.

## II. SUBMISSIONS BY ANIMAL PLANT HEALTH INSPECTORATE SERVICE, FOOD AND DRUG AGENCY AND ENVIRONMENTAL PROTECTION AGENCY

### I. How to protect anti GE food Consumers

- There is dialogue between the farmers planting varied crops in the same area so that appropriate co-existence mechanisms can be instituted;
- There are laws for state and federal governments;
- The laws vary from one state to the other; and
- Field trials for GM crops must be consented by the state and local governments.

### II. Program for Biosafety Systems (PBS)

- The concerns and challenges raised are good for they necessitate more research and development and this has led to increased knowledge and refinement of the scientific process for developing GMOs to meet consumer demand;
- Science has improved with time hence increased nutrition, economy etc
  Focus has expanded to varieties of crops that address both livelihood and lifestyle needs.

### 1. DELEGATION OBSERVATIONS

i. Brazil, which once had a ban on GMOs until 2004, is today the fastest adopter of GE where land under GM crops has increased to40 million ha in just a few years (by 2013);

ii. US leads in use of GE with 70.1 million ha of land cultivated in 2013;

iii. Sudan and Cuba are two new countries to have adopted GM technology (Bt-cotton);

iv. Europe imports more GM foods from Argentina – a country which is almost 100% GM, for most of EU's animal feeds like soya bean cake, 70% percent of EU's livestock feed is source from GM products;

v. China imports GE corn maize and soy, grows Bt cotton and does GE rice production;

vi. Individual tuff guard and guard of trade interests makes it for China, Europe and others to discourage African countries to venture into GE and GMOs so as to guard their markets;

vii. Europe has moved most of their lead researchers to the US to learn so that they eventually help to transfer GM technology to EU in the coming years;

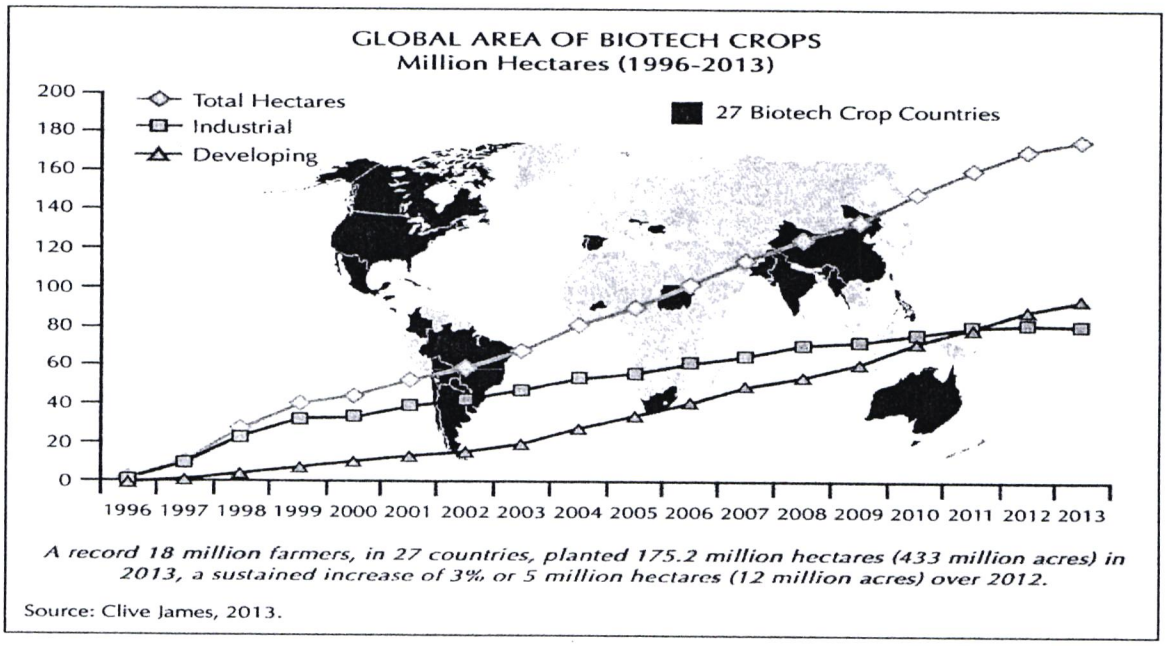


**Fig. 2: Global expansion of Biotech**

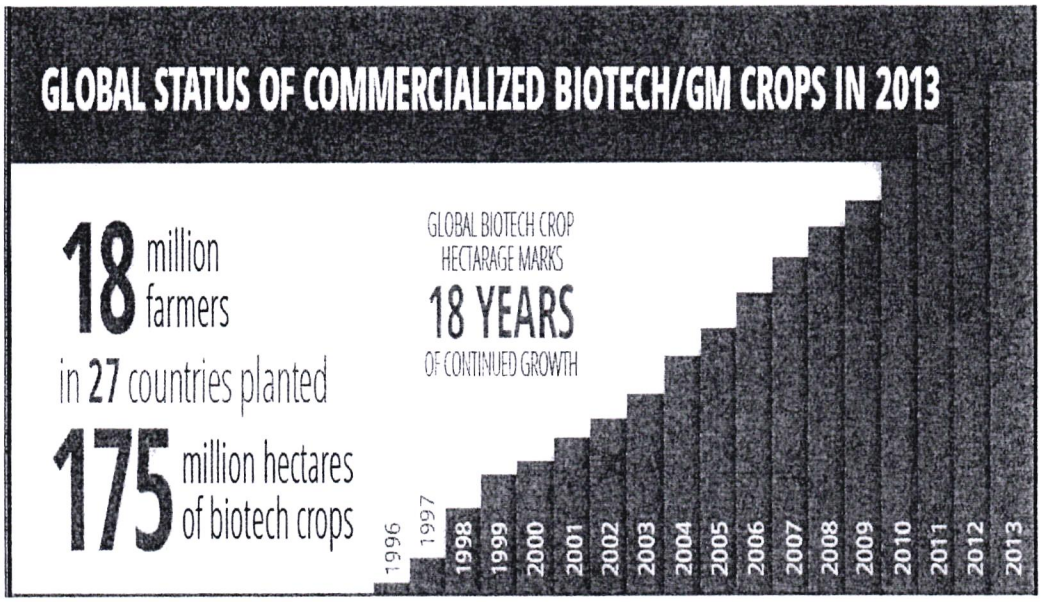


**Fig. 3: Global Status of Commercialized GM Crops in 2013**

viii. In Kenya we have the National Biosafety Authority (NBA), Kenya Bureau of Standards (KEBS), Kenya Plant Health Inspectorate Services (KEPHIS), National Environment Management Authority, Department of Public Health, Department of Veterinary Services working together to ensure and assure safety of GMO products?;

ix. Between an Agency and an Authority, which one would dispense services better?

The most important institutional set up is one that ensures state-of-the-art capacity that measures to international standards is maintained and sustained at all times to assure GMOs are safe for human consumption and that of the environment. Institutional such as the Program for Biosafety Systems and ISAAA exist to help facilitate the dual flow of scientific and biosafety information and knowledge generated through credible scientific methods for informed policy choices;

x. The EU has authorized import of 58 genetically engineered (GE) varieties for food and feed from the rest of the world, including the US. For example in 2013 the US exported to the EU $2.5 billion of corn and soybeans and 90% of all US corn and 93% of all US soybeans are GMOs; and

xi. GM crops have been commercialized around the world since 1996 and are today grown in 27 countries around the world a combined land area of nearly 170 million ha. This make GM technology the fastest growing agricultural technology ever invented perhaps comparable only to mobile telephony.

## III. SUBMISSIONS BY MONSANTO SEED COMPANY

The delegation learnt that the following: -

- Close to 90% of farmers using Biotechnology are small farmers concentrated mainly in Asia – India, China, and now in Burkina Faso and South Africa;
- Monsanto is doing a lot of work in Kenya through Water Efficient Maize in Africa (**WEMA**) project spearheaded by KARI with support from the AATF and CIMMYT;
- Bt Cotton in India (under brand name of Bollgard and Bollgard II) covers11 million hectares. Bollgard II is a 2nd generation of Bt-cotton both developed by Monsanto company;
- In Burkina Faso the program to grow Bt cotton started 2008 with8,500 and by December 2013, more than 400,000ha of land were under Bt cotton;
- Trials for Bt-Cotton have been on in Kenya and now they are ready for commercialization but the GMO ban is hindering commercialization, a big loss for the cotton sub-sector for market and value addition to necessitate quick pick;
- Kenya is an important hub for Monsanto and if the ban is lifted, it will benefit more since farmers will get more yields and harvests from their farms;
- Experience in India shows that there is an increase of USD64.10 per ha following adoption of Bt cotton;
- Cassava trials are on-going in Kenya and Uganda where VIRCA variety plant has been developed and currently on trials. Nigerian Agricultural Research and Organization and KARI are involved in the development of this variety which is resistant against Cassava Brown Streak Disease (CBSD) and Cassava Mosaic Disease (CMD);

- Bt-Maize confined field trials (CFT) in Kenya are done at Kiboko KARI Research farm in Ukambani; and
- Currently confined field trials (CFT) are on-going for WEMA hybrid maize variety that is being evaluated for drought tolerance at Kiboko KARI Research farm.

## 2. DELEGATION OBSERVATIONS

i. GMOs are fast spreading world over as a means of mitigating food production challenges. Adoption rate is very high and Kenya, as always, should take its position in the region as it had done before the temporary ban was imposed. Graphs below show the trends world over;

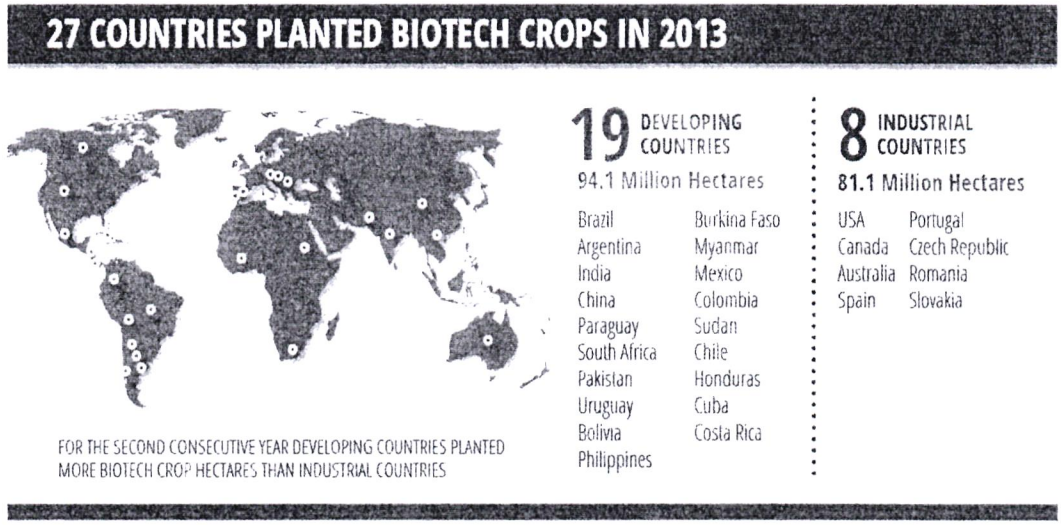


**Fig. 4: Countries that planted GE Crops in 2013**

ii. Kenya has workable biosafety regulations to adequately oversee Research and Development in GMOs. The country also has regulations on labeling but this has brought a range of challenges as has been the case in other parts of the world including the US states of California and Washington DC;

iii. Cotton Development Authority and Monsanto have been in collaboration on Bt Cotton for several years;

iv. KARI is not sufficiently funded for Research and Development to keep our scientists within the country for development;

v. Highly trained Kenyan scientists with tax-payers money (and indeed in Africa as a whole) are now leading research and development in biotech companies such as Monsanto, hence need for incentives to sustain them in the country;

vi. Precautionary measures should be put in place when the ban is lifted since activists funded by a network of businessmen against GMOs will rise to oppose the lift; and

vii. There is need to include all other players in the field e.g health, legal and other stakeholders to address any bona fide issues of concern created either through misinformation or the low awareness levels about biotechnology.

## IV. MINUTES

**MINUTES OF THEEIGHTY FIFTH SITTING OF THE DEPARTMENTAL COMMITTEE ON AGRICULTURE, LIVESTOCK AND COOPERATIVES (with the CS Health) HELD ON TUESDAY1ST JULY, 2014 IN COMMITTEE ROOM 5th FLOOR, CONTINENTAL HOUSE, PARLIAMENT BUILDINGS AT 10.30AM**

**PRESENT**

1. Hon. Adan M. Nooru, MBS, M.P - **Chairman**
2. Hon. KarekeMbiuki, M.P - **Vice Chairman**
3. Hon. Peter N. Gitau, M.P
4. Hon. WaitituMunyua, M.P
5. Hon. Maanzo Daniel Kitonga, M.P
6. Hon. Fredrick Outa, M.P
7. Hon. Mary Wambui, M.P
8. Hon. Silas Tiren, M.P
9. Hon. Korei Ole Lemein, M.P
10. Hon. Justice Kemei, M.P
11. Hon. Raphael Letimalo, M.P
12. Hon. Ferdinand Wanyonyi, M.P
13. Hon. KabandoWaKabando, M.P.
14. Hon. Phillip Rotino, M.P.
15. Hon. KimaniInchung'wah, M.P.
16. Hon. James OpiyoWandayi, M.P.
17. Hon. (Dr.) Victor Munyaka, M.P
18. Hon. John B. Serut, M.P
19. Hon. Patrick Wangamati, M.P
20. Hon. Benjamin Washiali, M.P

**ABSENT WITH APOLOGIES:**

1. Hon. Alfred K. Keter, M.P.
2. Hon. Paul SimbaArati, M.P.
3. Hon. Florence Mutua, M.P
4. Hon. Zuleikha Hassan, M.P.
5. Hon. John Kobado , M.P
6. Hon. AyubSavulaAngatia, M.P.
7. Hon. HezronAwitiBollo, M.P
8. Hon. Millie Odhiambo - Mabona, M.P

9. Hon. MaisonLeshoomo, M.P

**IN ATTENDANCE:**

**Ministry of Health**

| | | |
|---|---|---|
| 1. Mr. James Macharia | - | CS, Health |
| 2. Prof. Fred Segor | - | PS, Health |
| 3. Prof. KihumbuThaiya | - | Chairman, GMO Taskforce |
| 4. Dr. Joy Kiano | - | GMO Taskforce |
| 5. Dr. Anne Wangai | - | GMO taskforce |
| 6. Dr. KephaOmbacho | - | GMO taskforce |

**Kenya National Assembly Secretariat**

| | | |
|---|---|---|
| 1. Mr. Oscar Namulanda | - | Senior Clerk Assistant |
| 2. Ms. Tracy Chebet Emily Koskei | - | Clerk Assistant II |
| 3. Mr. Ahmad Adan Guliye | - | Clerk Assistant III |
| 4. Mr. Rodgers Kilungya | - | Hansard Reporter I |

**MIN.NO. 113/2014: PRELIMINARIES**

I. The meeting was called to order at Forty five minutes past Ten O'clock with a word of prayer from the Vice-Chairman.

II. The members of the Committee introduced themselves followed by the CS Health and his team.

**MIN.NO. 114/2014: ADOPTION OF THE AGENDA**

The Committee resolved to hold a meeting with the Cabinet Secretary for Health first before handling the House Keeping issues and thus agreed to the agenda as follows: -

1. Prayer
2. Meeting with the Cabinet Secretary Health
3. Confirmation of Minutes
4. Matters Arising
5. Any Other Business

**MIN.NO. 115/2014:** **SUBMISSION BY THE CABINET SECRETARY FOR HEALTH ON THE GMO REPORT**

The Cabinet Secretary for Health informed the committee that the GMO taskforce Report was ready but he could not share the recommendations of the Taskforce since he had written a memo to the Cabinet highlighting specific issues for the necessary action. He instead requested the Committee to allow the chairman of the Taskforce to give the insights of the report.

**I. Findings of the Taskforce**

- It could not prove whether GMO foods are fit for human consumption or not since it was not possible to do so in a short period.
- The country does not have the necessary legislation to assess the safety of GMO foods and there was need to institute a mechanism/ an independent body to clear GMO foods as being fit for human Consumption.
- There was need for proper infrastructure to monitor the production, testing and distribution of GMO foods.
- Seralini Report which had earlier been retracted was later republished in the European Scientists Journal. The report had informed the ban on GMO foods in Kenya.
- The EU countries have placed more stringent rules for clearing, usage and consumption of GMO food products.

**MIN.NO.118/2014:** **ANY OTHER BUSINESS**

I. Hon. Patrick Wangamati informed the committee that two members of the Committee were bereaved. Hon. John Serut, MP had lost his mother while Hon. Benjamin Washiali, MP had lost his sister. It was agreed that each member contributes Ksh 10,000 which will be divided between the two for support.

II. The Committee nominated following Members to travel to the UK on the trip organized by BAT. These are: -

1. Hon. Justice KipsangKemei, M.P – Leader of the Delegation
2. Hon. Mary WambuiMunene, M.P
3. Hon. KoreiLemein, M.P
4. Hon. Ferdinand Kevin Wanyonyi, M.P
5. Hon. Daniel KitongaMaanzo, M.P

**MIN.NO.119/2014: ADJOURNMENT**

There being no other business the chairman adjourned the meeting at 13.30 hours.

**Signature .....**

**HON ADAN MOHAMEDNOORU, MBS, M.P.**

**(Chairman)**

**Date.....**

## III. SUBMISSION BY THE CABINET SECRETARY MINISTRY OF HEALTH AND THE TASKFORCE ON GMO REGARDING KENYA'S BAN ON GM PRODUCTS

The taskforce on GMO was gazette on the 11th October, 2013 to review matters relating to genetically modified foods. The Cabinet Secretary Health and The Taskforce on GMO on their appearance before the Committee on Agriculture, Livestock and Co-operatives on 1st July 2014, informed the Committee that the ban on GMO foods in Kenya was a precautionary measure due to lack of information on the safety of GMO foods for human consumption.

The ban only applied to food products and not on non-food products such as Bt Cotton. The ban also did not affect advancement of research in Bio-technology which the Kenyan government has continued to support for years.

There have been various calls for the Lifting of the ban but the following issues were raised by the taskforce:

I. The is still no sufficient information to prove whether GMO foods are safe or not for human consumption;

II. The country does not have the proper legislation and mechanism to assess the safety of GMO foods;

III. The country does not have proper infrastructure to monitor development, testing and distribution of GMO foods; and

IV. GMO foods are not the only solution to the food security issue in Kenya, there are other options to explore.

## IV. SUBMISSION BY NATIONAL BIOSAFETY AUTHORITY

SUBMISSION BY THE NATIONAL BIOSAFETY AUTHORITY (NBA) ON GMO

Appearing before the Committee on 10th June, 2014 the National Biosafety Authority made its submissions through a memorandum highlighted as below:

i. NBA was established under the Biosafety Act No. 2 of 2009 to regulate activities relating to Genetically Modified Organisms (GMOs) in n implementing the National Biotechnology Development Policy published in 2006. This was in compliance with the international obligations under the Cartagena Protocol on biosafety which Kenya ratified in 2003;

ii. The mandate of NBA is to exercise general supervision and control over development, transfer, handling and use of GMOs so as to ensure safety of human and animal health and provide adequate protection of environment;

iii. To implement the Biosafety Act., towards which various regulations have been published. These include; labeling, Environment Release, contained use, Import and Export and transit regulations;

iv. Advise the Government on legislation and other measures relating to the safe transfer, handling and use of genetically modified organisms;

v. Promote awareness and education among the general public in matters relating to biosafety;

vi. In enforcing the Biosafety law, NBA coordinates all activities involving GMOs by consulting with a number of regulatory agencies as specified in the Biosafety Act including department of veterinary Services (DVS), Kenya Bureau of Standards (KEBS), Pest Control Board (PCPB), Kenya Plant Health Inspectorate Service (KEPHIS), National Environmental Management Authority (NEMA), Kenya Wildlife service (KWS), the Kenya Industrial property Institute (KIPI) and Department of Public Health. These agencies, except KWS, PCPB and KIPI sit in the Board of Management of the NBA, which make decision on all applications on GMOs;

vii. A total of nine (9) confined trials (CFTs), sixteen (16) laboratory and greenhouse trials, and twenty eight (28) imports and transit applications have been received, evaluated and approved since the establishment of the Authority.

## PROBLEM ANALYSIS FOR GMOS

The NBA analysed the problem as follows: -

i. The herbicide tolerant GM maize NK603 was first approved for cultivation in the Us in 2000, and currently the maize is approved for import and food use in over sixteen countries including; Argentina, Australia, Bulgaria, Canada, Colombia, Japan, Korea, Mexico, the Philippines, Russia, South Africa, Taiwan. Like any GM crop, the NK603 GMO maize went through a rigorous safety assessment in these countries before approval of food, feed and environmental release. From credible available literature, no adverse effects of NK 603 on human health have been found, over the entire period of use;

ii. On the 19th September, 2012, Seralini et al., published a paper claiming adverse effects of GM maize NK603 following a two year toxicological study using rats. They concluded that NK603 fed rats with or without herbicide development tumours and multiple organs damage and died earlier compared to the controls. The said paper has since been withdrawn by the publishers since the method used and data collected could not justify the conclusions reached;

iii. The publication triggered International debate on the safety of genetically modified organisms (GMOS) leading to some countries imposing a ban on GM food imports or research;

iv. During the sixteenth Cabinet meeting held on 8th November, 2012, the Cabinet instituted a ban on all GMO food imports until such a time that there will be sufficient information, data, and knowledge demonstrating that GM food is not a danger to public health.

v. The Cabinet further directed the Minister for Public Health and Sanitation, the Minister for Higher Education, Science and Technology and the Minister for Medical Services to establish a taskforce to evaluate the health effects of GMO foods, so that based on this knowledge, a policy decision can be made to either lift the ban or maintain it;

vi. Subsequent to the Cabinet's decision, the then Minister for Public Health and Sanitation imposed the ban on Wednesday, 21st November, 2012.

Following the ban, Kenya joined **Russia** which was the only other country that imposed a temporary ban on GM maize, NK603. However, on the 28th December, 2012, Russian Federal Service for Supervision of Consumer Rights Protections and Human Welfare who had imposed the ban on GM maize, NK603 lifted the ban.

Kenya therefore remains the only country in the world who has maintained the ban not only on NK603 but on all GM food imports.

The scientific paper by French scientists that had triggered the Government to impose a ban on all GM imports has since been retracted (November 2013) by the Journal that had published it. This was after it was established that the scientists had not adhered to internationally established and agreed procedures for evaluating GM foods.

## INFORMATION, DATA AND KNOWLEDGE DEMONSTRATING THAT GM FOODS ARE NOT A DANGER TO PUBLIC HEALTH

i. There was a large body of evidence so far gathered by the scientific community, regulatory bodies and international organizations such as the World Health Organization and the Food and Agriculture Organization (WHO/FAO), European Food Safety Authority (EFSA), Swiss Expert Committee for Biosafety, French Academy of Sciences and Medicine and Royal Society in London to mention a few that have come to the conclusion that GM foods are as safe as their conventional counterparts;

ii. To-date there has not been any published and reliable scientific data to demonstrate that GM products are any more hazardous than their conventional counterparts;

iii. Globally, in the last 20 years, 28 countries have approved and commercialized GMO, with acreage in excess of 170 Million hectares. In Africa, 4 countries namely; South Africa, Egypt, Sudan and Burkina Faso have commercialized GM technology, with other several countries including Kenya conducting research trials on a number of economically important crops; and

iv. No side effects directly linked to GM food/feed consumption or use has been reported in these countries.

## NATIONAL CAPACITY FOR REGULATING AND BIOSAFETY REGULATION AND TESTING OF GM FOODS

The NBA just like all other Biosafety Regulatory bodies worldwide has established a transparent science-based and predictable risk assessment process to guide decision making on applications for approval of research and commercial activities involving GMOs;

The safety assessment process on GM foods is on a case by case basis. As such, approvals or rejections are for each GMO, based on data generated on their safety;

In the decision making process, the Department of Public Health, among others are involved as they are part of the NBA Board, the organ that makes decisions on all GMO applications;

NBA has attained a critical mass of best talents for regulating and testing GMOs and their products. The Authority currently has a staff establishment of 42 staff. The Technical Division has 12 expertise staff (3 PhDs and 9 MSCs) in the fields of biotechnology, biosafety and related disciplines. Additionally, the Authority has a pool of experts working in universities and research institutions who from time to time are engaged to review and give independent opinions on GMO applications before decisions are made;

In terms of capacity to carry out surveillance, the Authority has opened 4 offices at major entry and exit points namely Mombasa, Busia, Namanga and Jomo Kenyatta International Airport (JKIA);

The Biosafety Inspectors manning the entry points are mandated to scrutinize shipping documents to ensure they are complete and have declared GMO status, monitor and take official samples from consignments entering the country and send them to our collaborating GMO testing laboratories;

Infrastructural capacity to detect GMs in the country is available in various public institutions and regulatory agencies (KEPHIS and KEBS) research institutes, including KARI's Biotechnology Centre and Public Universities;

NBA works closely with other regulatory agencies, including Kenya Bureau of Standards (KEBS), Pest Control Products Board (PCPB), Kenya Plant Health Inspectorate Service (KEPHIS), National Environmental Management Authority (NEMA), Kenya Wildlife Service (KWS), the Kenya Industrial Property Institute (KIPI) and Department of Public Health;

Within Sub-Saharan Region, NBA has the lead in supporting regional regulatory harmonization at COMESA and East African Community, and number of countries have since benchmarked with NBA as they continue to establish their regulatory framework. Countries that are actively benchmarking with the Kenyan regulatory system include Nigeria, Zambia, Uganda, Tanzania and South Sudan among others.

## 3. FOOD SAFETY EVALUATION OF GM FOODS

i. 6.1. Among the safety concerns of GM crops include; direct health effects (toxicity), tendency to provoke allergic reactions and alterations in food compositional properties;

ii. To assess for safety of GM foods, NBA has established a transparent, science-based and predictable process on a case by case basis for reviewing and making decisions on the development, transfer, handling and use of GMOs and related activities;

iii. This is based on risk assessment process anchored on internationally recognized agreements and Standards such as Codex Alimentarius Commission Principles (CAC), World Health Organization (WHO), Cartagena Protocol on Biosafety (CPB), Food and Agricultural Organization (FAO) and Organization for Economic Development and Corporation (OECD) consensus documents. These guidelines and other international regulatory authorities are considered to be adequate for assessment of safety of GM foods currently in the international market;

iv. These guidelines establish standards which have been used over the years by regulatory agencies and provide sufficient data and information that have shown that GM foods do not pose a danger to public health.

## 4. THE STATUS OF GM FOOD APPROVALS IN KENYA

i. NBA has approved a number of confined field trials involving GMOs strictly for research purposes under confinement;

ii. NBA has approved GM foods for importation into and transit through Kenya for humanitarian assistance and relief supplies prior to the ban;

iii. Approval of these applications was after a thorough risk assessment based on international standards;

iv. NBA has not approved any GM for commercial release in Kenya;

v. NBA maintains a roster of experts who have expertise on GMOs and provide independent opinion on the safety of GM products intended for approval by the Authority; and

vi. The composition of the NBA Board, the decision making body on all GMO applications, is also so diverse and brings a wide range of stakeholders including other Government agencies such as Department of Public Health and KEPHIS, scientists, farmers as well as representatives of consumers. This is important to ensure all stakeholder interests are taken into account in the final decision by the Authority.

## IMPACT OF THE GM FOOD IMPORT BAN

i. The impact of the ban has slowed down commercialization of Bt- cotton which supports the realization of Vision 2030 and Medium Term Plan II (2013-2017), which recognizes and gives priority to biotechnology as one of the tools for spurring economic growth and poverty alleviation;

ii. The performance of NBA has been adversely affected due to loss of revenue since the Authority has not received any application for Import and Transit since December 2012 as projected in its budget. The core activities of the NBA have therefore been adversely affected due to misinterpretation of the ban;

iii. National Biosafety Authority legal mandate has been infringed on and stakeholders' confidence reduced in ability to manage and regulate biotechnology and Biosafety in Kenya;

iv. The Government has invested heavily and continues to allocate funds in biotechnology and biosafety in terms of infrastructure and human capacity in Kenyan universities and research institutions and a number of projects, some at advanced stages, utilizing GM technology. The ban could reverse the gains achieved to date. In addition, the ban has led to de-motivation to researchers, students studying biotechnology and related disciplines and has also discouraged development partners from research support which does not augur well for the future of biotechnology;

v. In the event of drought and food shortages, the ban may deny Kenyans and the region as a whole an opportunity to access food during times of emergency since Kenya is a major transit corridor for food aid destined for the Greater Horn of the Africa region;

vi. In view of the ban access has been denied of food supplements containing GM ingredients such as corn soya blend for vulnerable and special needs people who use them due to health reasons including school feeding programs including loss of business and revenue as transit of GM food stuffs was re-routed to other alternative ports in the region; and

vii. Kenya is a signatory to various international agreements including Cartagena Protocol on Biosafety and World Trade Organization (WTO). Therefore, the ban has a negative impact on our international image / obligations, private investments and trade.

# V. REPORT ON THE POSITION OF THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES ON THE BAN OF GENETICALY MODIFIED (GM) FOODS IN KENYA

## 1.0BACKGROUND

TheNationalAssemblyDepartmentalCommitteeonAgriculture,Livestockand Cooperativesrequestedthefollowinginformation:TheMinistry'spositiononthebanofGeneticall yModified(GM)foodsinKenya.

## 2.0RESPONSE

### 2.1Introduction

Genetically modified (GM) plants, also called transgenic plants, are designedtoacquireusefulqualityattributessuchasinsectresistance, herbicidetolerance,abiotic stresstoleranceanddiseaseresistance,high nutritionalquality,highyieldpotential,delayedripening andenhanced ornamentalvalue amongothers.
Thus,GMplantscanpotentiallyaffectmanyaspectsofmodernsociety, includingagriculturalproduction.Despitethesepotentialapplications,the useofGMplantsforhumanwelfarehasbeenrestrictedowingtovarious concernsraisedbythepublicandcritics.Theseconcernsaredividedinto differentcategories,namely,health,nutritional,environmental,ecological, socio-economic,andethicalconcerns.DuringtheSixteenthCabinetMeetingheldon**8thNovember,2012**,t heCabinetinstitutedabanonallGMOfoodimportsuntilsuchatimethat therewillbesufficient information,data,andknowledgedemonstrating that GMO food is not a danger to public health. Subsequent to the Cabinet's decision, the then Minister for Public Health and Sanitation imposedtheban on **Wednesday,21stNovember, 2012**.

TheCabinetdirectedthethenMinisterforPublicHealthandSanitationto establishataskforcetoevaluatethehealtheffectsofGMOfoods,sothat

basedonthisknowledge,apolicydecisioncanbemadetoeitherliftthe ban or maintainit.Followingtheban,KenyajoinedRussiawhichwastheonlyothercountry thatimposedatemporary banonGMmaizeNK603.However,on28th December,2012,Russialiftedtheban.Kenyathereforeremainstheonly countryin theworldthathas maintainedthe ban notonlyonNK603but on allGM foodimports.

## 2.2Position oftheMinistryon theBan ofGenetically Modified (GM) Foods in Kenya

ThepositionoftheMinistryofAgriculture,LivestockandFisheriesonthe banofimportationofGeneticallyModified(GM)foodsintoKenyaisthat, thereis need to wait for theoutcomeof the work undertaken by a Taskforceconstituted by the Ministry ofHealth through legal notice number**13607dated11thOctober,2013**toreviewmattersrelatingto genetically modified foodsandfood safety.The Ministry willtakea standbased on theTaskforce'sreport.

## 2.3Attributes ofGenetically Modified(GM) foods

Theministrytakesnoteofvarious**attributes**ofGeneticallyModified(GM)foodsandplantsasfollows:

### a)PositiveAttributes

Foodsecurityremainsapriorityobjectivefor theMinistryofagriculture, livestockandfisheries,whichiskeentoaddressthechallengesfacingthe sectorandespeciallyensuringfoodsecurity.GMfoods promisetomeet thisneedina number of ways:

**i)Pestresistance:** Croplossesfrominsectpestscanbestaggering, resultingindevastatingfinancial loss to farmersleadingto foodinsecurity. Farmers use chemical pesticidesto control these pestswhile some consumersontheotherhanddonotwishtoconsumefoodthathasbeen

treatedwith pesticides because of potentialhealth hazards. GrowingGMfoodssuchas**Btcrops**thatareinsectresistantcanhelp eliminatetheapplicationof chemicalpesticidesandreducethecostof production.

**ii)Herbicide tolerance:** For some crops, it is not cost-effective to removeweedsbyphysicalmeanssuchastilling,sofarmersoptforuseof herbicides (weed-killer) to destroy the weeds, a time-consuming and expensiveprocess,whichrequiresmuchcaresothattheherbicidedoes not harm the cropplant or the environment.Cropplantsthataregeneticallyengineeredtoberesistanttooneeffective herbicide could help preventenvironmental damage by reducing the amountof herbicides needed.

**iii) Disease resistance:** Scientistsare conducting research to create plantswithgenetically engineered resistancetocropdiseases.Examples areworkonresistancetoCassavaMosaicandBrownStreakDiseasewhich isbeingcarriedout.

**iv) DroughtTolerance/SalinityTolerance:**Asthepopulationgrows andimpactsofclimate change felt,farmerswillneedtogrowcropsin locations previously unsuited for cultivation. Anexample is**Water Efficient MaizeforAfrica(WEMA) being**testedinKenya.Under moderatedrought,WEMADroughtTolerantmaizecombined withinsect protection isexpectedto increase yields by**20–35%.**

**v) Nutrition:** Malnutrition iscommoninthirdworldcountrieswhere impoverishedpeople rely on a single cropsuch asriceasthe main staplein their diet. However, rice does notcontainadequateamountsofall necessarynutrientstopreventmalnutrition.Plantscientistshavecreateda strainof"golden"ricecontaininghighcontentofbeta-carotene**(vitamin A).** Kenyaiscurrentlyintheprocessofdevelopingbiofortifiedcassavaand sorghumthatwillbehigh yieldinganddiseaseresistantwithconsumer- preferredcharacteristics.

**b) Concerns Relatedto Health andNutritionalStatus ofGMOs.**

**i)NutritionalStatus**

Itisacknowledgedthatconsumptionofproductsof GMplantsmay create health problems or may lead to the development of newer microbialstrains that may bepathogenic. Further,theplantsthemselvesmaybesusceptibletosuchrisks.The

PublicandcriticsofGMfoodsarealsoskepticalaboutthenutritional content andqualityof the GM plants.

**ii)Susceptibilityto Allergens**

Oneofthemajorconcernswithnon-traditionalproteinsinGMfoodsis theriskofintroducing allergens(usuallyglycoproteins)intothefood supply of humansand animals. Thepublicis concernedabout the natureofthesenewfoodproteinsastheirallergenicornon-allergenic qualities areunknown.

Ontheotherhand,thescientistsbelievethatthefoodallergensarefoundonlyinafewdefinedsources(peanutandothergrain legumesshellfish,treenuts,etc.),andhence,onlyadozenfoodsmayproduce allergenic reactions.

**iii) Transferof antibiotic resistancegenetomicrobesandreduced efficacy of antibiotic therapy.**

ThePublicisalsoconcernedaboutthepotentialrisksassociatedwithgene transfer fromGMOderivedproducts tomicrobes in the guts of humansand animals.Itisspeculated thattheconsumptionofGMfoodscontaining antibiotic resistance marker gene (e.g. kanamycin andneomycinor ampicillin)byhumansandanimalsmayleadto transferofthesegenes fromGMfoodtomicrofloraintheguto fhumansandanimalstransforming them into strains that couldberesistant to antibiotic therapy.

**2.4FoodSecurityPrograms/Interventionstoincrease productivity**

The Ministry is undertaking the followingtoincrease productivity:

### i) Fundingfor foodsecurity

Inthecurrentfinancialyear**2014/2015**budget,itisappreciatedthattheMinistryofAgriculture,Livestockand Fisherieshasbeenallocated**Ksh36.981billion** towardsboostingfoodproduction,thatisexpectedto resultinreductionincostoflivingparticularlybyreducingfoodpricesand boosting overallruraldevelopment.

Thefundsaredirectedtokeyflagshipprojectsincludingirrigation,input subsidy, strategic grainreserve,water harvesting and Mechanization, FisheriesandLivestock dvelopmnt TheMinistryiskeenonplaying itsrolebypromotingcompetitiveandcommercialorientedagriculturethrough utilization of modern andefficient agriculturaltechnologies.

ItisworthnotingthatthisCountryisendowedwithawiderangeofAgro EcologicalZonesthatprovidesagreatpotentialforvariousfoodcropssuch asmaize,beans,Irishpotatoesandsweet potatoesinadditiontoother cropssuchasWheat,Rice,Pyrethrum,Coffee,Tea,Cotton,Sugarcaneand HorticulturalCrops

### ii) NationalIrrigation Programme

TheMinistryhasdeliberatelyplacedirrigationandstormwaterharvesting as a priority National agenda. Through the**Expanded National IrrigationProgramme** (ENIP)implementednationwideinthevarious countiesfrom**2010**;**180**communitybasedirrigationprojectshavebeen identifiedacrossthecountryforsupport.Thisencompassessmallholder irrigation schemes, medium community schemes andpublicschemes.
ToimplementtheseprojectstheGovernmentduringthisfinancialyear**(2014/2015)**allocated**Kshs.1 1.7 billion**was allocatedfor the development of irrigation anddrainage infrastructure.Targets for increased

foodsecurityincludesubstantialinvestmentinGalanaandKulaluRanches for the 10,000 acremodelfarm ofirrigatedland.

**iii)Fertilizers andimprovedseeds**

TheMinistryhasmadearrangementstocontinueavailingfertilizersand improvedseedsataffordablepricestofarmers.Forthispurpose,**Kshs.3 billion has been allocated** in the current financial **year 2014/15**, where **Ksh2.5billion**will purchase fertilizer and**Ksh0.5 billionseeds.**

**iv)Traditionalhighvaluecrops:**Theministryhasensuredadequate supplyofhybridseedsand anassortmentoftraditionalhighvaluecrop seedsto meet the requirements of each season.Thisyear,the Government hassetaside**Ksh62million**formultiplicationanddistributionofvarious traditionalhighvalue cropplanting materials.

**v) Fertilizer strategy**

TheMinistryisalsospearheadingtheimplementationofthe**Vision2030 flagshipproject**onthethree-tier**FertilizerCostReductionStrategy** forfarmerstohavetimelyandreliablesupply of the commodity.The governmenthasthereforeputinplacealongtermsustainablestrategyfor establishingafertilizermanufacturingplantinthecountry.Aninvestorhas been identified andFeasibility study completed where Eldoret is the proposedsiteforthefactory.Duringthe Financialyear2014/2015the investorwillfinalizethearchitecturalandstructuraldesignsandcommence the construction work.

**vi) StrategicGrain Reserve(SGR)**

Towardsaddressing food availability in thecountry the government through**StrategicGrainReserve** (SGR)purchased**1,024,824bags** (90kg)of maize through

theNationalCerealsBoardat acost**Ksh3billion** in the year**2013/14**to improvethebuffer stock. DuringthemonthsofMarch/Aprilthegovernmentmoved**135,571bags**(90kg)ofmaizeto**23ASAL** countiestoimprovetheavailabilityofgrains inthelocalmarket. Further, theGovernmentisalsointheprocess of realising**500,000millionbags**ofmaizefromthestrategicreservesto the localmarkets tostabilizegrain availabilityand prices.

**vii) Agriculturalmechanization**

The Ministry**intendsto strengthen on-farm agricultural mechanizationtoenhance agricultural productiontoachieve development**goalsasenvisionedinvision2030.Thegovernmenthas concludedfinancingnegotiationswiththeBrazilianGovernmenttosupply**1,500 tractorsof**variouscapacitieswithassociatedimplementsandequipments.

**viii) Livestock Sub-sector**

Thelivestocksub-sectorcontinuestoplayasignificantroleasitprovides employment,food,foreignexchangeandrawmaterialsfortheagro-based industries.Thesub-sectorisalsotheprimarysourceoflivelihoodinmost parts of the countryespeciallythe aridandsemi-arid lands(ASAL).

In an effort to create a vibrant livestock sector in the Country, the government in conjunctionwith DevelopmentPartners has been implementinganumber oflivestockdevelopmentprojectsasawayof improvingproductivity.

These programmesare Agriculture SectorDevelopment Support Programme,Small-HolderDairyCommercializationProject, Farmers"FieldSchoolsand PromotionofFarmers"Innovations, andSpecialProgrammefor Food Security.

Alltheseprojectsareaimedatdevelopingamorevibrantlivestocksector in theCountry in terms of

infrastructure, rehabilitation of rangelands, marketdevelopmentandsupporttocommunitybasedlivestockeffortsand drought mitigation initiatives in order to boost productionfor foodsecurity.

**ix) Fish farming**

Fishfarmingisakeysub-sectorinthiscountywherefishingisdoneeither inthelakesorundertakeninbothprivateandcommunityowneddams.To supplementfishproductionfromLakeNaivasha,severalinterventionshave been implemented through the National and County government with supportfromprojectssuchastheKenyaAgriculturalProductivityand Agribusiness Project, Community Development Trust Fund and AgriculturalSector Development Support Programme.

**x) NationalAcceleratedAgriculturalInput AccessProject(NAAIAP):**

The programmehas 2 components:

a)KilimoPlustargetstheresourcepoorfarmerswhoareprovidedwitha packageofseeds,fertilizer andtrainingtocultivateatleastoneacreof landtomeethouseholdneedsandsurplusforsale.Theseinputsare providedfree of charge through voucher system for at least 2 years.

b)KilimoBiasharatargetsthemoreendowedfarmersbyprovidingthemwith lowcost credit topurchase inputsand increase theirproduction.

## 3.0CONCLUSION

- Foodsecurityand economicwell-beingofthefarmers,remains apriority objectivefor our Nation. Despite severalfood security initiativesthathavebeenundertakenbythe NationalandCounty Governmentswithsupportofdevelopmentpartners,Kenyahasnot yet

attainedfoodself-sufficiency.

- Publicopinionregardingtheapplicationanddevelopmentofgenetic engineeringislikelytobeanimportantfactorinfluencingthefuture developmentofthetechnologyanditssubsequentapplicationwithin the commercialsectorin thiscountry.
- Itistherefore,recommendedthatscientificresearchaimedatriskanalysis, prediction,and prevention,combinedwithadequate monitoringandstewardshipshouldbedonesothatthenegative impactofGMproducts,ifany,maybekepttoaminimum.Further,it isviewedthatcase-by-casestudiescanhelpinsolvingtheraised concerns.-recommendation
- GMtechnologyisanadditionaltoolinthefarmers'toolbox**butNOT**theonlyone. Itisavalue-additiontechniquethat canbe usedcomplementarilyandin anintegrativemannerwithotherexisting technologies.

# VI. SUPPLEMENTARYINFORMATION

## 1.0Kenya's Vision 2030

- In linewith Vision 2030,Kenyaaspires to**transformthe agricultural sectorto a commercially oriented sector**.This involvesaradicalshiftinagriculturalproductionthroughasustained application of knowledge, information andtechnology.The role of the Ministryintheformulationandimplementationofenablingpoliciesis therefore very critical.

- Thetwinchallengeof**foodandincomesecurity**inthedevelopingcountriesandespeciallysub-SaharanAfricahasdominatedpublic debatesfordecades.To datethechallengepersistsandiseven worsenedbythe ever rising population increase.

- Populationgrowthhasdirectimplicationsonavailablelandinthe ruralareas where the main economicandsocialactivity isagriculture. Africanagriculture remains predominantly traditionaland most countriesexhibitahighdependencyonfoodaid,whichaccountsfor a quarterofallglobalfoodaidshipments. Reversing thistrend requiresstrategic,politicaland**technologicalinterventions**that wouldddramaticallyraiseagriculturalproductivitywhileconservingthe naturalresourcebase.Thisisnotonlyimportantbutalsourgentin fooddeficitcountries such as Kenya.

- **ImprovingtheproductivityofKenya'sagriculture is**central to meetingthe challenges of feedingthe growingpopulation,creating wealth,reducingpovertyandmanagingthe degradationofnatural resources.

Aconcertedefforthastobemadeinaddressingthe country'svulnerabilityto climatechangeanditsbioticandabiotic impact onagricultural productivity, as well as its policy and institutionalreformagenda.

- Acontinuousreformprocessincludingthesuccessivelaunchingof theStrategyforRevitalizationofAgriculturein2003followedbythe AgriculturalSectorDevelopmentStrategy (ASDS)in2009hasover thelast13yearsemphasizedtheneedforpolicy,legal,institutional andregulatoryreformsasarequisitetoagriculturalsectorgrowthin Kenya,aswellasitsenhancedroleineconomicdevelopmentinline withthe aspirations of Vision 2030.

- The role of science, technology and innovation including the application of biotechnology in the economic transformation of developingcountriesincludingKenyahasbeenasubjectforpublic policyandmanyatimetheensuingcontroversieshavenothelpedto generateconsensusaroundpotentialbenefitslikely toberealized througharesponsibleexploitationofmodernbiotechnologyincluding geneticengineering.

**2.0Facts about GMOs**

i. Brazil,whichoncehadabanonGMOsuntil2004,istodaythe fastestadopterofGeneticEngineering(GE)wherelandunderGM cropshasincreasedto**40millionha**injusta fewyears(by2013)
ii. USleadsinuseofGEwith70.1millionhaoflandcultivatedin 2013
iii. SudanandCubaaretwonewcountriestohaveadoptedGMtechnology (Btcotton).
iv. EuropeimportsmoreGMfoodsfromArgentina–acountrywhich isalmost100%GM.Most ofEU'sanimalfeedslikesoya beancake and 70% percent of EU's livestock feed is sourced from GM products.
v. China imports GE corn maize andsoy;grows Btcotton andGErice
vi. VestedtradeinterestsdiscourageAfricancountrieslikeKenyato venture into GEandGMOs so as to guardtheirmarkets

vii. EuropehasmovedmostoftheirleadresearcherstotheUSto learnGEsothattheyeventuallyhelptotransferGMtechnologyto EU in the coming years.

viii. InKenyawehavetheNationalBiosafetyAuthority(NBA),KenyaBureau of Standards (KEBS), Kenya Plant Health Inspectorate Services(KEPHIS), NationalEnvironmentManagementAuthority, DepartmentofPublicHealth,Departmentof VeterinaryServices workingtogether to ensure andassure safety of GMOproducts.

ix. The EU has authorizedimport of 58genetically engineered(GE)varieties for foodandfeedfrom therest of the world, including the US.For example in 2013 the US exportedto the EU $2.5 billion worth of corn andsoybeansand90% of allUS corn and93% of allUS soybeans are GMOs.

x. GMcropshavebeencommercializedaroundtheworldsince1996 andaretodaygrownin27countriesaroundtheworldacombined landarea of nearly170 million ha.

## 3.0GMO Status in Kenya

i. GMOsarefastspreadingworldoverasameansofmitigatingfood production challenges.

ii. KenyahasworkablebiosafetyregulationstoadequatelyoverseeR&D onGMOs.Thecountry alsohasregulationsonlabelingbutthishas brought arangeofchallengesashasbeenthecaseinotherpartsof the worldincludingthe US states of California andWashington DC;

iii. CottonDevelopment Authority and Monsanto have been incollaboration on BtCotton for severalyears;

iv. KARIisnotsufficientlyfundedforResearchandDevelopmentto keepour scientists withinthecountry for development;

v. HighlytrainedKenyanscientistswithtax-payersmoney(andindeedinAfricaasawhole)arenowleadingresearchanddevelopmentin biotechcompaniessuchasMonsanto,henceneedforincentivesto sustain them inthecountry.

vi. Precautionarymeasuresshouldbeputinplacewhenthebanisliftedsinceactivists fundedbya networkofbusinessmen against GMOswill rise to oppose the lift;and

vii. Thereisneedtoincludeallotherplayersinthefielde.g.health,legal andotherstakeholderstoaddressanybonafideissuesofconcern created eitherthroughmisinformationorthelowawarenesslevels about biotechnology.

**4.0Demystifying GMOs in Kenya**

(a) ThereissufficientinformationtoprovethatGMOfoodsaresafefor human consumption

- An estimated two trillion meals containing biotech-derivedingredientshavebeeneatengloballyfor18yearswithouta single substantiatedcase of ill-health.
- There'sscientificconsensusthattherearenofoodsafetyissuesuniquetoGMfoodsascomparedtoconventionalfoods.Inboth cases,foodsafety is an issue that needsattention.
- There is widespread agreement among scientists andinternationalhealthorganizationsthatbiotechcropsandfoods are safe.
- TheEuropeanCommissionreleaseda2011compendiumof50 researchprojectspresentingindisputableevidenceofthesafety of biotech foods.
- ThefoodsafetyissuesforGMOsaresimilartothatofnon-GMOproducts.
- IssuesofassessingsafetyareofhigherstandardsforGMOsthan conventionalproducts.Safetyassessmentismuchmorerigorous on GMOs than traditionalfood.
- In addition, thereexist internationallyandlocalrobust regulations to address safety assessment and concerns.

Codex Alimentations guidelines, WHO guidelines provide guidance on howto assess the safety of GM foods;

- TheseprotocolsfortestsofGMfoodshavebeenevaluatedand passedbytheFoodandAgricultureOrganizationoftheUnited Nations (FAO) andWHO.
- According to WHO, "Bt protein iscurrently usedas a conventionalinsecticideinagricultureandissafeforhuman consumption"
- AllGMfoodsintheinternationalmarketshavebeenassessed andpassed as safe under

the set guidelines

- Approvalsinthecultivatingcountrieshavebeengrantedbythe competentauthoritiesafterarigorousriskassessmentprocess to provesafety.

**(b) Kenyahasproperlegislationandmechanismtoassessthe safety ofGMO foods.**

- Kenyaissignatorytotheinternationalinstrumenton Biosafety known as the**Cartagena Protocolon Biosafety**(CPB)
  - oTheProtocol specifically provides a guide for the regulation of handlinganduse of GMOs
  - oTodomesticatetheProtocol,theGovernmentpublished the**National BiotechnologyDevelopmentPolicyin theyear 2006.**
- ThisPolicyprovides guidanceinresearch,developmentanduse of biotechnology in various fields such asagriculture,environment,human health and industry which;
  - Elaborate the vision of the Government on matters of developmentand applicationofbasicandappliedsciences inbiotechnology
  - Providesdevelopers/researchersand usersof biotechnology a clearframework inwhich to operate
  - Promotepublicunderstandingofthepotentialbenefitsof Biotechnology

(c)**The National Biosafety Authority** wascreatedbyanActof Parliament, the **Biosafety Act of 2009** and is the competent government agencychargedwith regulatingGMOs in Kenya.

- Provisionforregulatoryagenciesinvolvementinthedecision making through NBA Board
- Acoordination structureexists between NBA regulatory agencies involvedin food safety and Department of Public Health is a member
- NBAindeliveringitsmandatetoensuresafetyworksinclose collaborationwiththe regulatoryagenciesasspecifiedinthe BiosafetyAct–KEPHIS,KEBS,DeptofVet Services,NEMA, PublicHealth, PCPB andKWS

- Decision making is aconsultative and inclusive process involvingthe relevant agencies involvedinfood safety

**d) Kenyahasproperinfrastructuretomonitordevelopment, testinganddistribution ofGMO foods.**

- KARIhasbeenundertakingresearchonGMcropsforseveralyears
- NationalUniversitieshaveprograms inbiotechnology where research on GMOs is very active with hundreds of young researchers.
- Establishedinstitutions-

NBA,KEPHIS,KEBS,PublicHealth,DVSandotherregulatoryagenciesdomonitordevelopment, testing and distribution of GMOfoodsin the country

- Thereare laws, regulations and standards that these agenciesapplyinthecourseofmonitoring,development, testing and distribution of GMOfoods.
- TheKenyaBureauofStandardshasdevelopedstandards namely:**KS2182: 2009**onthe**"Codeofpracticeforhandling, transferanduse ofgeneticallymodifiedorganismsandderivedproducts"**and**KS2225:2010** on **"Genetically modified organisms and derived products– Labelingoffoodandfeed".**Thesestandards are taken into account by the Authority when making decisions to authorize GM foods.

**(e) GMOfoodsarenottheonlysolutiontothefoodsecurity issuein Kenya butcompliments other tools-SUBM**

□**GMtechnologyisanadditionaltoolinthefarmers'toolbox but NOT the onlyone.** It isavalue-additiontechniquenota farmingsystem.

□GMtechnologyisusedcomplementarilyandinanintegrativemanner withotherexistingtechnologies.Cropimprovementisdonebyuseof conventionalbreeding,improvementofagronomictraitsandgenetic modification

□Someproductionconstraintsandplantdiseaseshavebeenaroundformanyyears,forwhichconventionalbreedinghasbeenaddressing them but withlimitations

□GMisgivinganedgeindevelopingpestanddiseaseresistantcrops for increasedagriculturalproductivity.

□Itisimportanttherefore,tomakealltechnologiesavailable,explain benefitsandriskstousersandletthemdecidewhichonestoadopt fortheirbenefits,hencetheneedforintegrationofGMOswithother Technologies in food production.

## VII. KENYA UNIVERSITY BIOTECHNOLOGY CONSORTIUM EXPERT OPINION ON GENETICALLY MODIFIED FOODS

The government was elected on a platform of creating jobs, especially for the youth, enhancing trade and infrastructure, and ensuring food security by improving our agricultural system to make it more productive. In line with Vision 2030 blue print, the government has honored these pledges and is on the right path to achieving the objectives by tirelessly embarking on fixing the infrastructure (including the standard gauge rail, LAPSSET) and economic stimulus programs for job creation (such as the UWEZO fund). To prepare the ground for technology uptake, the government has undertaken to increase budgetary allocation to Science, Technology and Innovation (STI) from 1% to 2% of total revenue (Science and Technology Act 2013), investing in school laptop programme, as well as establishment of regional technology hub (Konza City). Other government efforts include expansion in the number of public Universities that offer biotechnology courses at degree level (approval of new courses), support for incubation centers, and direct government funding to biotech/GM research. These interventions show the government's resolve to benefit from modern farming systems through biotechnology. In this direction, the government has edged closer to a key Millennium Development Goal (MDG), of cutting the number of hungry people by half by 2015. Only one thing now stands in the way to realizing this goal – the current ban on genetically modified foods. There is a background to this ban:

### Background to ban on GM foods

In September 2012, a team of French Scientists published results from a two year study involving feeding of rats on a herbicide (Roundup) and Roundup tolerant GM maize (Roundup Ready). Publishing in the Elsevier Journal 'Food and Chemical Toxicology' (Seralini*et al.*, 2012), the authors interpreted observed tumors in rats to be caused by genetic modification as well as the glyphosate that makes up the 'Roundup' herbicide. Following this publication, which was apparently drawn to the attention of the government, the Kenya Cabinet issued an executive order on 8th November 2012 prohibiting the importation and consumption of GMO foods in Kenya. The publication by Seralini*et al.* was on 28th November 2013 withdrawn by both the journal, *Food and Chemical Toxicity*, and the publisher, *Elsevier Science*, following an elaborate

investigation on the data presented and the review process, which revealed that the study was based on flawed data and interpretation. The High Council for Biotechnology (HCB; a team of scientific experts commissioned by The French government on 24 September 2012 to provide an opinion on the paper by Professor Séralini's team) found that the publication failed to establish relationship between GM foods and tumor. Further, the European Food Safety Authority (EFSA) found this study to be of insufficient scientific quality for safety assessments (EFSA, 2012). Although Seralini*et al.* had claimed that very low dilution of Roundup herbicide caused more tumors than GMO maize, and that the herbicide was more toxic at the lowest dilutions, the condemnation of this publication now justifies the government's continued support for the use of Roundup in local farms for weed control.

In May 2014, six months after the withdrawal of the paper by Seralini*et al*, it was republished in a different Journal, 'Environmental Sciences Europe'. This was done by the second journal to retain useful discussions that emanated from the publication, rather than to disseminate its content. In order to avoid anybody thinking that they agree with Seralini*et al findings*, the journal included a clear and concise caveat at the beginning: "*Progress in science needs controversial debates aiming at the best methods as basis for objective, reliable and valid results……In this sense, ESEU aims to enable rational discussions dealing with the article from G.-E. Séralini et al by re-publishing it. By doing so, any kind of appraisal of the paper's content should not be connoted*" (Page 3). This means that (1) from these debates, readers will know the faults with methods and analysis used by Seralini's et al, (2) the journal does not in any way approve of the data and interpretation.

The earlier publication by Seralini et al had far reaching implications, with Kenya and Russia prohibiting GM foods within their territories, although Russia shortly later lifted the ban following the invalidation of the study, and on consultation with scientific experts. In October 2013, the government of Kenya, in cognizance of possible negative effects of maintaining the ban on GM foods, appointed a taskforce through the Ministry of Health to investigate whether the grounds on which the ban was effected were sound (Gazette Notice No. 13607).

**Approved GM foods are safe for human and animal health**

Through rigorous risk assessments, GM foods have been shown to be safe just like their non-GM counterparts. However, the principles and processes of GMO development and biosafety assessments are generally not well understood, thereby contributing to the negative attitude toward GM foods. The World Health Organization (WHO) asserts that "The GM products that are currently on the international market have all passed the risk assessment conducted by national authorities. These different assessments in general follow the same basic principles, including an assessment of environmental and human health risks. The assessments are thorough and have not indicated any risk to human health" (WHO, 2002). Biosafety assessments by other eminent organizations indicate that approved GM products are safe for human consumption, animals and the environment., the Food and Agriculture Organization of the United Nations (FAO), Canadian Food Inspection Agency (CFIA), German Competent Authority (GCA), the United States Food and Drugs Administration (FDA) and the European Food Safety Authority (EFSA) have all concluded that GM foods are safe for human consumption. Overall, these respected regulators agree that genetically modified plants are substantially equivalent to conventional varieties. Locally, NBA has asserted the safety of GM foods through a ministerial brief to Parliament in 2011.

The safe application of GM technology has been demonstrated in human medicine, where it is used to produce various drugs such as insulin for managing diabetes, breast cancer, and vaccines currently on trial in Kenya for Hepatitis B and HIV.

**Kenya has requisite capacity to handle and regulate GM foods**

Kenya has invested heavily in legal, human and infrastructural capacity for GM research, and currently has capacity to manage processes and procedures for detecting, testing and assessing the safety of GM foods.

*Legal and Regulatory Capacity*: Kenya is one of the pioneer African countries to develop a biotechnology policy and a Biosafety law that regulates GMO development, release, use, import, export and transit. The regulatory framework for GMOs is spelt out in the Biosafety Act of 2009 which established the National Biosafety Authority (NBA) to regulate GMO activities in the country. Other regulators that work with NBA include Ministry of Health (MoH), Ministry of

Agriculture (MoA), Department of Veterinary Services (DVS), Kenya Bureau of Standards (KEBS), Pest Control Products Board (PCPB), Kenya Plant Health Inspectorate Service (KEPHIS), National Environment Management Authority (NEMA), Kenya Wildlife Services (KWS), and Kenya Industrial Property Institute (KIPI). The government has put large sums of money in establishing and staffing NBA and the other regulatory institutions such as KEPHIS to ensure biotechnology is safely applied. NBA has so far led the enactment of four regulations that implement the Biosafety Act. These regulations ensure compliance with all activities undertaken within a field, introduction into the environment, and Import, Export and Transit of genetically modified organisms. These ensure regulation and monitoring of all GMOs from development to consumption. The Authority has inspectors in all key areas such as ports of entry, field trials, and along product value chains to ensure compliance. In the last 2 months, KEBS has developed a Standard for market surveillance, which is now at stakeholder review stage, to reinforce efforts on compliance.

*Research and human capacity*: Institutions that conduct research on GM technology and products in Kenya include KARI, Universities, Companies and regional and international research organizations. These institutions have highly qualified staff, with internationally recognized scientists holding Doctorate degrees in biotechnology and related fields. In terms of infrastructure, the laboratories are well equipped to handle different aspects of GM research. Modern biotechnology is being used to improve crop varieties and animal breeds adapted to tolerate drought, pests and diseases and other production constraints. The government has invested millions of taxpayers' money on research on improved biotech/GM crops like the *Bt* cotton developed through the Kenya Agricultural Research Institute (KARI), which currently employs 44 scientists with doctorate, masters and bachelors degrees in biotechnology (Karembu et al. 2012). African Agricultural Technology Foundation (AATF) is supporting development of The Water Efficient Maize for Africa (WEMA), drought tolerant and insect resistant maize in Kenya, Uganda, Tanzania, South Africa and Mozambique. Others include Bio-fortified Sorghum and Banana with resistance to banana bacterial wilt. Currently, over 200 scientists in the public and private sectors are engaged in biotechnology research and development activities countrywide, 45% of who are employed in the public sector (Karembu et al. 2012). Indeed, GM technology holds the key to effective control of the Lethal Maize Necrosis Disease (LMND).

**Increasing global acceptance of GM technology**

Apart from GM, biotechnology is applied in many other fields. Whereas these applications of biotechnology in other fields like medicine, environment and mining, have basically been accepted, its application in producing GMOs continues to draw unwarranted mixed reactions particularly in the developing world. Since the first GM crop was commercialized in 1996, millions of farmers in over 30 countries worldwide have adopted the technology. Economic gains estimated at USD 98.2 billion (KShs. 8.5 trillion, which is about eight times our annual budget) have been realized globally at farm level mainly due to reduced cost of production (less ploughing, fewer pesticide sprays and lower labour costs). These gains partly explain the rising global adoption of biotech crops from a mere 1.7 million hectares in 1996 to a whopping 175.2 million hectares in 2013, representing more than 100-fold increase during the past 18 years (James, 2013). In fact, this is the fastest rate of technology adoption in the history of agriculture; where a total of 27 countries (65% from the developing world) grew biotech crops for food, feed and fiber. Even so, in Africa only four countries (South Africa, Egypt, Burkina Faso and Sudan) have commercialized GM crops such as *Bt* maize, Soya beans and *Bt* cotton. *Bt*cotton generated USD 300 Million for Burkina Faso in 2013 – a benefit that Kenya could enjoy by adopting GM technology.

**Ban on GM foods affects trade, food security and human health**

*Trade and food security:* Kenya is one of the countries in Sub-Saharan Africa that depends mainly on agriculture but has largely remained food insecure. Current production challenges to farming in Kenya include degraded and nutrient deficient soils, crop pests and diseases, unreliable rainfall, limited skills and poor access to and limited utilization of appropriate agricultural technologies. Kenya will remain isolated in world trade as majority of food and cereal commodities go GM. Ban on GM imposes non-tariff barriers to trade with neighbors and other trading blocks. This is a serious setback for a country that has normally set the pace for other countries in the region in many matters including trade and governance. Within the country, humanitarian and emergency food responses in drought hit areas by organizations such as the World Food Programme (WFP) and the International Committee of the Red Cross (ICRC) will be affected. The ban forces these agencies to divert their cargo to neighboring countries

hence denying Kenya the revenue and associated employment opportunities, including local grain handlers.

*Impact on the ban on food prices:* Due to limited non-GM cereals, Kenya cereal millers are operating at less than 50% capacity. This negatively affects efficiency leading to higher production costs that are eventually shifted to consumers. With the current economic hardships, high food prices are a recipe for industrial and civil unrests.

*Health and disease burden:* According to the National Aids Control Council and the Kenya National Bureau of Statistics, approximately 6% of adult population in Kenya is currently HIV infected, translating to 1.6 million people living with HIV. Many of those depend on fortified blended and specially formulated food rations (such as corn-soy blend), most of which contain GM, given that about 90% of soya beans available in the global market is GM. This means a ban on GM foods is a ban on life support for more than 1.6 million Kenyans.

**Conclusion.**

The current ban on GM foods is due tosafety. Given facts to show that the genetic modification mechanism cannot in itself make the products more toxic than the ordinary foods. In conclusion, looming food crises can be averted by allowing trade and consumption of GM foods in Kenya. It is time Kenya harvested the benefits from the heavy investments already put into GM technology, in solving food insecurity, attracting agribusiness related investors, promoting biotech entrepreneurship by the youth for job creation, as well as positioning the country among the major players in the Biotech economy and the country's economy.

## ANNEXES

1. COMMITTEE MINUTES

2. ADOPTION LIST

3. TASK FORCE SET UP BY MR. JAMES MACHARIA IN NOVEMBER 2013 TO REVIEW MATTERS RELATING TO GENETICALLY MODIFIED (ENGINEERED) FOODS/PRODUCTS (GMOS) AND FOOD SAFETY.

# MINUTES OF THE 58TH SITTING OF THE DEPARTMENTAL COMMITTEE ON AGRICULTURE, LIVESTOCK AND COOPERATIVES DURING THE CONSIDERATION OF REPORT FROM THE TASKFORCE ON GENETICALLY MODIFIED PRODUCTS AND ADOPTION OF THE COMMITTEE REPORT ON GENETICALLY MODIFIED PRODUCTS HELD ON THURSDAY 24THNOVEMBER 2016, 9TH FLOOR HARAMBEE PLAZA, PARLIAMENT BUILDINGS AT 10:30A.M.

**Present**

1. Hon. Adan Mohamed Nooru, MBS, CBS, M.P – **Chairperson**
2. Hon. Ferdinand Wanyonyi, M.P
3. Hon. Kabando Wa Kabando, M.P
4. Hon. Daniel Maanzo, M.P
5. Hon. (Dr.) Victor Munyaka, M.P
6. Hon. Mary Wambui, M.P
7. Hon. Peter N. Gitau, M.P
8. Hon. Raphael Letimalo, M.P
9. Hon. Maison Leshoomo, M.P
10. Hon. Silas Tiren, M.P
11. Hon. John Kobado, M.P

**Apologies**

1. Hon. Kareke Mbiuki, M.P
2. Hon. Florence Mutua, M.P
3. Hon. Paul Simba Arati, M.P
4. Hon. Benjamin Washiali, M.P
5. Hon. Korei Lemein, M.P
6. Hon. Fredrick Outa, M.P
7. Hon. Waititu Munyua, M.P
8. Hon. James Wandayi Opiyo, M.P
9. Hon. Alfred K. Keter, M.P
10. Hon. Justice Kemei, M.P
11. Hon. John B. Serut, M.P
12. Hon. Patrick Wangamati, M.P
13. Hon. Benjamin Andayi. M.P
14. Hon. Kimani Ichung'wah, M.P
15. Hon. Millie Odhiambo - Mabona, M.P
16. Hon. Ayub Savula Angatia, M.P.
17. Hon. Aisha Jumwa, M.P
18. Hon. Jude Njomo, M.P

**Kenya National Assembly Secretariat**

1. Mr. Benjamin Magut -First Clerk Assistant
2. Ms. Angeline Naserian -Third Clerk Assistant
3. Mr. Ahmed Guliye - Third Clerk Assistant
4. Mr. Noah Too -Research Officer
5. Mr. David Ngeno - Research Officer

**Min. 248/2016: Preliminaries**

The meeting was called to order at 10.47a.m. and prayers were said by Hon. Ferdinand Wanyonyi, M.P

**Min.249/2016 Consideration and Adoption of the Report of the Taskforce from Ministry of Health on Genetically Modified Foods.**

The Chairperson told the meeting that taskforce report from the Ministry of Health was presented to the committee and it would be important if the Draft report on GMO is considered and adopted.

The Committee therefore deliberated on the taskforce report and made the following recommendations:

1. There is need to involve the local independent scientists within National Institutions using Government funding to research matters relating to GMO's.
2. There is need to kick start Commercialization of Bt-Cotton, however the government should put in place safety nets to ensure the byproducts of non-food GMOs do not find way into the food chain.
3. NBA should have a structured working relationship with other bodies to harmonize the process of developing, testing and regulating GMO products.
4. The Committee recommends that the government to encourage and support the development of this technology while at the same time as for all the other technologies, putting in place safety measure so as to ensure that the GM technology delivers the promises to humanity.
5. Further to the above recommendation Number 4, the Committee recommends that the ban on GM imports remains **un-lifted** until such a time when the following conditions are met:-

a) **New Legislation on the Safety of GM Food for Human Consumption be put in place**

New Legislation/regulations be put in place on the safety of Genetically Modified Foods for human consumption. The Committee noted that no GM product has so far been tested for safety for human consumption by Biosafety Authority. The present Biosafety Act that was passed by Parliament in 2009 has no specific provision for testing GM products for safety for human consumption.

b) **Requirement for Acute and Sub-Acute Toxicity Testing laws/regulations has been in place**

That all GM products must pass a preliminary, independently verified, 90-day animal feeding study, which cover the acute and sub-acute phase of testing for human consumption. The 90- day feeding tests will qualify the GM producer for the issuance of a Class A permit from the Food Safety and Quality Control Unit of the Ministry of Health. This permit should be for a limited period not exceeding two (2) years.

c) **Requirement for Chronic Toxicity Testing laws/regulations has been put in place.** That all GM products must pass an independently verified year animal feeding chronic toxicity test. This test will rule out carcinogenicity, teratogenicity, etc. The Chronic toxicity tests will qualify the GM producer for the issuance of a Class B permit from the Food Safety and Quality Control Unit of the Ministry of Health. This permit should be for a period not exceeding five (5) years.

d) **Requirement for Long-Term and Epidemiological Surveillance Testing laws/regulations has been put in place.**

That the long term tests will involve animal testing for at least three generations to rule out any transgenerational harm. The epidemiological tests will take the form of surveillance by the Ministry of Health on human populations for at least two generations i.e. from childhood to adult hood for the first generation and their offspring. This testing will use the usual epidemiological tools for surveillance. The long term and epidemiological

surveillance testing will qualify the GM producer for the issuance of a Class C permit declaring the product safe for human consumption and needing no further tests.

e) **Responsibility for Reparation laws/regulations for has been put in place.**
That any GM producer whose product causes harm as confirmed by metabolomics, by animal and human testing and or through accepted new technologies involving in silica (computer) modelling will be held fully responsible for making good the harm and for reparation. The issuing authority may withdraw any permit if later testing including chronic testing and surveillance reveals harm.

f) **Definition of the Role of the Food Safety and Quality Control Unit of the Ministry of Health has been put in place.**
That the specific role of GM food safety evaluation for human consumption is at the State Department of Health. Therefore they should be responsible for issuing the permits after consultation with the appropriate regulatory agencies and the Pharmacies and Poisons Board. But in case of severe famine where there is threat or loss of life, the president on the advice of the Cabinet, may instruct the Food Safety and Quality Control Unit to issue a special permit for the importation of life-saving food for a limited period provided that such cannot be used seed for cultivation and has been declared fit for human consumption. Notwithstanding this, every effort will be made to source the food from non-GMO sources failing which emergency GM food may be allowed in.

**Min. 250/2016: Adjournment**

There being no other business to discuss, the meeting was adjourned at 1.45p.m.

Signature .....

**HON. ADAN MOHAMED NOORU, MBS, CBS, M.P.**

**(Chairperson)**

Date.....


THE REPUBLIC OF KENYA

**MINISTRY OF HEALTH**

# THE FINAL REPORT OF THE TASK FORCE SET UP BY MR JAMES W. MACHARIA IN NOVEMBER 2013 TO REVIEW MATTERS RELATING TO GENETICALLY MODIFIED FOODS AND FOOD SAFETY

Tabled before
The Committee on
Health on
14/4/2014 By
the Cabinet
Secretary
Ministry of Health.

**June 2014**

**Declaration**

The taskforce has so far undertaken the task given and this report constitutes factual and impartial findings as well as recommendations to the best of our knowledge and belief. We believe that this report will update you on our findings on the work we needed to do as per 11th October 2013 gazette notice. We trust that our recommendations will inform government policy and have a positive impact on the safety assessment of GM foods in relation to the health of Kenyans. We were privileged to have been asked to contribute to the current efforts to formulate policy regarding GM foods.

The team wishes to thank and the Ministry of Health for entrusting us with this opportunity.

Prof. Kihumbu Thairu Chairman ----------

Date June 10th 2014

**Members of the Task Force**

| | | |
|---|---|---|
| Prof. Kihumbu Thairu | Chairman | Founding member KEMRI, member KEMRI Board of Management |
| Dr. Kepha Ombacho | Secretary | Chief Public Health Officer, Ministry of Health |
| Prof. Solomon Mpoke | Member | Director KEMRI |
| Prof. Samuel Gudu | Member | Principal, Rongo University College |
| Prof. Shaukat Abdulrazak | Member | CEO, National Commission for Science, Technology and Innovation |
| Prof. Marion Mutugi | Member | Biomedical Research Scientist, Trainer and Manager, JKUAT |
| Dr. Nancy Budambula | Member | Senior Lecturer, Department of Botany, JKUAT |
| Dr. Anne Wangai | Member | Chief Research Scientist, Crop Protection & Virology, KARI |
| Mrs Evah Oduor | Member | Biochemist, private consultant |
| Dr. Joy Kiano | Member | GMO scientist, private sector |
| Dr. Johnson Irungu | Member | Director, Crops development, Ministry of Agriculture, Livestock and Fisheries |
| Mr. Robert Kilonzo | Recorder | Ministry of Health |
| Dr. Willy Tonui* | Member | Chief Executive Officer, NBA |

*** withdrew from membership of the taskforce on 27th January 2014**

Letter of Appointment to the Task Force

**MINISTRY OF HEALTH**
**OFFICE OF THE CABINET SECRETARY**

**Telegrams:"MINIHEALTH",**
**Nairobi**
**Telephone Nairobi 2717077**
**Email: cabsecretary@health.go.ke**
***When replying please quote***

**AFYA HOUSE**
**CATHEDRAL ROAD**
**P O Box 30016 -00100**
**NAIROBI**

**Ref. No. MOH/DC/2/5**

**Date:** 8th November 2013

Dear

**RE: APPOINTMENT AS A MEMBER OF THE TASK FORCE TO REVIEW MATTERS RELATING TO GENETICALLY MODIFIED ORGANIC FOODS (GMO) AND FOOD SAFETY**

In exercising the Mandate of the Cabinet Secretary, Ministry of Health under Section 4 and 11 of the Public Health Act Cap 242 and Section 27 of the Food Drugs and Chemical Substance Act, Cap 254 Laws of Kenya, I am pleased to inform you that you have been appointed as a member of the above task force.

Your appointment takes effect from 11th October 2013 as dated on Gazette Notice No. 13607.

The Terms of Reference are as stated in the Gazettement. I take this opportunity to congratulate you on your appointment.

Yours

**James W. Macharia**
**CABINET SECRETARY**

Enc.

**Table of Contents**

**Definitions**[1]

| | |
|---|---|
| *Bacillus thuringiensis* (Bt) | bacteria that produce a toxin against certain insects; the toxin genes are important for transgenic approaches to crop protection |
| Biodiversity | the variability among living organisms from all sources and the ecological complexes of which they are part |
| Biolistics | a technique to generate transgenic cells, in which DNA-coated small metal particles (tungsten or gold) are propelled by various means fast enough to puncture target host cells; also known as micro projectile bombardment |
| Biosafety | refers to the avoidance of risk to human health and safety, and to the conservation of the environment, as a result of the use for research and commerce of infectious or genetically modified organisms |
| Biotechnology | technological applications that use biological systems, living organisms, or derivatives thereof, for the production of goods and services |
| Clone | group of cells or individuals that are genetically identical |
| Cloning | the process of making identical copies of an organism, cell, or DNA sequence |
| Cloning vector | a small, self-replicating DNA molecule (e.g. a plasmid or viral DNA chromosome) into which foreign DNA is inserted in the process of cloning genes or other DNA sequences of interest |
| Codex Alimentarius | an international regulatory body (part of FAO) responsible for the definition of a set of international food standards |
| DNA Construct | a chimeric DNA molecule, carrying all the genetic information necessary for its transgenic expression in a host cell |

[1] Sources:
FAO Glossary of Biotechnology for Food and Agriculture
http://www.fao.org/biotech/biotech-glossary/en/
National Institutes of Health. National Human Genome Research Institute. "Talking Glossary of Genetic Terms."
http://www.genome.gov/glossary/
Susan Allender-Hagedorn and Charles Hagedorn
An agricultural and environmental biotechnology annotated dictionary
http://filebox.vt.edu/cals/cses/chagedor/glossary.html

| | |
|---|---|
| Disease resistance | the genetically determined ability to prevent the reproduction of a pathogen, thereby remaining healthy, either by pathogen exclusion, by preventing pathogen spread or by tolerating pathogen toxin |
| Enzymes | proteins that catalyse specific chemical reactions but are not used up in the reaction |
| Enolpyruvyl-shikimate 3-phosphate synthase (EPSPS) | an enzyme produced by virtually all plants, which is essential for normal metabolism, and for the biosynthesis of aromatic amino acids |
| Essential amino acids | an amino acid required for normal metabolism, but which cannot be synthesized by an organism and therefore has to be supplied via feed or food |
| GM event | is defined by the insertion of DNA into the plant genome as a result of a single transformation process |
| GM crop | a crop that contains one or more GM events |
| Gene | the unit of heredity transmitted from generation to generation during sexual or asexual reproduction |
| Genetically modified organisms (GMOs) | any organism whose genetic material or DNA has been altered in a way that does not occur naturally by a process that is completely different from natural breeding |
| Genetic engineering | the process of using recombinant DNA (rDNA) technology to alter the genetic makeup of an organism |
| Genome | the entire set of genetic instructions found in a cell |
| Glyphosate | an active ingredient in some herbicides, especially Roundup©, killing plants by inhibiting the activity of plant EPSPS |
| Herbicide | a substance that is toxic to plants; the active ingredient in agrochemicals intended to kill specific unwanted plants, especially weeds |
| Herbicide resistance | the ability of a plant to remain unaffected by the application of a herbicide |
| *In situ* | experimental treatments performed on cells or tissue rather than on extracts from them |
| *In vitro* | experimental treatments performed on cells, tissue or organs |

| | |
|---|---|
| | cultured in an artificial environment |
| *In vivo* | biological processes that take place within a living organism |
| Pesticides | toxic chemical products such as insecticides, fungicide, and herbicides that kill harmful organisms (pests) |
| Recombinant DNA (rDNA) | technology that uses enzymes to cut and paste together DNA sequences of interest |
| Resistance | the ability of any living organism to mitigate the magnitude of damage the organism suffers when exposed to hostile chemicals or conditions |
| Stacked traits | are combined GM trait products within a single plant that have been produced by either conventional breeding of parental lines with single GM events or by the sequential or simultaneous transformation of two or more traits into a recipient plant |
| Substantial Equivalence | is a concept used in safety assessment of all GM foods, where the GM food is compared to the traditional counterpart and considered the same if it demonstrates the same characteristics and composition as the conventional food |
| Tolerance | the ability of a plant to maintain its fitness despite being exposed to hostile chemicals, organisms or environment |
| Transgene | is an isolated gene sequence used to transform an organism |
| Transformation | the uptake and integration of DNA in a cell, in which the introduced DNA is intended to change the phenotype of the recipient organism in a predictable manner |

**Abbreviations & Acronyms**

| | |
|---|---|
| AGRA | Alliance for Green Revolution in Africa |
| AMPA | α-Amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid |
| ANOVA | Analysis of Variance |
| BNF | British National Formulary |
| BSO | Biosafety Officer |
| Bt | *Bacillus thuringiensis* |
| BWTC | Biological Weapons and Toxins Convention |
| CAC | Codex Alimentarius Commission |
| CaMV 35S | Cauliflower mosaic virus 35S promoter |
| CEN | European Committee for Standardisation |
| COMESA | Common Market for Eastern and Southern Africa |
| CPB | Cartagena Protocol on Biosafety |
| DNA | Deoxyribonucleic acid |
| DVS | Department of Veterinary Service |
| EAC | East African Community |
| *E. coli* | *Escherichia coli* |
| EFSA | European Food Safety Authority |
| ELISA | Enzyme-linked Immunosorbent Assay |
| EPSPS | 5-enolpyruvylshikimate-3-phosphate synthase |
| EU | European Union |
| FAO | Food and Agricultural Organisation of the United Nations |
| FDA | Food and Drug Administration (USA) |
| GDP | Gross Domestic Product |
| GM | Genetically Modified |
| GMO | Genetically Modified Organism |

| | |
|---|---|
| IBC | Institutions' Biosafety Committee |
| ILRI | International Livestock Research Institute |
| ISO | International Organisation for Standardisation |
| ISAAA | International Service for the Acquisition of Agri-biotech Applications |
| JKUAT | Jomo Kenyatta University of Agriculture and Technology |
| KARI | Kenya Agricultural Research Institute |
| KEBS | Kenya Bureau of Standards |
| KEMRI | Kenya Medical Research Institute |
| KENAS | Kenya Accreditation Service |
| KEPHIS | Kenya Plant Health Inspectorate Services |
| KIPI | Kenya Intellectual Property Institute |
| KNAS | Kenya National Academy of Sciences |
| KU | Kenyatta University |
| KWS | Kenya Wildlife Service |
| MMUST | Masinde Muliro University of Science and Technology |
| NBA | National Biosafety Authority |
| NACOSTI | National Committee of Science Technology and Innovation |
| NEMA | National Environment Management Authority |
| NGO | Non-Governmental Organisation |
| OECD | Organisation for Economic Co-operation and Development |
| ORF | Open reading frame |
| PAGMF | Pesticide Associated Genetically Modified foods |
| PBS | Program for Biosafety Systems in Kenya |
| PCPB | Pest Control Products Board |
| PCR | Polymerase Chain Reaction |
| RNA | Ribonucleic acid |

| | |
|---|---|
| SANGL | Southern African Network of GM Detection Laboratories |
| SD | Standard Deviation |
| TFA | Trans fatty acids |
| TOR | Terms of Reference |
| UNEP | United Nations Environment Program |
| UON | University of Nairobi |
| UNSCR | United Nations Security Council Resolution |
| WHO | World Health Organisation |

## Summary

Science is the reasoned investigation or study of phenomena and often times when applied and has utility value, is referred to as technology. Thus the term technology refers to the making, modifying, combining or using knowledge regarding tools, machines, techniques, crafts, systems, methods or organisms in order to produce desired products, solve problems, fulfil needs, or satisfy wants.

Inarguably, technologies have had a profound effect on human ability to control and adapt to their natural environments. Initially, humans used technology to convert natural resources into simple tools in an attempt to increase the available sources of food. Recent technological developments have phenomenally increased the ability of man to effectively and efficiently utilize available physical and biological resources. Not all technology has however had a positive impact on humans for some technological processes have produced unwanted or 'adverse' or 'harmful' unintended results. Thus the ethical challenge of balancing of harm and benefit is crucial in technology in general but particularly in biotechnology that involves live forms.

Genetic manipulation (GM) that culminates in genetically modified organisms (GMOs) involves such technologies. Such organisms have undergone manipulation of their hereditary material to produce organisms not ordinarily found in natural form. Thus, like other technologies, specific technologies that produce GM plants and animals, require careful analysis to establish whether the intended benefits outweigh any accompanying harms not just to humans but also to other organisms and the environment at large.

This taskforce was mandated by the Cabinet Secretary for Health to review matters relating to genetically modified foods and food safety so as to inform government policy regarding the maintenance or lifting of a ban emanating from a Cabinet decision on 8th November 2012. The terms of reference of this taskforce are specific to a context of Kenya, a developing country with specific challenges of food security.

In this report, definitions, abbreviations and acronyms, and background information regarding the topic and taskforce are first provided. International guidelines in respect to determination of safety of GMOs are enumerated. After setting the stage, each TOR is then discussed, relevant references quoted and recommendations thereof provided. Finally, general conclusions and recommendations are presented before a list of references and appendices annexed.

**From our review of the scientific information and mechanisms in place, we have come to the conclusion that the safety of GM foods has not been conclusively demonstrated to allow for the unconditional lifting of the ban. However, new valid safety assessment tests for human consumption have been identified. This needs new legislation put in place.**

**Foreword**

Following a decision of the 16th Cabinet meeting held on 8th November 2012, the Minister of Public Health and Sanitation was directed to use the existing legal framework for public health to ban genetically modified (GM) food imports with immediate effect. This ban would remain in force until a review and evaluation of scientific information on safety of GM foods on human health is undertaken.

The ban is not permanent. It is dependent on a thorough assessment of GM food safety and subject to an informed policy decision.

It is in view of this directive that the Cabinet Secretary for Health, in a Gazette Notice (No 13607) of October 11th 2013, appointed a taskforce to review and report on matters relating to GM foods and food safety, with a view to recommending whether to maintain or lift the existing ban.

The full Terms of reference (TOR) were outlined as follows:

1. To perform a review of literature on scientific data from clinical trials on effect(s) (both short- and long-term) of GMO foods on human and animal health;
2. To assess infrastructural capacities in Kenya to monitor GMO products in the country;
3. To make recommendations on GMO foods and food security in the country;
4. To make recommendations on safety of GMO foods to human health;
5. To assess and make appropriate recommendations on the general administration and management of GMO food imports into Kenya and in particular:-
    a. adequacy of qualified human resource capacity to monitor research, use and importation of GMO products in the country;
    b. approval procedures for import of GMO food by the relevant regulatory agencies;
    c. examination of the legal framework and systems for biotechnology on GMO foods in the country and in the region;
    d. coordination of regulatory agencies;
6. To revisit published and controversial research papers on safety assessment of GMO foods;
7. To analyse the possible reasons and underlying factors for ban of GMO importation, cultivation and/or trade by some countries;

8. To develop a policy direction and advice the government on whether to maintain or lift the ban; and

9. To look into any other issues pertinent to the safety of GMO foodstuffs which are not specifically identified in the above Terms of Reference

In addition the above, the taskforce was further mandated to:

a. co-opt any resource persons as and when necessary on short-term basis to assist in fulfilment of the terms of reference;

b. make reports updated fortnightly to the Minster for Public Health and Sanitation, outlining any matters that may require urgent action; and

c. make recommendations on the actions to be undertaken by any persons(s) including the Government on matters relating to GMOs and food safety

**Procedures**

During the first meeting, the taskforce developed a work plan consisting of the following:

1. Regular meetings of the entire taskforce
2. Development of data collection tools
3. Thematic sub-committee work group meetings
4. Individual literature reviews
5. Consultative meetings
6. Ministry briefings
7. Secure online information sharing
8. Convene a public hearing
9. Collation, classification and analysis of information
10. Report writing

## 1.0 INTRODUCTION

### 1.1 Preamble: What is at the heart of the controversy?

The world faces a crisis around assuring food security for its citizens – nearly 1/3 of food produced or planted never reaches the table because of losses related to climate, storage, crop diseases & pests. Widespread uptake of sustainable practices in agriculture and food supply chains is essential to meet current and future threats to food security and environmental resilience.

According to the Ministry of Agriculture, some of the causes of food insecurity in sub-Saharan Africa can be attributed to low agricultural productivity coupled with policy, institutional and technological challenges, high seasonal and year-to-year variability which is often linked to insufficient water for crop and livestock production.

Extreme weather events arising from the global climate changes are known to cause damage to infrastructure (such as warehouses and roads), resulting in detrimental impacts on food storage and distribution, to which the poor will be most vulnerable.

About 80% of the Kenyan population live in rural areas and derive their livelihoods from agriculture. Small-scale farmers produce a range of crops including the major cash crops: coffee, tea, maize and horticultural produce; and also a range of livestock including poultry, cattle sheep, goats and pigs.[2]The small-scale farmers dominate Kenya's agriculture accounting for about 75% of total agricultural output. This contrasts with Africa's largest maize producer, South Africa, where small-scale farmers produce only 5% of the food.

In the recent years, and especially starting from 2008, Kenya has been facing severe food insecurity problems. These are depicted by a high proportion of the population having no access to food in the right amounts and quality. Most food system investments are focused on boosting global food supply, expanding the role of agribusiness and increasing trade rather than on reinvigorating local markets and smallholder producers[3].

The technological response has been to develop crops that have high nutritional value and incorporate weather- and pest-resistance. This begins with the traditional method of selecting and storing the seed of the most successful plant to modern, laboratory-based, biotechnological methods such as Genetic Engineering (GE) or Genetic Modification (GM).

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[2] A R Peters, G Domingue, I D Olorunshola, S J Thevasagayam, B Musumba and J M Wekundah (2012) A survey of rural farming practice in two provinces of Kenya. 1. Demographics, agricultural production and marketing. Livestock Research for Rural Development **24**(5)

[3] Beddington J, Asaduzzaman M, Clark M, Fernández et al. (2012). Achieving food security in the face of climate change: Final report from the Commission on Sustainable Agriculture and Climate Change. CGIAR Research Program on Climate Change, Agriculture and Food Security (CCAFS). Copenhagen, Denmark. Available online at: www.ccafs.cgiar.org/commission

The lab-based GM technology brings in genes across species. Genetically modified crops (GM crops) have been created to express proteins that result in characteristics of particular interest to research or industry such as increased resistance to pests, herbicides, drought or cold, or to improve nutrient content or total crop yield.

> The vast majority of GM crop plants that are commercially available worldwide have been designed to express proteins that confer either insect pest resistance, herbicide tolerance, or both.

The overall acreage under genetically modified (GM) crops and the number of countries adopting them for commercialisation has continued to increase since 1996, when GM crops were first commercialized and many resource-limited countries have since adopted the technology. In the last 15 years, GM crop producing countries claim to have benefited from adoption of this technology in the form of improved crop productivity, food security, and the income to farmers and industry.

As a matter of fact, promoters of GM crops see these plants as having the potential to provide solutions to hunger, malnutrition and food security problems that plague limited-resource countries, particularly, those in the sub-Saharan Africa, where agricultural productivity tends to be low. It has been a long held belief that the production of certain GM crops, especially those designed to have insect-pest resistance traits, would result in substantial decrease in use of chemicals for pest control.

The bulk of research funding in the field of GM crop production is from the agri-biotech industry. Many of the industry scientists populate the regulatory bodies' safety review panels. Because modern biotechnology is still relatively new, many scientists thrust with regulatory work also have had their research funded by industry. This has the added potential for conflict of interest in its regulation. Furthermore, the developers and regulators do not have independent verification of their safety evaluation data: It is the obligation of the developer to provide the completed safety assessment dossier, which is then reviewed by the regulator before the release of the GM product.

Governments of countries with emerging economies like Kenya need to carefully evaluate the balance between widespread hunger in the population (food security) and the ambiguity surrounding GM food crop evaluation (food safety).

Without a doubt, this modern biotechnological advancement has the potential to solve many agricultural, technological, nutritional and environmental issues that face humanity. However the principles of: First Do No Harm "*Primum non nocere*" need to be applied as the guiding principle in this field.

This is because one of the most successful GM crops in the world is maize. In Kenya we love maize. We eat maize as porridge in the morning; ugali at lunchtime; and githeri/ nyoyo, and more ugali etc. for supper. It is also used in combination with other cereals as part of the special occasion foods. We also feed our animals maize. Therefore the discourse around safety of GM foods, particularly maize is of public health importance in Kenya and this region.

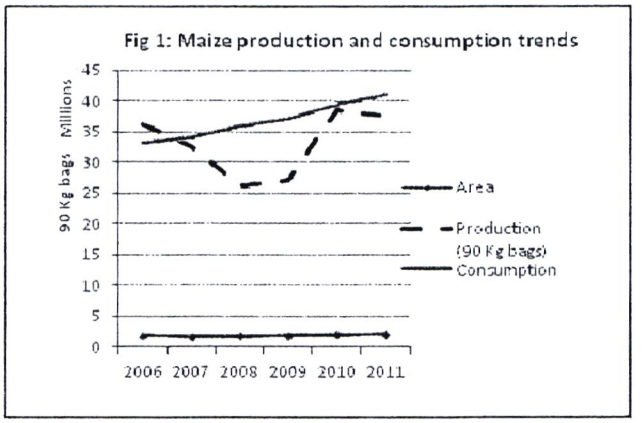
### 1.2 Agricultural Output

Kenya's main food crops are classified into: cereals (maize, wheat, sorghum, rice, millet); pulses (beans, pigeon peas, cow peas, chick peas, green grams); and roots and tubers (Irish potatoes, sweet potatoes, cassava, arrow roots and yams). Maize is the main staple food in Kenya followed by beans, Irish potato, rice and wheat. Other important sources of food include banana, arrow roots, cassava, sweet potatoes and vegetables. Apart from crop produce, the other sources of food include meat, milk, eggs, fish and other livestock products.

In Kenya Production of major food crops have generally been below consumption levels as illustrated here below:

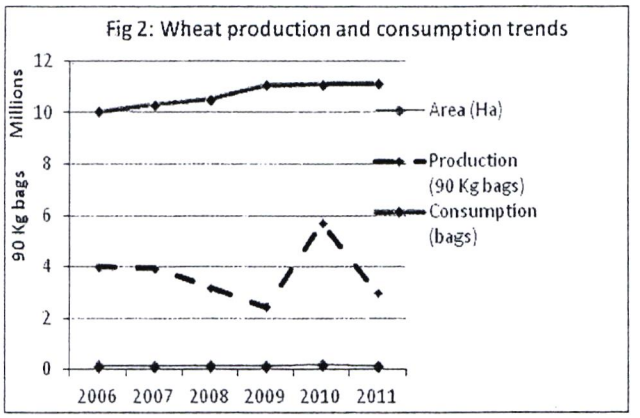
#### a) Maize

Since 2006, maize production has been below the consumption levels in the country. After the 2008 drought, production has been improving as shown in Figure 1. In 2011 maize production declined marginally compared to 2010 due to challenges such as shortage of certified seed, inadequate rainfall, outbreak of Maize Lethal Necrosis Disease (MLND), and increased consumption of green maize among others.




#### b) Wheat

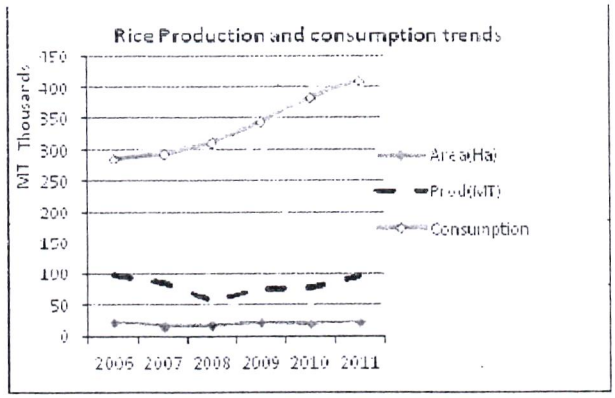
Wheat production has been steady since 2006 and started increasingly in 2009 to 2010. However, in 2011, production declined by 48% as shown in Figure 2. The huge fluctuations were caused by erratic rains in the major growing regions and huge increases in cost of key inputs like fertilizer and fuel. Since 2006, the demand for wheat products has been increasing



beyond the local production capacity.

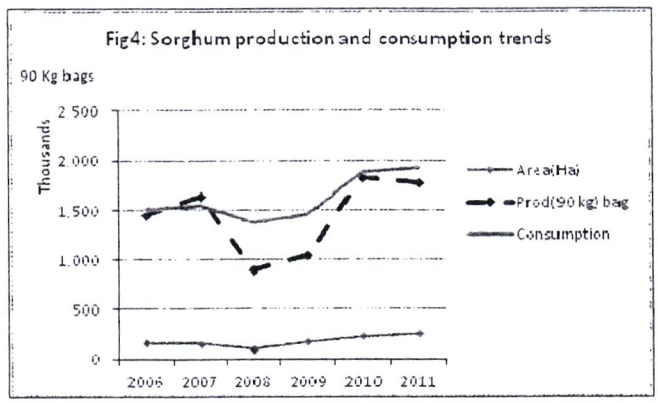
c) **Rice**

Rice is one of the cereal crops with increasing demand since 2006 as shown in Figure 3. Since 2008, the Government has been promoting rice production through rehabilitation and expansion of major rice producing irrigation schemes, promotion of upland NERICA rice, provision of rice mills to farmer groups, development of a rice seed supply system among other initiatives. It should be noted that in Asia, rice is the staple crop which has been found to sustain the highest density of human population.



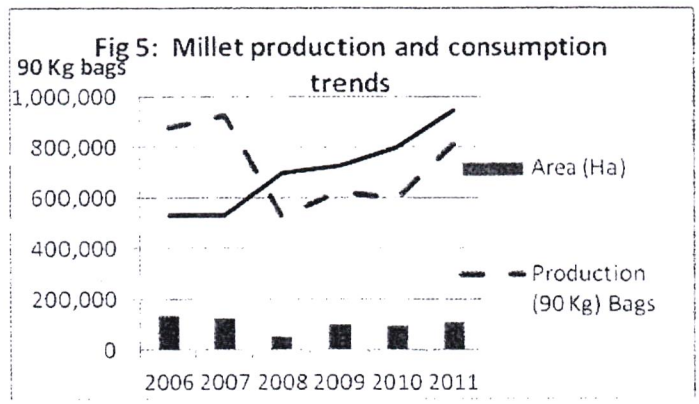

d) **Sorghum**

Sorghum is a key strategic crop being promoted as part of crop diversification under the Traditional High Value (Orphan) Crops Programme. Since 2006, crop area and production has been increasing except in 2008 when production dropped due to poor weather conditions as shown in Figure 4. Since 2007, the Government has been supplying seeds to needy farmers, especially in the Arid and Semi Arid Lands (ASAL).




e) **Millet**

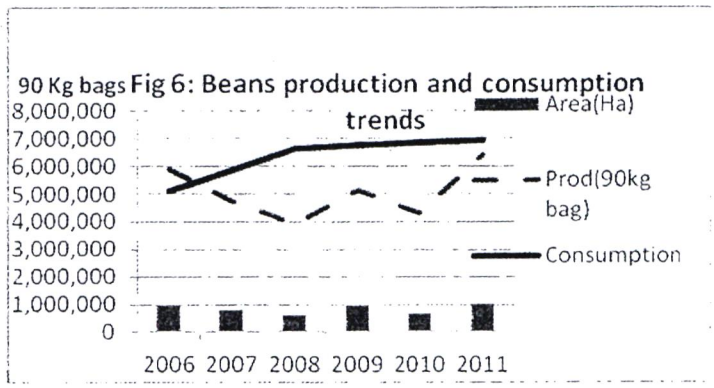
Like sorghum, millet is also being promoted as part of crop diversification under the Traditional High Value (Orphan) Crops Programme. Nutritional awareness has led to significant increase in demand for millet as shown in Figure 5. Since 2008, production has been increasing though demand is still higher than local production. Under Traditional High Value (Orphan) Crops Programme, the Government has



been multiplying and supplying seeds to farmers, especially in the ASAL areas. It should be noted that sorghum and millet were the staple grain before maize was introduced.

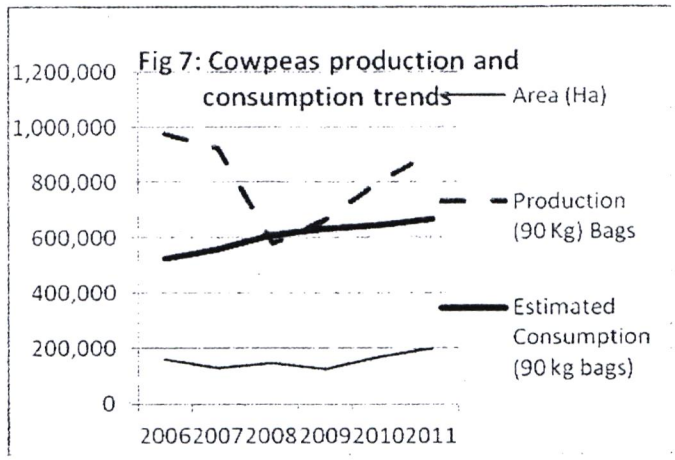
**f) Beans**

Consumption of Beans has been increasing steadily since 2006 as shown in Figure 6. Since 2006, production has been increasing except in 2008 due to drought. Apart from increased research on high yielding varieties, the Government has been providing seeds of beans to farmers under the Traditional High Value (Orphan) Crops Programme.



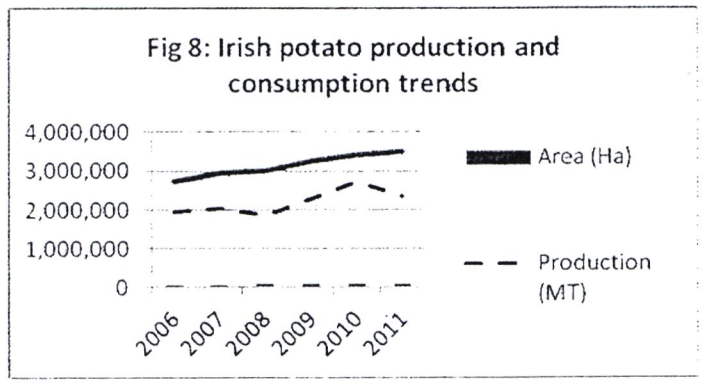

**f) Cowpeas**

Cowpea is a dual purpose crop used for both green leaves and grain consumption. While area and production have increased since 2006, production in 2008 was affected by long drought. Cowpea is among the traditional high value crops being promoted by the Government in the ASAL areas. See Figure 7.



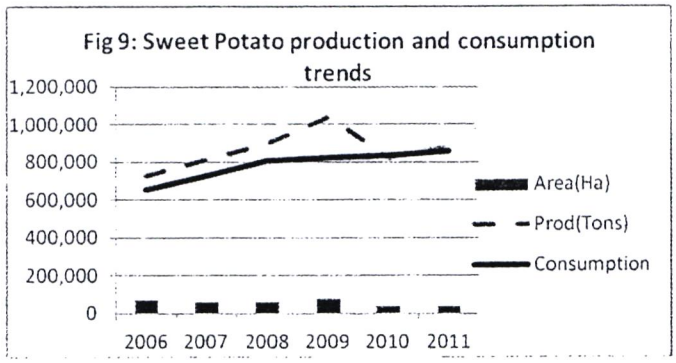

**h) Irish Potatoes**

Since 2006, the consumption levels of Irish potatoes has been increasing as shown in Figure 8. The Government is working closely with private sector to address major production challenges, especially multiplication and supply of certified seed, marketing and value addition.




**h) Sweet Potatoes**

Sweet potato is among the traditional high value crop being promoted by the Government to enhance crop diversification for food security. Since



2006, production levels have been higher than local consumption as shown in Figure 9. The Government has been multiplying and supplying planting materials to farmers under the Orphan Crops project.

**i) Meat Production**

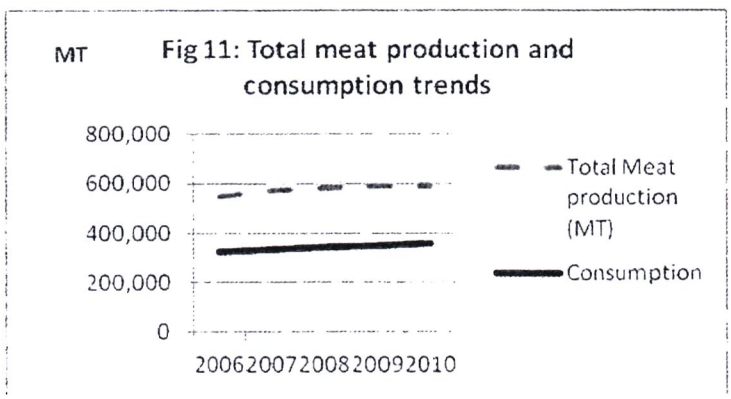
Main source of meat in Kenya include cattle, goats, sheep, pigs and chicken and camel in some parts of Kenya, but data is not available. Table 7.1 below shows the production levels of meat from these sources between 2006 and 2010.

**Table 1.1 Total Meat Production trends**

| Year | **2006** | **2007** | **2008** | **2009** | **2010** |
|---|---|---|---|---|---|
| Cattle | 430,000 | 445,000 | 458,000 | 465,000 | 462,831 |
| Goat | 42,600 | 44,450 | 41,670 | 46,321 | 46,450 |
| Sheep | 37,500 | 40,300 | 39,187 | 40,765 | 41,625 |
| Pig | 16,800 | 16,400 | 16,200 | 16,130 | 16,230 |
| Chicken | 21,460 | 23,460 | 24,284 | 25,176 | 25,620 |
| **Total Meat** | **548,360** | **569,610** | **579,341** | **593,392** | **592,756** |
| **Consumption** | **326,000** | **334,150** | **342,300** | **350,450** | **358,600** |

Source: Countrystat; FAOstat

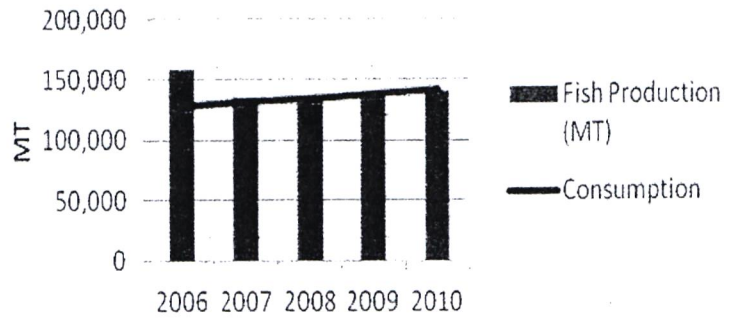
National meat consumption has been increasing since 2006 as shown in Figure 11. The country produces enough meat for domestic demand. Cattle provide the main source of meat followed by goats and sheep respectively. Camel meat is also valued in parts of Kenya. On other hand, pigs provide the least source of meat for local consumption.



**j) Fish production**

Main sources of fish in Kenya include rivers, ponds, lakes and the Indian Ocean. Since 2006, Fish consumption demands have marginally surpassed local production levels as shown in Figure 12. In the last five years, several programmes and projects are being implemented in collaboration with private sector in order meet the rising demand.

Fig 12: Fish production and consumption trends




**k) Milk production**

Since 2006, consumption of milk has increased steadily while production has also been increasing except in 2008 due to severe drought (see figure 13). The main sources of milk include cows', goats' and camel as shown in table 1.2.

Figure 13: milk production and consumption trend

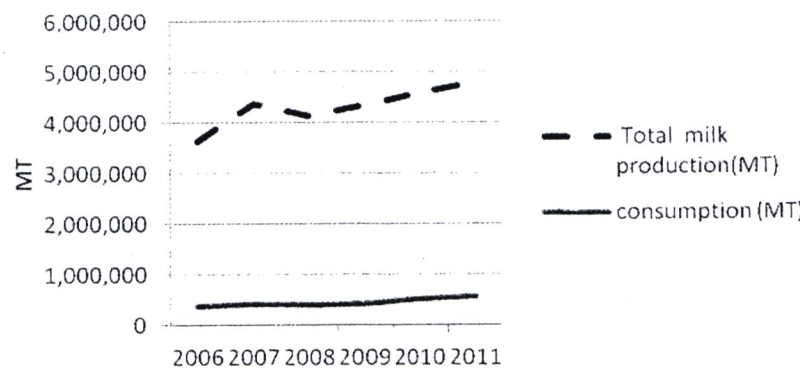



**Table 1.2 Milk production trend in Kenya**

| Year | **2006** | **2007** | **2008** | **2009** | **2010** | **2011** |
|---|---|---|---|---|---|---|
| Cow milk (MT) | 3,500,000 | 4,230,000 | 3,990,000 | 4,191,179 | 4,418,315 | 4,645,451 |
| Goat milk (MT) | 105,000 | 108,000 | 110 | 118,459 | 122,130 | 125,802 |
| Camel milk (MT) | 32,200 | 32,500 | 27,000 | 31,781 | 32,499 | 33,217 |
| Total (MT) | **3,637,200** | **4,370,500** | **4,127,000** | **4,341,419** | **4,572,944** | **4,804,470** |
| consumption (MT) | **360,149** | **423,111** | **398,511** | **406,531** | **515,746** | **548,997** |

Source: Kenya Dairy Board

About 46% of Kenya's population live below the poverty line of per capita 1USD per day while 17.5% of the population are estimated to suffer from chronic food insecurity and poor nutrition (Republic of Kenya, 2006). During periods of shock such as drought and floods, about 2.5 to 3.5 million people usually require food aid assistance. Investment, innovation and a deliberate effort to empower the world's most vulnerable populations will be required to construct global and local food systems that have the capacity to adapt to climate change and to ensure food security.

The current food insecurity problems are attributed to several factors, including the frequent droughts in most parts of the country, high costs of domestic food production due to high costs of inputs especially fertilizer, high global food prices and low purchasing power for large proportion of the population due to high level of poverty. Food systems must shift to better meet human needs, and, in the long term, reach a balance with the planet's resources. This will demand major interventions, at local to global scales, to transform current patterns of food production, distribution and consumption.

### 1.3 History of the Development of GM Foods

The moment the US Supreme Court decided that biological life could legally be patented, the "Biotech Revolution" began in earnest, in mid-1980. Ananda Mohan Chakrabarty, a microbiologist at the General Electric Company, had just developed a type of bacterium that could ingest oil but attempts to patent this invention were turned down by the US Patent and Trademark Office (PTO) on the grounds that life forms were not patentable. The Supreme Court ruling, however, overturned the PTO ruling considering that the process that produced a form not found naturally was patentable, giving a "green light" for further GMO research approved its release in 1986. Soon after, the PTO decided that the Chakrabarty ruling could be extended to all plants and seeds, or the entire plant kingdom.

By the late 1980s, Scientists had then begun to transfer genes that produced the insect-killing *Bacillus thurigiensis* (Bt) toxin into crop plants with the intention of better insect control and reduced costs to farmers. The move was welcomed by farmers even though no efforts were made to increase yield potential or increase growth rates of the crop plants (FAO, 2001). The insect-resistant crop plants were engineered to ensure the toxin was produced in every cell of the plant. However, differences were soon observed in the distribution of the toxin within the plants as they grew, as well as the unintended mortality of predators and parasites that ate the insect pests (FAO, 2001).

A decade later the first genetically-modified crop, the "Flavr-savr" tomato, with delayed ripening characteristics, was commercialized. This product was eventually abandoned in 1996 because it was found to cause stomach lesions and death to mice during animal feeding trials (Martineau, 2001).

*By the end of the 20th Century about a dozen of the major US crops including maize, soybeans, potato, beets, papaya, squash, tomato, cotton had been modified genetically, with nearly 90% of all transgenic crops grown worldwide being herbicide (glyphosate) tolerant. Consequently, glyphosate-containing herbicides have eventually replaced alternative herbicide formulations and taken over the international herbicide manufacturers market (Duke & Powels, 2008).*

Agricultural biotechnology involving genetic modification of organisms offers the promise to produce crops with improved agronomic characteristics (e.g. insect resistance, herbicide tolerance, disease resistance, and climatic tolerance), and enhanced consumer benefits (e.g. better taste and texture, longer shelf life, and higher nutritional value) (Lemaux, 2008). There is also the promise of enhanced food security for the poorest nations of this world. As GM foods like maize, soybeans and potatoes find their way into the consumer market place, it is necessary to subject these products to a careful and complete safety assessment before commercialization.

### 1.4 Background to GM Crop Production

Genetically modified organisms or GMOs are organisms (animals, plants, bacteria or fungi) whose genetic material or DNA has been altered in a way that does not occur naturally by a process that is completely separate from natural breeding. This process is referred to as genetic engineering or gene manipulation and is designed to allow for the exchange of DNA between species that would never have been able to interbreed in nature.

Genetically modified organisms (GMOs) are one of several products of biotechnology. Modern biotechnology, encompasses a diversity of disciplines in both the basic and applied sciences and technologies involving the application of *in vitro* nucleic acid techniques such as recombinant DNA (rDNA) technology; particle bombardment of nucleic acids into cells or organelles; and cell fusion across reproductive or recombinant barriers. There are close to 130 GM plants[4,5] created of which maize, soybean, rapeseed (canola), sugar beet, potato, rice and even cotton form part of food or animal feed produce. Examples GM crop plants approved in various countries for commercialisation and planting and/or for import for food and feed use are listed in Table 1.3.

Virtually all GM crops commercialised worldwide have been designed to either absorb and or produce pesticide toxins that confer insect-pest resistance, herbicide tolerance or both.

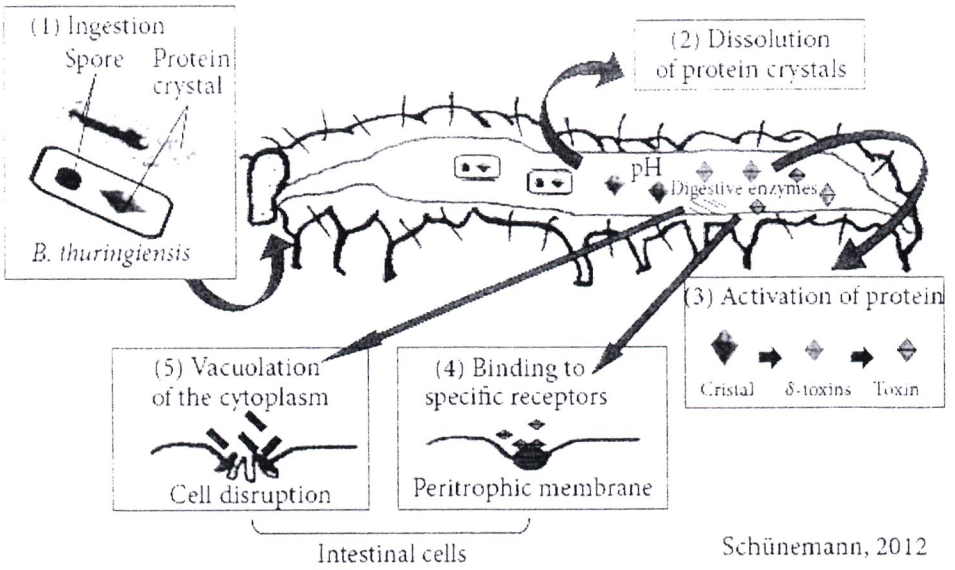
[4] EU Register of authorised GMOs_ http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

[5] Biosafety Scanner_ http://en.biosafetyscanner.org

## 1.5 Insect-resistant GM Crops

The insect resistant GM crops have been designed to produce a protein that is toxic to the larvae of many insect pests including beetles and weevils (Coleoptera); and butterfly and moth species (Lepidoptera). Coleoptera and Lepidoptera constitute the largest group or order in the Class Insecta. Their larvae are recognised as the most destructive insect pest to the vegetation of agricultural crop plants. The insect killing toxin originates from a soil-dwelling bacterium, *Bacillus thuringiensis* (Bt), one of the most important biopesticides on sale worldwide.

**Figure 1.1** Mode of action of *Bacillus thuringiensis* in Lepidoptera: (1) ingestion of bacteria; (2) solubilization of the crystals; (3) activation protein; (4) binding of proteins to the receptors; (5) membrane pore formation and cell lysis




- Source Schünemann (2012) in Schünemann et al (2014)

This bacterium produces crystalline proteins (Cry proteins) that selectively kill specific insect pests. These Cry proteins are stomach poisons that must be eaten by the insect pest in order to kill it. The stomach poisons are activated within the insect's digestive tract into the toxic form of the protein. The proteins bind to specific receptors on the intestinal lining and rupturing the cells. The importance of the Cry proteins is therefore due to their toxic properties, which are produced after ingestion by insect pests, especially of the Lepidoptera and Coleoptera orders (butterflies and moths and beetles and weevils, respectively).

There are several different strains of Bt and therefore different Cry proteins each with insecticidal activity to different insect pests. Insect-resistant GM plants express variations of the Bt toxin that enables these plants to produce their own pesticides against different insect

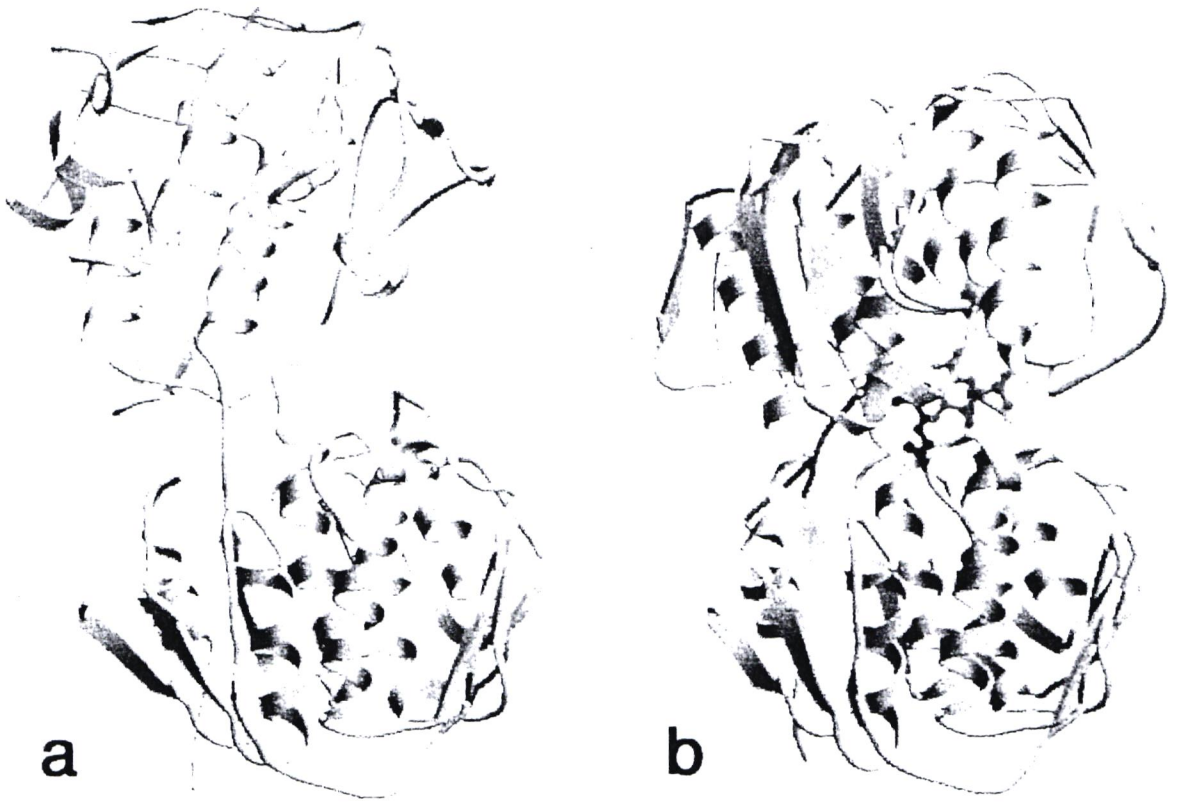
pests such as the maize borer, the cotton bollworm, the soybean looper and the tobacco budworm (OECD, 2012).

### 1.6 Herbicide-tolerant GM Crops

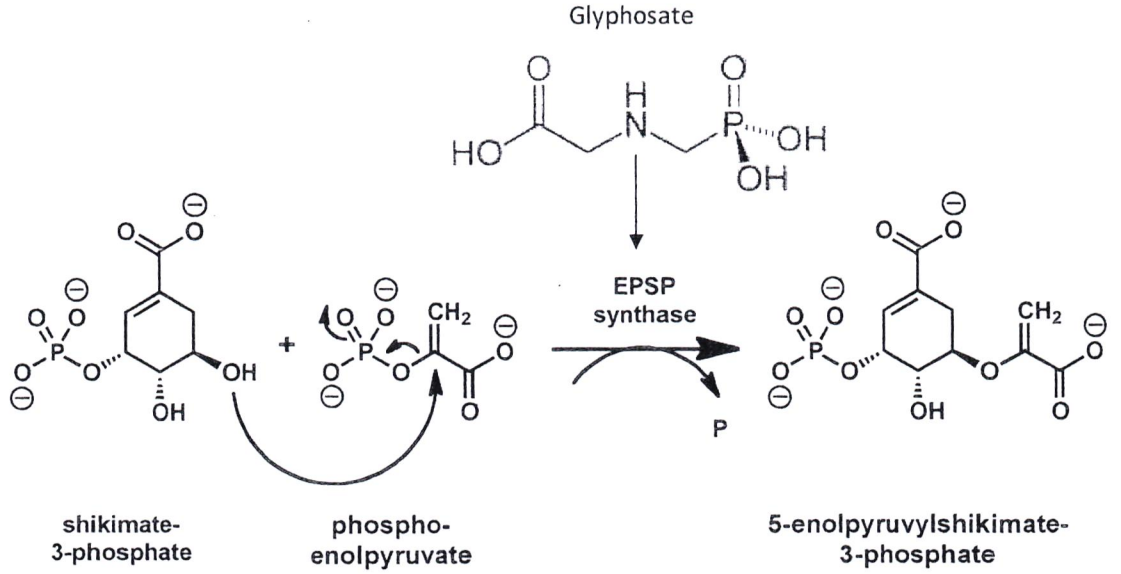
The herbicide tolerant GM crop plants have been designed to tolerate herbicides such as the glyphosate-based herbicide, *Roundup* brand. Glyphosate is a non-selective herbicide that is active on a wide variety of plant species (Duke & Powels, 2008). The glyphosate molecule is analogous to a major substrate in plant's shikimate pathway that leads to the formation of essential amino acids. The molecule competes for a key enzyme of the pathway, 5-enolpyruvylshikimate-3-phosphate synthase or EPSPS, shutting it down and resulting in the eventual death of the plant.

The biosynthesis of aromatic amino acids in plants, bacteria and microbes relies on the enzyme EPSPS. The enzyme is made up of two domains, with the active site located within the interdomain cleft. The enzyme is activated upon binding with its substrate molecules, forming a closed structure as illustrated in the figure below, courtesy of Schönbrunn et al (2001):

**Fig 1.2 Cartoon of EPSP synthase in the open and closed conformation.** (a) Unliganded state (open) as reconstructed from the depositeda-carbon atoms (Protein Data Bank entry code 1EPS). (b) Liganded state (closed). S3P and glyphosate are shown as ball-and-stick models in green and magenta, respectively.



The glyphosate molecule is a competitive inhibitor of EPSPS that occupies the binding site of phosphoenol pyruvate, one of the substrates of the enzyme, inhibiting the enzyme and shutting down the shikimate pathway, and leading to the eventual death of the plant.




Herbicide-tolerant GM plants are able to tolerate chemical weed control processes such as spraying, by producing an alternate EPSPS protein that is resistant to glyphosate, thus offering the farmer a more flexible weed-management system (Benbrook, 2012).

The GM crops that are both insect resistant and herbicide tolerant are hybrids of the two types of GM crop varieties that have been cross-bred to produce both types of GM proteins. Crops expressing these combined proteins are referred to as having **stacked traits**, examples of which are listed in Table 1.4.

### 1.7 Conclusion

The Kenyan agricultural industry is dominated by small-scale farming, whose production is highly dependent on rainfall. The lowest national output for agriculture over the past decade has been almost entirely attributable to low rainfall and disease outbreak. Farmers and consumers alike are also plagued by increased costs of fertilisers, high global food prices and low purchasing power. Global GM crop production has focussed on two key traits: herbicide tolerance and insect-pest resistant. Food assurance in Kenya, whichever the source, will arise predominantly from access to safe, affordable foods in spite of changing weather patterns.

**Table 1.3 Examples of Commercially Approved[6] GM Crops Worldwide[7]**

| Country | Cotton | Maize | Soybean | Canola | Rice | Sugar beet | Potato | Tomato | Wheat |
|---|---|---|---|---|---|---|---|---|---|
| USA[8] | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | |
| Canada | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | |
| New Zealand | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | |
| Australia | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | | |
| China | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | | |
| South Africa | ✓ | ✓ | ✓ | ✓ | ✓ | | | | |
| Argentina | ✓ | ✓ | ✓ | | | | | | |
| Brazil | ✓ | ✓ | ✓ | | | | | | |
| Egypt | ✓ | ✓ | | | | | | | |
| EU[9,10] | | ✓ | ✓ | | | | | | |
| India | ✓ | | ✓ | | | | | | |

[6] Approval may be for sale but not cultivation in some countries

[7] Source: ISAAA's GM Approval Database (http://www.isaaa.org/gmapprovaldatabase)

[8] Does not apply to all states of the USA

[9] GM maize: 88% grown in Spain, 7% in Portugal, the remainder in Romania, Slovakia and the Czech Republic (http://www.ipsnews.net/2013/03/spain-leads-the-eu-in-gm-crops-but-no-one-knows-where-they-are/)

[10] the EU imports approximately 40 million tonnes of raw GM soy products for animal feed, primarily from Brazil, the United States and Argentina (http://www.gmoompass.org/eng/grocery_shopping/crops/19.genetically_modified_soybean.html)

**Table 1.4 Lists of Major Gm Events Destined for Human Consumption**[11]

| Crop | Description | Event Name (Trade name) | Crop Worldwide Cultivation/ Coverage as per countries |
|---|---|---|---|
| Maize | Glyphosate herbicide tolerance | **NK 603 (Roundup Ready™ corn)** | 42 million hectares, grown in 17 countries: leading countries USA, Argentina and South Africa/ 35% of global planting |
| | Insect resistance (Bt) | **MON 810 (Yield Guard)** | |
| | Stacked event, Glyphosate herbicide tolerance + Insect resistance (Bt) | **NK 603 x MON 810 (YieldGard™ CB + RR)** | |
| Soybean | Glyphosate herbicide tolerance | **MON 04032 (Roundup Ready™ Soybeans)** | 69 million hectares, grown in 11 countries: leading countries USA, Argentina and Brazil 81% of global planting |
| | Stacked event, Glyphosate herbicide tolerance + Insect resistance (Bt) | **MON 87701 x MON 89788 (Intacta™ Roundup Ready™ 2 Pro)** | |
| Cotton | Glyphosate Herbicide tolerance | **MON 1445 (Roundup Ready™ Cotton)** | 16 million hectares, grown in 15 countries: leading countries, USA, China and India 81% of global planting |
| | Stacked event, Glyphosate Herbicide tolerance + Insect resistance (Bt) | **MON 1445 x MON 531 (Roundup Ready™ Bollgard II™ Cotton)** | |
| Rapeseed (Canola) | Glyphosate Herbicide tolerance | **MON 89249 (Roundup Ready™ Canola)** | 6.2 million acres, grown in Canada 30% of global planting |

[11] Source: International Service for the Acquisition of Agri-biotech Applications (ISAAA) GMO Compass (Figures are until 2009)

## 2.0 STANDARDS FOR ASSESSING THE SAFETY OF GM CROPS

Standards Provide universal tools for guiding applicants on the suitability, adequacy and credibility of data and information that must be provided to facilitate risk assessment for GM food safety and approval of GM food imports. They can also be used to facilitate regulation:

> *"...if novel technology is left unregulated, it will be the technocrats (those who simultaneously promote and oversee technology) who decide society's fate, not law-makers."*
>
> - Brendan Gogarty, LLB (2005)

### 2.1 The Codex Alimentarius Commission Guidelines for GM Food

The Codex Alimentarius Commission (CAC) is an intergovernmental body established between 1961 and 1963 by conference resolutions of the Food and Agriculture Organisation (FAO) and the World Health Assembly (WHA) **to protect consumers' health while ensuring fair practices in the food trade.**

In the 53rd World Health Assembly member states requested the WHO Director General to **'...support member states in providing the scientific basis for health related decision regarding genetically modified foods'**[12]. Following this request, in 2003 the CAC developed guidelines

*"...for the conduct of food safety assessment of foods derived from recombinant-DNA plants"*[13],

that included analytical, nutritional and toxicological research measures. **These guidelines established the framework of food safety assessment from which international food safety agencies were able to develop their own standards for assessment of food safety.**

The goal of the assessment is to determine with the best scientific evidence available whether, according to intended use, the food causes any harm when prepared, used, and or eaten. The conclusion of the assessment is whether the food is as safe as the conventional non-modified food. **In the instance where characterisation of the GM food indicates that available data may be insufficient for a thorough safety assessment, animal testing may be deemed necessary** (Atherton, 2002).

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[12] Fifty-third World Health Assembly WHA53.15. Agenda item 12.3. Food Safety http://www.who.int/foodsafety/publications/biotech/WHA53.15.pdf

[13] Guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA plants. CAC/GL 45-2003 http://www.bfr.bund.de/cm/343/codex_principles_and_guidelines_on_foods_derived_from_biotechnology.pdf

The CAC safety assessment principles for GM foods describe methods for conducting safety assessment for GM-derived foods that include the following stepwise safety assessment processes:

- identification of gene of interest, including sequence analysis of flanking regions and copy number;
- source of gene of interest;
- composition of GMO;
- protein expression product of the novel DNA;
- potential toxicity;
- potential allergenicity; and
- possible secondary effects from gene expression or the disruption of the host DNA or metabolic pathways, including composition of critical macronutrients, micronutrients, antinutrients, endogenous toxicants, allergens and physiologically active substances.

These principles dictate a premarket case-by-case evaluation of the direct effect from the inserted gene and of any unintended effects that may arise as a consequence of insertion of the new gene. The Codex principles for GM foods require an investigation of the following:

1. *The direct health effect (toxicity);*
2. *Tendency to provoke allergic reactions (allergenicity);*
3. *Specific components thought to have nutritional or toxic properties;*
4. *Stability of the inserted gene;*
5. *Nutritional effects associated with the specific genetic modification; and*
6. *Any unintended effects which could result from the gene insertion.*

- Source: FAO/WHO (2005)

Through the Codex Alimentarius Commission (CAC) and other organisations, countries have begun to address standards for assessing the risk of GM foods as a means of ensuring their safety. Developed by the FAO, WHO and the OECD, the concept of substantial equivalence was introduced as a basis for assessing the safety of human consumption of a novel food (FAO, 2001; FAO/WHO, 2001).

## 2.2 Substantial Equivalence

Several international organisations have addressed the issues associated with the safety assessment of GM crops and have agreed, in general, that the assessment of the potential impact of GM crops with respect to human health requires – as a starting point for safety evaluation – an integrated, step-wise, case-by-case approach that is directed by the results of comparisons between the GM crop and its conventional counterpart (FAO/WHO, 2001).

> *Substantial equivalence is based on the principle that if a novel or GM food can be shown to be essentially equivalent in composition to an existing food then it can be considered as safe as its conventional equivalent.'*
>
> – FAO/WHO Consultation 1996[1].

Substantial equivalence is but one approach being used in the risk assessment of GM food and is intended to evaluate whether the GM food is as safe as its traditional counterpart, where such a counterpart exists.

> *The concept of substantial equivalence was developed in recognition of the limitations of conventional toxicology on food produce due to the complexity and variation in composition of food (FAO, 2001; FAO/WHO, 2001). Moreover, it was devised as useful starting point in the safety assessment of novel foods.*

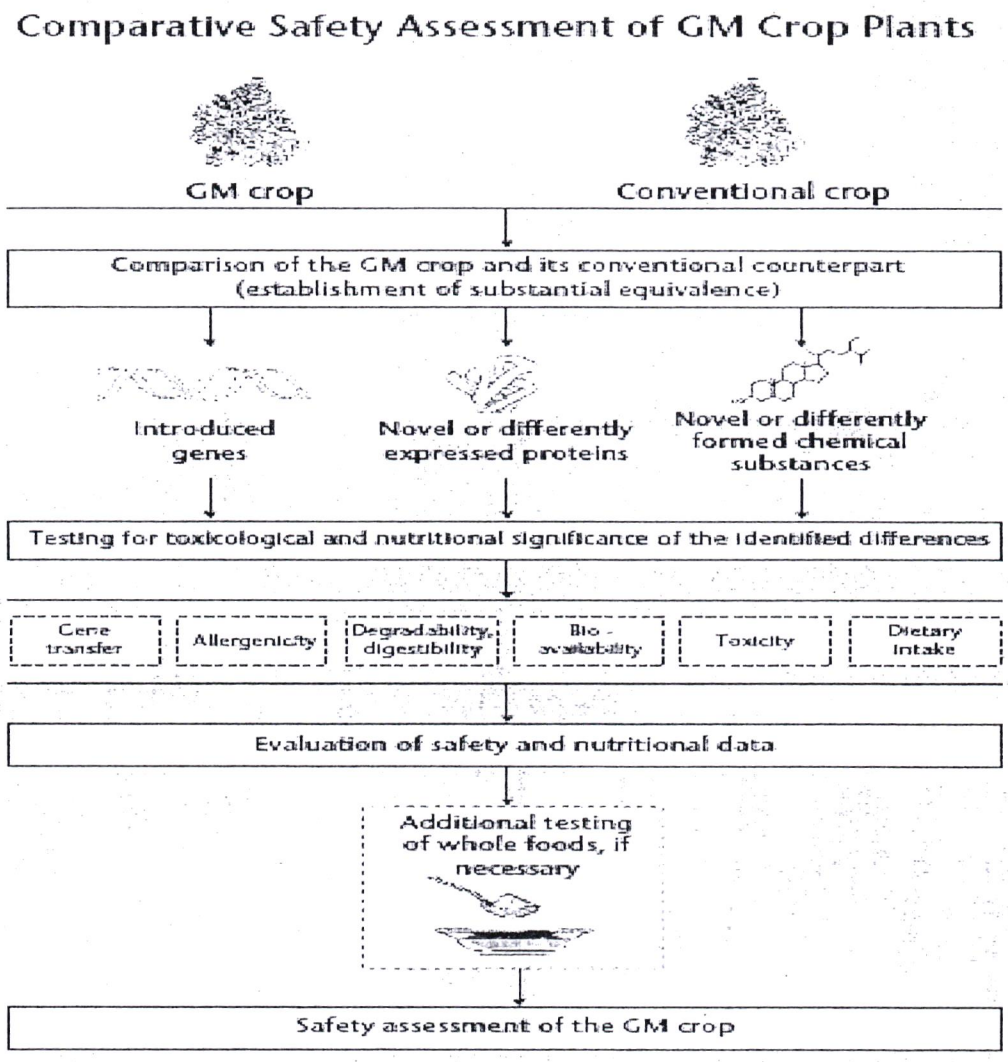
Substantial equivalence cannot provide evidence of safety as the term itself is highly subjective and, as outlined below, is the product of a number of tests and chemical analyses that each provides specific evidence of safety (Chesson, 2001). The analyses applied are usually determined in part by the known characteristics of the conventional counterpart; by the manner of the genetic modification and in part by the degree of presumed hazard (Chesson, 2001):

1. When substantial equivalence can be established for a food product then it is considered as safe as its traditional counterpart and no further evaluation is necessary;
2. When substantial equivalence can be established save for specific defined differences, then further assessment will be necessary on these differences;
3. Should no conventional counterpart exist, or substantial equivalence cannot be established then the test design should be on a case-by-case basis taking into consideration the unique characteristics of the food

**In the instance where characterisation of the GM food indicates that available data may be insufficient for a thorough safety assessment, animal testing may be deemed necessary** (Atherton, 2002).

The figure below is a summary of the comparative safety assessment procedure that underpins the concept of substantial equivalence (Entransfood, 2004):

**Figure 2.1 Comparative Safety Assessment for the Evaluation of GM crop Plants**



## 2.3 The Guiding Principles on food safety assessment of GM Crops

The CAC principles on food safety assessment are not intended to apply to whole foods due to the complex nature of food substances, and as such the safety assessment of possible toxicity of expressed substances in GM food is reviewed under **article 37** of the guidelines, which states that:

> *'...conventional toxicology studies may not be considered necessary where the substance or a closely related substance has, taking into account its function and exposure, been consumed safely in food.* ***In other cases, the use of appropriate conventional toxicology or other studies on the new substance may be necessary.'***

The guidelines, in **article 39**, recognize the need to carry out more in-depth studies of the potential toxicity of non-protein substances that have not been safely consumed in food.

> ***'Potential toxicity of non-protein substances that have not been safely consumed in food should be assessed on a case-by-case basis depending on the identity and biological function in the plant of the substance and dietary exposure.'***

In the case of GM crops expressing insecticidal protein toxins, or crops that are tolerant to herbicide application, novel proteins not normally found in the mammalian system are expressed with, or without possible pesticide residues and are recognised under **article 54** that states:

> ***'Some recombinant-DNA plants may exhibit traits (e.g. herbicide tolerance) which may indirectly result in the potential for accumulation of pesticide residues, toxic metabolites, contaminants, or other substances which may be relevant to human health.'***

Under these circumstances therefore, **the safety assessment of potential accumulation and consumption of such substances should be considered and assessed under the conventional procedures for evaluating the safety of chemicals in human health.**

The introduction of an entirely new protein, not previously found in the food chain presents new challenges if no definitive test to determine the potential allergenicity of a novel protein exists. Absence of sequence similarity with known allergens and low *in vitro* stability under proteolytic or digestive conditions do not preclude the presence of a potential allergen and/ or possibly that the application of GM foods have the potential to make food less safe.

> *"Some experts consider that the use of sera from polysensitized patients is important for the testing of allergenicity. Areas of improvement of risk assessment of allergens include mechanistic studies of animal models and genomic techniques."*
>
> - WHO (2005)

Currently elements of an allergenicity assessment include a comparison of the sequence of the transferred gene (including the flanking regions at the site of insertion) with sequence motifs of allergenic proteins from databanks, an evaluation of the stability of the newly expressed proteins against digestion, and animal and immune tests, as appropriate.

The DNA construct introduced into the GM crop should be considered within an assessment investigating the possibility of horizontal gene transfer or transfer of DNA into the mammalian gut: especially if the gene itself or its promoter is derived from a viral source as the potential exists for sequences unrelated to the target being introduced as part of the construct. The safety assessment of the construct should also include an evaluation of the selectable marker genes, especially with respect to gene transfer to microorganisms that exist in the gastrointestinal tract of human beings, as this transfer cannot be ruled out. Special emphasis must therefore be made to the role of antibiotic resistance marker genes in humans (WHO 2005).

FAO/WHO consultations (FAO/WHO, 2001) have also discussed the potential risks of gene transfer from GM foods to mammalian cells or gut bacteria. These panels have suggested that it may be prudent in a food-safety assessment to assume that DNA fragments survive in the human gastrointestinal tract and can be absorbed by either the gut microflora or somatic cells lining the intestinal tract. It was agreed that the assessment needs to take into account a number of factors including, but not limited to, the specific characteristics encoded by the DNA sequences, the characteristics of the receiving organism, and the selective conditions of the local environment of the receiving organisms.

**2.4 Regulating Food Safety**

In the late 1970's and '80s, regulatory requirements were intended to prevent the accidental release of microorganisms from research facilities. By the 1990's regulation had been developed for contained use and the deliberate release of GMOs. International regulatory systems covering GM food safety (the Codex principles) and environmental safety (The Cartagena Protocol on Biosafety) came into force in 2003. These systems elaborated on the permanent human-health and environmental safety assessment requirements for all GMOs and GM foods, with no history of safe food or environmental use:

> *"The concept that allows for the comparison of a final product with one having an acceptable standard of safety is an important element of a GM food safety assessment. This principle was elaborated by FAO, WHO and OECD in the early 1990s and referred to as 'substantial*

*equivalence' (FAO/WHO 1990). The principle suggests that GM foods can be considered as safe as conventional foods when key toxicological and nutritional components of the GM food are comparable to the conventional food (within naturally occurring variability), and when the genetic modification itself is considered safe (OECD 1993)."*

*-Source WHO/FAO (2005)*

The Cartagena Protocol on Biosafety (CPB) is the global treaty that reaffirms and incorporates the precautionary approach to biotechnology. The treaty promotes the controlled adoption and uptake of GM technology by members and has provisions that specifically address the safety concerns of consumers. The parties currently number 125 member countries among which several African and Asian countries are signatories to the treaty. Kenya is a signatory to the Protocol and thus obligated to it. **However, by being a signatory to the CPB, a member state cannot be held liable to prosecution if they choose not to comply with the standards.**

The standards outlined by the CPB are only meant as guidelines for member states to use when formulating their own regulatory framework. The protocol does however require member countries to establish supporting legal structures.

In the development of GMOs using modern biotechnology/recombinant-DNA techniques, the international rules provide for a mandatory integration of risk assessment at every stage of development to protect, environment, humans and animals from health hazards as provided for by the Cartagena Protocol to the conventions of biological diversity. It is the task of the producers of the GMOs to evaluate the safety and to assess the risk of their products to human health and the environment.

### 2.5 The Food Safety Assessment Procedure for GM Food/ Feed

As stipulated by the Kenyan law and under the Cartagena protocol on Biosafety, it is the responsibility of the National Biosafety Authority (NBA) to regulate research and commercial activities involving GMOs **with a view of ensuring the safety of human and animal health as well as the protection of the environment.**

*"NBA conducts risk assessment to identify and evaluate the potential adverse effects of the genetically modified organisms on human health and the environment as stipulated in the fifth schedule of the Biosafety Act, 2009. Such an assessment is also intended to prevent laboratory acquired infections while dealing with biological agents, prevent escape of the GM organisms into the environment, classify biological agents according to risk and appropriate containment laboratories to ensure safety."*

- Source NBA: Guidelines and checklists for risk assessment

Applications for the introduction of GM foods intended for placement in to markets or for environmental release are made to NBA via relevant research institutions' biosafety committee (IBC) or by independent applicants. The NBA then assesses the application on the basis of the National Guidelines for the Release of Genetically Modified Organisms in to the Environment. The NBA then consults the relevant ministries and regulatory agencies such as KEBS, Department of Health and KEPHIS for their advice. Independent experts are also consulted for their advice in particular material under assessment. The reports from the agencies and experts are then looked at by a technical committee who then forwards its recommendations to the NBA Board who make the final decision on approval.

Decisions are made based on risk assessment process anchored on internationally recognized agreements and Standards such as Codex Alimentarius Commission Principles (CAC), World Health Organization (WHO), Cartagena Protocol on Biosafety (CPB) and Food and Agricultural Organization (FAO). The risk assessment guidelines as specified by CAC and Organization for Economic Development and Corporation (OECD) consensus documents are considered in the evaluation of safety and are accepted on the basis of meeting WHO food safety standards and the Kenyan's levels as set out by Public Health and KEBS.

The NBA Food/ Feed Safety Assessment Procedure uses substantial equivalence as the benchmark for assurance of safety:

> *"The goal of the safety assessment is to determine whether the modified food or feed product is as* ***safe as the conventional counterpart.***"
>
> - Source NBA: SOP for Food Safety Assessment Procedure

The food safety assessment procedure assists the biosafety officer of the NBA to determine whether the GM food or feed is substantially equivalent to its conventional counterpart and that no issues regarding toxicity, allergenicity or nutritional composition have arisen. The food safety standards are based on the CAC guidelines (2003) for conducting food safety assessments on foods derived from recombinant DNA plants (Box 2.1)

### 2.6 Safety Assessments for Products that are Developed from within the Country

To date, no GM crop has been approved for release in to the environment. For GM crops developed within the country, the current practice involves continual safety assessment during product development. Each step in the development cycle, starting from containment in the laboratory, to confined field trials has to be approved for compliance using the stipulated guidelines.

| |
|---|
| In line with global practices, safety of imported GM food is based on the information provided by the applicant (GMO manufacturer) and from any other external sources as necessary. Under the present system the applicant's information is derived from his or her own data, not from independently accredited evaluators. |

For imported GM food crops, the safety assessment is done prior to importation. Confirmation of the safety of the GM food is carried out upon application for import, as outlined in figure 2.2.

***Box 2.1 Excerpt from the NBA SOP for Food Safety Assessment** [SOP No: NBA/TEC/SOP/005]*

1. **PROCEDURE/METHOD**

**1.1. Conducting Food Safety Assessment**

1.1.1. An applicant submits an application for Environmental Release and/or placing in the Market and Import, Export or Transit. The application shall be accompanied by a food/feed safety assessment report.

1.1.2. The application is received as per the SOP on receiving, administrative screening and acknowledging GMO applications

1.1.3. Evaluation of the application shall ensure that the information provided includes the following among others:

1.1.3.1. *The food/feed product*

1.1.3.1.1. The introduced trait

1.1.3.1.2. The purpose of introduction

1.1.3.2. *Molecular characterization*

1.1.3.2.1. Genetic modification

1.1.3.2.2. Sequence of inserted genes

1.1.3.2.3. Expression of inserted genes

1.1.3.2.4. Marker genes used for transformation

1.1.3.3. *Compositional analysis*

1.1.3.3.1. Results from analysis of material collected from field trials

1.1.3.3.2. Analysis: Macronutrients, Micronutrients, Anti-Nutrients and Secondary Metabolites for which the crop is known to contribute significantly to the diet

*1.1.3.4. Toxicity*

1.1.3.4.1. New proteins and mode of action

1.1.3.4.2. Amino acid sequence similarity especially to known toxins

1.1.3.4.3. In vitro digestion of novel proteins with emphasis on simulated gastric fluid

1.1.3.4.4. Acute oral toxicity in validated rodent models, when there is potential for dietary exposure

1.1.3.4.5. Animal feeding studies for the whole food/feed product, if necessary

1.1.3.5. *Allergenicity of the new proteins*

1.1.3.5.1. Gene source and history of allergenicity

1.1.3.5.2. Amino acid sequence similarity to known allergens

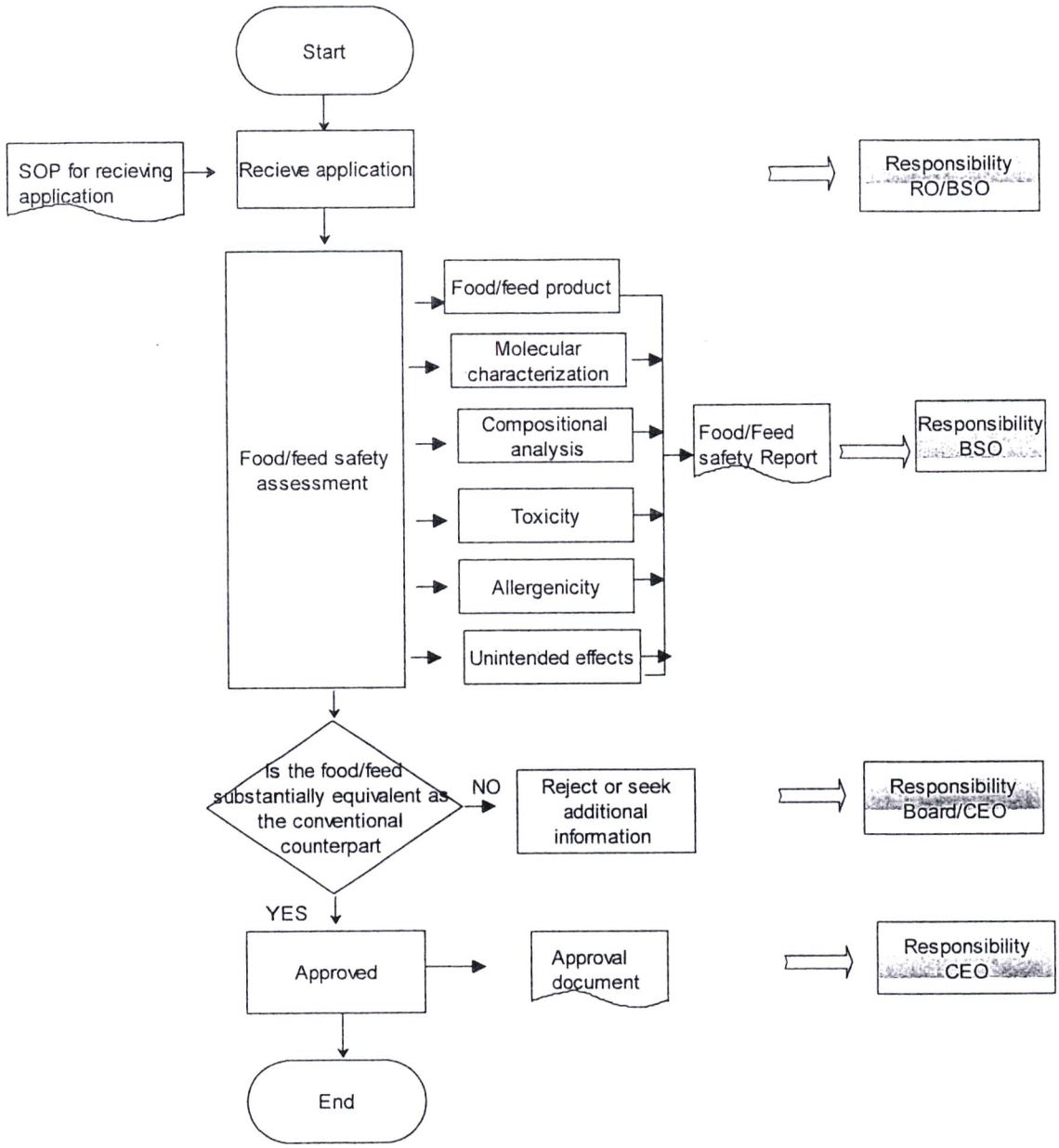
1.1.3.5.3. In vitro digestion of novel proteins with emphasis on simulated gastric fluid

1.1.3.6. *Unintended effects*

1.1.3.6.1. Availability of data on any unanticipated effects that may occur in the future.

**NB:** NBA on its own discretion may decide to conduct an independent food/feed safety assessment where in its opinion such assessment would be useful in making the final decision.

**Figure 2.2 Food/feed Safety Assessment flowchart**



## 2.7 Conclusions on the Safety Assessment of GM Foods for Human Consumption

The Government of Kenya (GOK) has put in place control measures to assure and ensure that all GM activities or products approved in Kenya are safe. In 2006, the Cabinet approved the National Biotechnology Development Policy; in 2008, Parliament passed the Biosafety Bill, which then became law in 2009 – the Biosafety Act. The GOK has developed various regulations to implement the Biosafety Act No 2 of 2009. These include the following regulations on:

- Contained use – covers any GMO-related activities or research under containment and/or confinement such as within laboratories, glasshouses and confined field trials
- Environmental release – covers activities during the commercialisation of GMOs and that involves environmental release and marketing
- Import, export and transit – cover the movement of GMOs into and out of the country and the safe transit within the national borders, in conjunction with the above regulations on release
- Labelling – cover aspects of traceability of the GMO and consumer awareness of products containing GMOs
- Currently under preparation is a draft regulation on handling, packaging, storage, and transportation of GMOs.

Within these regulations the assessment of safety of the GMO for human consumption is determined *"...**in accordance with Kenyan standards and laws prior to Environmental Release and/or placing in the Market and Import, Export or Transit.**"*[14]

However, the regulations contained within the National Biosafety Act fail to directly address the assessment of safety of GM foods for human consumption. The law that addresses human safety refers to occupational health. The Fourth and Fifth Schedules describe approval for contained use and contingency plans, respectively.

> The current safety regulations of Kenya make no reference whatsoever to the safe consumption of GM foods.

[14] NBA: SOP for Food Safety Assessment Procedure

## 3.0 GM MAIZE: A CASE STUDY

### 3.1 The GM Maize event NK603

The genetically modified maize event NK603, developed by Monsanto Company, has received the most number of regulatory approvals (James, 2012). The product known as Roundup Ready© 2 Corn (Maize) was approved by the FDA for deregulation in 2000, becoming a commercially available crop in USA and Canada in 2001[15]:

> Based on the information Monsanto has presented to FDA, we have no further questions concerning grain and forage from the Roundup Ready® NK603 corn at this time. However, as you are aware, it is Monsanto 's continued responsibility to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.
>
> Sincerely yours.
>
> /s/
> Alan M. Rulis. Ph.D.
> Director
> Office of Premarket Approval

**An excerpt from the FDA approval letter to Monsanto (see Appendix I for the full letter)**

European approval of the crop for food and feed followed in 2004[16]. It was developed as an herbicide resistant crop that allowed for the use of the glyphosate-containing herbicide, Roundup, as a weed control option for maize[17, 18]. Championed as a cost-saving, profitable, high yielding crop, the GM Maize was promoted to farmers as a product that enabled more effective weed management during cultivation; increased crop yields while also lowering overall production costs, with the eventual reduction in herbicide usage[19].

### 3.2 The Genetic Modification Procedure

The GM maize NK603 is modified to contain two copies of the *Agrobacterium ssp* CP4 DNA encoding proteins with reduced affinity to glyphosate, an inhibitor of the enzyme EPSP synthase that is crucial in plant and bacterial metabolism. The NK603 event was chosen for commercialization as:

> *"...the event that embodied the most optimal profile of tolerance, agronomics, and molecular characteristics."* (Hammond et al 2004).

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[15] FDA approval letter to Monsanto (October 18th, 2000); FDA report on NK603 (August 30th 2000) – attached

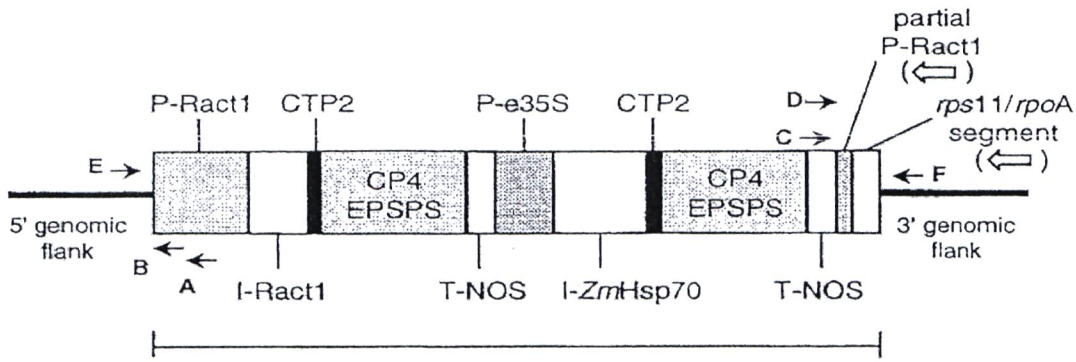
[16] CERA http://cera-gmc.org/index.php?evidcode%5B%5D=NK603&hstIDXCode%5B%5D=1&auDate1=&auDate2=&action=gm_crop_database&mode=Submit

[17] EU Commission Decision, 03 March 2005/448/EC http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:158:0020:0022:EN:PDF

[18] ISAAA GM approval online database http://www.isaaa.org/gmapprovaldatabase/default.asp

[19] Monsanto safety assessment of NK603, submitted to EFSA (2002) - attached

The transgenic cassettes were constructed within the *MluI* restriction endonuclease site of the plasmid PV-ZMGT32 and transformed into pre-cultured maize embryo cells by the particle bombardment method (Hammond et al 2004). The plasmid construct carries 2 *cp4 epsps* transgene cassettes driven by the rice actin 1 gene (P-Ract1) and an enhanced Cauliflower Mosaic Virus 35S (P-e35S) promoters respectively (Hammond et al 2004). The construct was designed to generate full vegetative and reproductive tolerance to glyphosate during commercial application (Heck et al 2005). The NK603 event illustrated in Figure 3.1 was found to contain one insertion site containing a single copy of the linear DNA of PV-ZMGT32 used for transformation. Both *cp4 epsps* gene cassettes within the single insert were also deemed to be intact (Heck et al 2005).




*(Source: Heck et al., 2002, Crop Science 45(1):329-339)*

**Figure 3.1 NK6043 transgenic integration site**

Listed below is an outline of the key features that make up the transgenic construct used in the creation of the GM maize event NK603, described in the online GMO Register of approved GM events[20].

**P1-Ract1/ I2-Ract1** : 5' region of the rice actin gene containing the promoter, transcription start site and first intron (McElroy et al., 1990).
**TS3-CTP2** : DNA sequence coding for the N-terminal chloroplast transit peptide (Klee et al., 1987)
**CS4-cp4 epsps** : DNA sequence coding for the native CP4 EPSPS protein (Padgette et al., 1996).
**T5-nos** : 3' transcript termination sequence of the nopaline synthase (nos) coding sequence from Agrobacterium tumefaciens which terminates transcription and directs polyadenylation (Fraley, et al., 1983).
**P-e35S** : Promoter and leader for the cauliflower mosaic virus (CaMV) 35S RNA (Odell et al., 1985) containing the duplicated enhancer region (Kay et al. 1987)
**I-Hsp70** : Intron from the maize heat-shock protein 70 gene (Rochester et al., 1986).
**TS-CTP2** : DNA sequence coding for the N-terminal chloroplast transit peptide (Klee et al., 1987)
**CS-cp4 epsps l214p**:DNA sequence coding for the CP4 EPSPS L214P protein (Padgette et al., 1996).
**T-nos** : 3' transcript termination sequence of the nopaline synthase (nos) coding sequence from *Agrobacterium tumefaciens* which terminates transcription and directs polyadenylation (Fraley, et al., 1983).

**Box 3.2** A summary of the inserted DNA fragment inherited from KN603

[20] GMO register, with references therein:
http://gmoinfo.jrc.ec.europa.eu/gmp_report.aspx?CurNot=B/FR/06/12/08

Description of function of the DNA sequences of the GM event NK603[21]

| Name | Description | Functions |
|---|---|---|
| **** | | |
| 5'FRund | Undesired genomic sequence at the 5' flanking region | Not known. |
| P-ract1 | Sequence of the constitutive promoter of the rice (*Oryza sativa*) actin gene | Constitutive promoter. |
| I-rAct1 | Intron of rice (*Oryza sativa*) actin 1 gene | Transcription increase intron. |
| ctp 2 | Leader sequence encoding a chloroplast transit peptide from *Arabidopsis thaliana* | Chloroplast transit peptide. |
| cp4epsps | Sequence encoding the EPSP enzyme (5-enolpiruvilshikimate- 3-phosphate synthase) from Agrobacterium sp. strain CP4 | Glyphosate tolerance. |
| 3' nos | 3' termination sequence of the nopaline synthase gene from *Agrobacterium tumefaciens* T-DNA | Terminator. |
| P-e35S | Constitutive promoter of CaMV 35S gene | Constitutive promoter. |
| I-Hsp70 | Intron of heat shock protein 70 from *Zea mays* | intron. |
| ctp 2 | Leader sequence encoding a chloroplast transit peptide from *Arabidopsis thaliana* | Chloroplast transit peptide. |
| cp4epsps | Sequence encoding the EPSP enzyme (5-enolpiruvilshikimate- 3-phosphate synthase) from *Agrobacterium sp.* strain CP4 | Glyphosate tolerance. |
| 3' nos | 3' termination sequence of the nopaline synthase gene from *Agrobacterium tumefaciens* T-DNA | Terminator. |
| 3'FRund | Undesired genomic sequence at the 3' flanking region | Not known. |
| **** | | |

[21] Source Biosafety scanner:

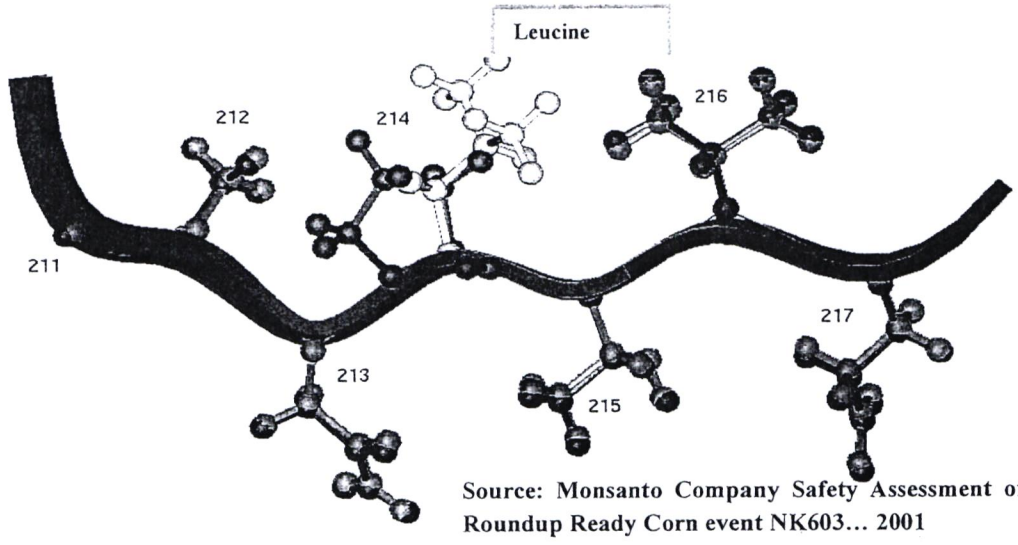
http://en.biosafetyscanner.org/mostraevento.php?dascheda_evento=27&id=44&dascheda=10

The transgenic expression of *cp4 epsps* gene product supports aromatic amino acid synthesis in the plant when treated with the herbicide Round Up. This is because herbicide tolerance is conferred to the plant only when all cell types receiving a significant dose of the herbicide are still able to express the resistant CP4 EPSPS enzyme.

> *"When plants are treated with the herbicide, glyphosate is delivered to all cell types from the leaves in much the same way as the products of photosynthesis and is therefore found in high concentrations in meristematic tissue, roots, young developing organs and inflorescence – all areas where a fully functional aromatic amino acid pathway is needed"*

The two promoter system of the transgene was introduced owing to impaired early male reproductive development determined previously in single P-e 35S/ CP4 EPSPS transformants. This impairment was complemented by the P-Ract 1/ CP4 EPSPS, which has higher expression in the corn anther, but lower expression in the mature tissues of the corn plant (Heck et al, 2005).

Of the two changes observed in the P-e 35S/ CP4 EPSPS coding region, one led to a silent codon substitution while the second resulted in a leucine to proline substitution at position 214 of the 455 CP4 EPSPS polypeptide – CP4 EPSPS L214P; The P-Ract 1/ CP4 EPSPS coding region was unaltered (Heck et al 2005). According to the Monsanto Company Safety Assessment of the NK603 event (2002), the observed amino acid substitution did not affect the active site of the EPSPS enzyme and the *in vitro* assays and biochemical activities of the expressed protein were indistinguishable from the native form of the enzyme (Monsanto Company 2002). The L214P substitution did not appear to affect predicted secondary and tertiary structure of the proteins, as shown in Figure 3.2.




**Source: Monsanto Company Safety Assessment of Roundup Ready Corn event NK603... 2001**

Figure 3.2 Ribbon diagram of CP4 EPSPS and CP4 EPSPS L214P near the residue 214 region of the enzymes.

The CP4 EPSPS is shown in blue and the CP4 EPSPS L214P is shown in red. Side chains of Leu-214 in CP4 EPSPS and the Pro residue in CP4 EPSPS L214P are shown in yellow and green, respectively. This close up view around the 214 regions of CP4 EPSPS and CP4 EPSPS L214P clearly shows that the mutation does not affect the structure in that region and

> However, when the expression of CP4 EPSPS in the NK603 event was analyzed at a nucleotide level, two nucleotide changes were revealed in the P-e35S/ CP4 EPSPS coding region that were not present in the originating PV-ZMGT 32 plasmid, and had been stably inherited and maintained in subsequent generations in the GM maize.

hence is not anticipated to affect activity (Figure 3.3).

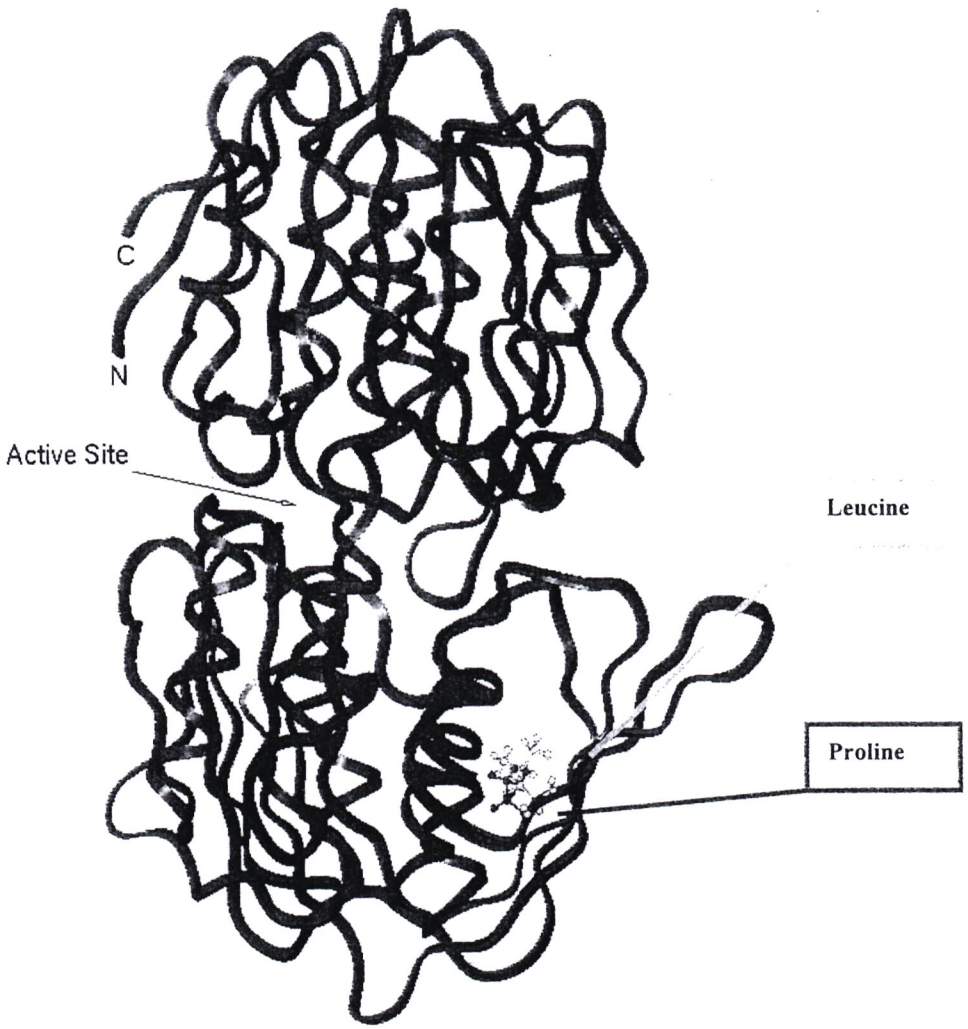



**Figure 3.3 Structures of CP4 EPSPS and CP4 EPSPS L214P.** The structures are shown as ribbon diagrams with the CP4 EPSPS in blue and CP4 EPSPS L214P in red. The Leu-214 residue in native CP4 EPSPS is displayed in yellow and the Pro-214 residue in CP4 EPSPS 214P is shown in green. The Figure shows that Leu 214 (yellow) is not in the active site and the replacement of Leu with Pro does not perturb the structure of the CP4 EPSPS enzyme[1].

According to Heck et al (2005), additional unexpected DNA segments were also seen to be integrated into the transformation cassette that had not previously been present at the point of transformation and were thought to be by-products of the transformation event that flanked the integration site of the transgene in the maize genome.

> *"The DNA segment immediately adjacent to the 3'-end of the double gene cassette in NK603 is a 217bp* ***inverted duplication of the 5'-end of the cassette*** *that corresponds to positions 150 – 366 of PV-ZMGT32 and* ***includes the first 166bp of P-Ract 1****(positions -835 to -670 from transcription start site)... [that] is unlikely to have any significant contribution to transcriptional regulation of CP4 EPSPS transgene or adjacent maize genomic sequences... A second segment of co-integrated DNA with perfect identity to rP123 gene cluster of the corn plastid genome is fused downstream of the duplicated portion of P-Ract 1."* (Heck et al 2005)

### 3.3 The Safety Evaluation of NK603

The Monsanto Company safety assessment of the NK603 event in the first instance established the absence of any deleterious effects caused by the nucleotide changes introduced to the transgene. This was performed by bio-informatics analyses of similar proteins within combined databases consisting of all publicly available protein sequence information at that time, and concluded that the introduced change was a "well-tolerated substitution"(Monsanto Company 2002).

Potential allergenicity and toxicity of the transgene were also assessed. The former was assessed by a bio-informatics alignment of the protein sequence with publicly available protein sequences for known allergens. Acute oral toxicity was investigated by performing feeding trials on mice using purified samples of the novel protein that had been expressed in *E. coli*. Finally digestibility of the novel protein in the gut was assessed *in vitro* using simulated gastric juices. The findings from the three evaluations were used to establish the safety of the novel protein. **By using substantial equivalence studies**, the Company was able to conclude that the GM maize event NK603 had similar agronomic, phenotypic and nutritional characteristics to conventional corn:

> *"Based on the principle of substantial equivalence as articulated by the World Health Organization, Organization for Economic Cooperation and Development as well as the United Nations Food and Agriculture Organization, these data support the conclusion that corn event*
> *NK603 is as safe and nutritious as conventional varieties of corn in the market in the today."*

According to Hammond et al (2004), the food safety standard for a GM food crop is established once the food is determined to be as safe as food produced by conventional breeding methods. Safety assessment is considered as an assessment of two key areas of potential risk:

1. The potential risk posed by the introduced trait in terms of the novel proteins' properties and function.

2. The potential risk posed by the insertion of a transgene into the plant genome, which may cause pleiotropic effects.

By performing a comparative safety assessment of the GM food crop with its conventional counterpart, the authors believe that the level of risk of the GM food can be assessed, especially where it can be shown that the conventional counterpart has a history of safe consumption:

> *"The outcome of this assessment is to assess whether the genetically modified crop is comparable to the existing non-transgenic crop."*
>
> - Hammond et al (2004)

In order to assess the safety of the NK603 GM maize event, Hammond et al (2004) performed **a 90-day safety assurance study in rats in line with the OECD guidelines** on repeated-dose 90-day oral toxicity studies in rodents (OECD, 1998). The published 90-day toxicity study by Hammond et al (2004) has been reviewed as one of the best published, longest studies of the day that had, up until then, been performed with mammals (CRIIGEN report, 2007).

The study presented findings of a 13-week comparative feeding study between Sprague Dawley rats fed with grain from the herbicide tolerant NK603 GM maize event and rats fed diets containing a variety of non-transgenic grain controls. The study found no signs of acute oral toxicity, rapid *in vitro* digestibility of the transgenic protein and no indication of adverse effects in the animal feeding trails. Indeed on the face of this trial they stated in their application for commercialisation of the GM maize within the European Union in 2005[22]:

> *"NK603 is substantially equivalent to the near isogenic comparators used in the study.*
> ***Some statistically significant differences were observed, but were likely to have occurred by chance and deemed not to be of biological significance.***
> *The observed differences were generally small and were not consistent across trial sites..."*
>
> - Monsanto Safety Assessment application to the EU (2005)

[22] Application for authorization to use NK603 maize in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed, including the use for cultivation of varieties. Section 7: Information on any toxic, allergenic or other harmful effects on human or animal health arising from the GM food/feed. Article 7.1:Comparative Assessment (Attached)

### 3.4 Health Concerns raised about the GM maize event NK603

In 2007, Séralini et al. published a reanalysis of the Monsanto raw data used in the submission of the safety assessment of the GM maize event NK603 and concluded that the data revealed signs of liver and kidney toxicity in the GM-fed rats. The authors observed that the GM varieties were capable of inducing a state of hepatorenal toxicity in laboratory animals: that is consumption of the GM maize was linked to disruption of the major diet detoxification organs in laboratory rats fed for a period of three months.

> *"The rat feeding studies typically performed in support of regulatory authorisations for GMOs last for a maximum of 90 days; a sub-chronic period equivalent to 7 to 9 years in a human..."*
>
> Source: Séralini et al (2007); de Vendômois et al (2009)

The Sprague Dawley rat is extensively used as a mammalian experimental model. It is considered a good human equivalent model that has been used for over 30 years in cancer research (Soffritti et al 2002). The incidence of basic tumor development is considered similar to humans with approximately similar cancer incidences (Belpoggi 2011) as outlined in Figure 3.4.

### The GM Maize event MON 810

Bt maize events for example MON 810 and MON 863 have been genetically engineered to produce a natural insecticide toxin, collectively referred to as Bt toxins. These toxins, derived from the soil bacterium, *Bacillus thuringiensis* (Bt), are used in agriculture as an insecticide in both conventional and organic agricultural practices.

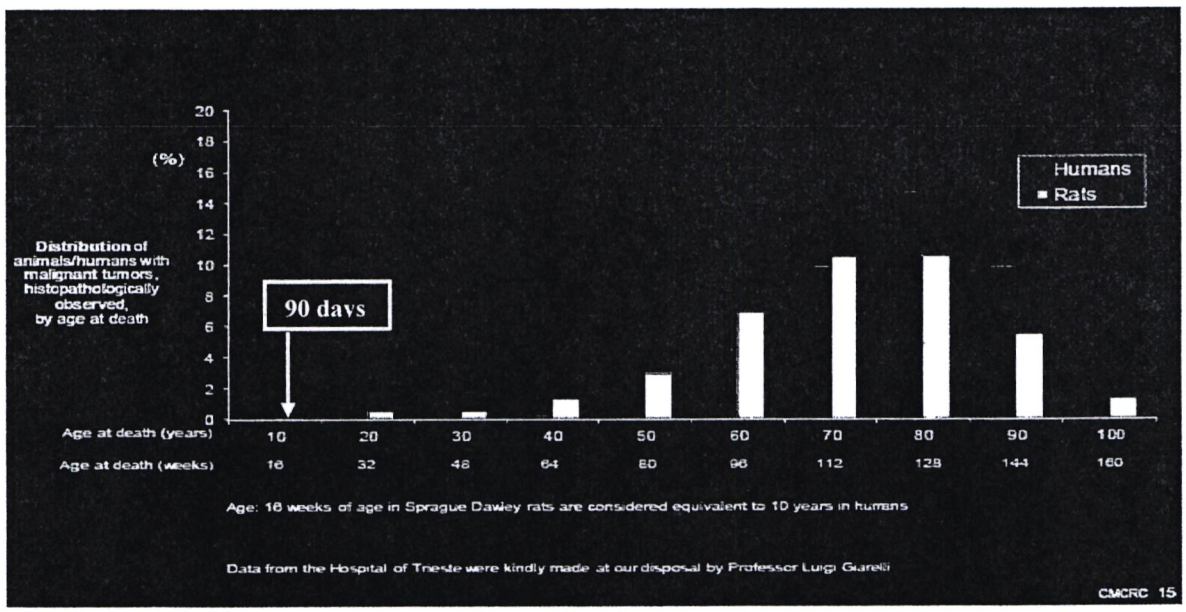
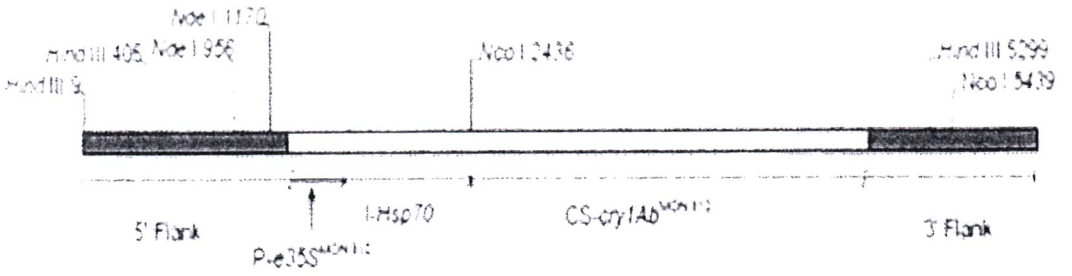



**Figure 3.4** The Human-equivalent model – Malignant tumour incidence in the life span of humans and the Sprague Dawley rat (Belpoggi 2011)

MON 810 was developed by Monsanto in the 1990s and engineered to produce the Bt toxin Cry1Ab that is toxic to Lepitdopteran pests such as the European corn borer (*Ostrinia nubilais*). It was one of the first genetically modified plants to be allowed for cultivation in Europe, approved in 1998 (VIB, 2010).

MON 810 was developed by particle bombardment of embryonic maize tissue, using a mixture of two plasmids: PV-ZMBK07 and PV-ZMGT10, expressing *cry1Ab* and *cp4epsps* respectively. The plasmid PV-ZMBK07 contained the *cry1Ab* coding sequence under control of the cauliflower mosaic virus (CaMV) 35S promoter and the 3'-nopaline synthase (nos 3) terminator. Messenger RNA transcription was enhanced by the maize heat shock protein leader sequence under the influence of the constitutive promoter sequence.

Upon transformation, the MON 810 line expressed a truncated *cry1Ab* cassette that was missing the *npt II* selection marker and part of the plasmid backbone. Further, none of the plasmid PV-ZMGT10 had been integrated.

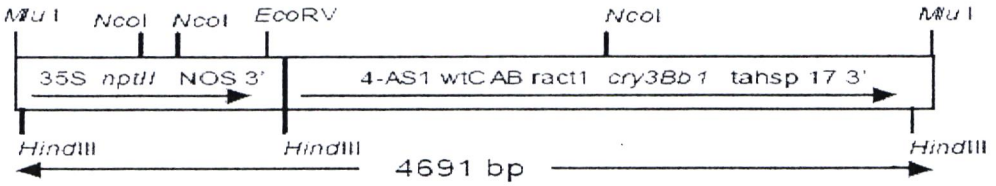



| Name | Description | Functions |
|---|---|---|
| **** | | |
| 5'FRund | Undesired sequence at the 5' flanking region | Not known. |
| P-e35S | Constitutive promoter of CaMV 35S gene | Constitutive promoter. |
| Cry1Ab | Sequence encoding Bt endotoxin of *Bacillus thuringiensis var. kurstaki* | Insect resistance Lepidoptera resistance. |
| 3'FRund | Undesired sequence at the 3' flanking region | Not known. |
| **** | | |

### 3.5 Development of Bt Maize events

#### 3.5.1 The GM Maize event MON 863

MON 863, developed by Monsanto, was engineered to produce a synthetic version of the Bt toxin Cry3Bb1, toxic to Coleopteran pests such as the corn rootworm (*Diabrotica virigifera*). The DNA fragment, outlined below as a schematic representation of its genetic elements, was made up of two gene cassettes for the expression of the proteins CRY3Bb1 and NPTII.




The nucleotide sequence of the bacterial *cry3Bb1* gene was modified to optimise its expression in monocotyledons, by introducing a 5'-end restriction sequence of GCC at positions 4, 5, and 6, resulting in the addition of an alanine residue at position 2 of the protein. Further downstream amino acid substitutions were included to enhance the protein's insecticidal activity.

The protein structure of Cry3Bb1 has been elucidated (Galitsky et al 2001). The structure is made up of three domains: I, a seven-helix bundle (residues 64-294 in red); II, a three-sheet domain (residues 295-502 in blue); and III, a beta-sandwich domain (residues 503-652 in gold) as shown in Figure 3.5

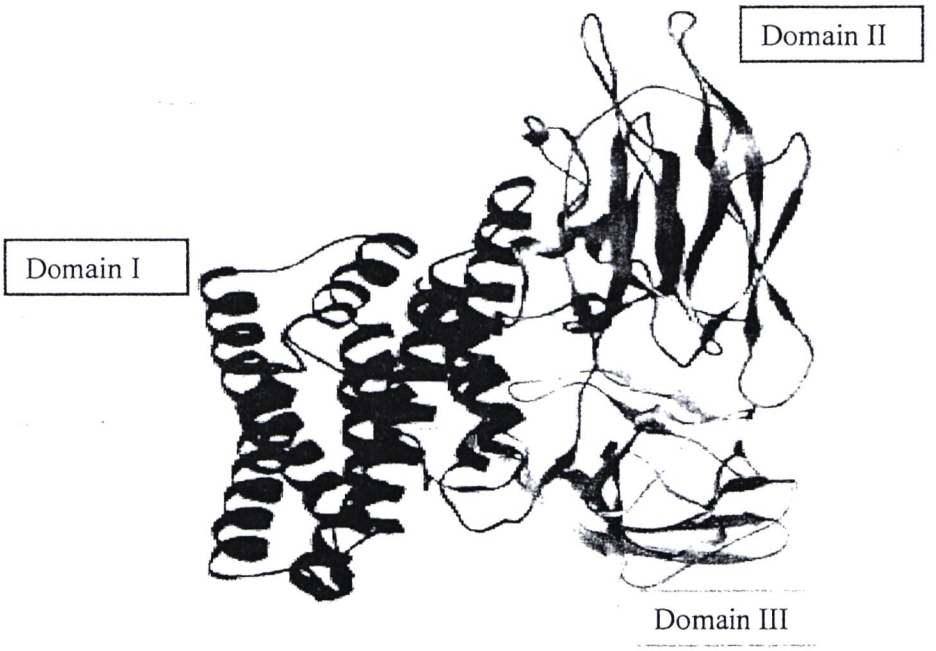



**Figure 3.5** The proposed structure of the active form of Cry3Bb1 protein (Galitsky et al 2001)

MON 863 was generated by transformation of maize callus cells in tissue culture using particle bombardment of purified DNA fragments containing *cry3Bb1* and *nptII* genes together with regulatory elements as outlined in the table above. The 4691bp DNA fragment used in the maize transformation event had been isolated from a plasmid vector PV-ZMIR132 by restriction with *Mlu I* restriction endonucleases. It was this purified fragment, designated ZMIR132 that was used to produce MON 863.

The *nptII* gene was included as a selectable marker coding for neomycin phototranspherase II, a protein that confers antibiotic resistance to the following antibiotics: neomycin, paromonmycin, kanamycin and geneticin (G418) sulfate. Its function within the DNA fragment was to enable the identification of successfully transformed maize plants with the *cry3Bb1* variant.

| Name | Description | Functions |
|---|---|---|
| **** | | |
| 5'FRund | Undesired sequence at the 5' flanking region | Not known. |
| P-e35S | Constitutive promoter of CaMV 35S gene | Constitutive promoter. |
| nptII | Sequence encoding the NPTII enzyme (neomycin phosphotranspherase) from Tn5 transposon of *E. Coli* | Antibiotic resistance. |
| ble truncated | Partial sequence encoding antibiotic (bleomycin) resistance of transposon Tn5 of *E. coli* | Not known. |
| 3' nos | 3' termination sequence of the nopaline synthase gene from *Agrobacterium tumefaciens* T-DNA | Terminator. |
| P-4AS1 | Synthetic constitutive promoter derived from CaMV 35S promoter | Constitutive promoter. |
| wt CAB | 5' untranslated sequence from wheat (*Triticum aestivus*) chlorophyll gene | Transcription increase. |
| I-rAct1 | Intron of rice (*Oryza sativa*) actin 1 gene | Transcription increase intron. |
| cry3Bb1 | Sequence encoding Bt endotoxin from *Bacillus thuringiensis var. Kumamotoensis* | Resistance to insects Resistance to Coleoptera. |
| 3'tahsp 17 | 3' termination sequence of wheat heat shock 17 gene | Polyadenylation site. |
| 3'FRund | Undesired sequence at the 3' flanking region | Not known. |
| **** | | |

Fragment ZMIR132 contained novel DNA sequence changes designed to enhance the insecticidal activity against the corn root borer pest. This modified CRY3Bb1 protein (designated CRY3Bb1.11098) varied from the native bacterial protein. Upon characterisation of the protein expressed in MON863, the producers identified further amino acid changes that were unexpected and unintended. The MON 863 maize event produces a protein that differs from the native Bt protein by 7 amino acids and from the CRY3Bb1.11098 variant by 2 amino acids, that were introduced after the transformation event. The changes are listed in the table below:

Table 3: Summary of amino acid changes to Cry3Bb1

| Original amino acid | Position | New amino acid |
|---|---|---|
| - | 2 | Alanine |
| Aspartic acid | 166 | Glycine |
| Histidine | 232 | Arginine |
| Serine | 312 | Leucine |
| Asparagine | 314 | Threonine |
| Glutamic acid | 318 | Lysine |
| Glutamine | 349 | Arginine* |

* unintended amino acid change

*-Source Food Standards Australia New Zealand (2004)*

The unintended changes came about from a 10bp truncation of the 3'-end of the ZMIR123 DNA fragment. The loss of this 10b segment of DNA did not affect the 3'-end transcription termination sequence of the fragment, but did result in the deletion of 2 restriction sites for the enzymes *Mlu I* and *Hind III*. The second change in resulted in an amino acid substitution at position 349 of the CRY3Bb protein from glutamine to arginine.

> *"In conclusion, the [EFSA GMO] Panel considers that the information available for MON 863 addresses the outstanding questions raised by the Member States and considers that MON 863 will not have an adverse effect on human and animal health or the environment in the context of its proposed use."*
> - *Source EFSA Journal (2004)*

Notwithstanding, some member states were still not convinced and maintained restrictions on this GM maize event.

### 3.6 Investigating GM Food Safety Data

In 2003 Monsanto Company applied to the EU to for authorisation to place food and food ingredients derived from MON863 (Bt maize) on the market. Upon review of the safety assessment, Germany found correlations between the MON863 protein product and toxins known to both humans and animals, based on amino acid sequence homologies. France

questioned the toxicology test data. Specifically blood changes observed in GM fed rats were deemed not to have any biological relevance when compared with the controls. The Biomolecular Engineering Commission of France (Commission du Genie Biomoleculaire de France – CGB) experts however, approved the MON863 safety tests, albeit by a narrow margin.

By 2004, EFSA had published its opinion on MON863:

> *"**Some differences were observed in haematological parameters, including total white blood, lymphocyte and basophil counts...***
> ***"...a statistically significant lower incidence of mineralised kidney tubules was noted for rats fed 33% MON863 maize compared to those fed the control maize during histopathology after termination.**"*

These and other differences were referred to **as having no biologically relevant effect compared to the controls and that MON863 was as safe as its conventional counterpart.** Differences in opinion between the panel of experts of the CGB were revealed showing that concerns had been raised over the safety of MON863 but these had gone unchallenged.

CRIIGEN, in 2005, published its own findings on the Monsanto Company rat-feeding study, performing a reanalysis of the statistical data, observing that:

> *"... [the] findings clearly indicate major failures of statistical analysis [by] Monsanto."*

CRIIGEN concluded that a **complete reassessment of all data from the feeding study was needed.** Nevertheless in 2006, the European Commission had authorised more food and food ingredients derived from MON863 maize and EFSA approved 3 MON863 derivatives: MON863 x MON810; MON863 x NK603; and MON863 x MON810 x NK603 events.

The following year CRIIGEN published reports on the safety of the maize events NK603 and MON863 respectively, reanalysing the crude statistical data used by Monsanto in the 90-day rat feeding study (Hammond 2004). On MON863, the group concluded that **the data presented could not be used to confirm the safety of the GM maize and that longer experiments were "essential" in order to evaluate the real nature and extent of possible pathology**.

> *"In considering that human and animal populations could be exposed at comparable levels to this kind of food or feed that has been authorised in several countries, and that these are the best mammalian toxicity tests available, **we strongly recommend a new assessment and longer exposure of mammals to these diets with cautious clinical observations, BEFORE CONCLUDING THAT MON863 IS SAFE TO EAT.**"*

In the NK603 report, CRIIGEN observed that significant differences reported by Monsanto during the 90-day feeding study had been deemed not biologically meaningful and not attributable to the GM event, and that rats fed on GM corn containing NK603 responded similarly to rats fed on parental and reference control grain. In one instance, significant differential effects between male and female rats fed on the GM maize were deemed not biologically relevant and could not be attributed to the GM event itself – these conclusions brought about without reference to a toxicologist's interpretation of the data and with no independent verification of the histological studies of the organs affected.

> *"...where Monsanto had claimed that statistically significant changes that had been found in the GM-fed rats were biologically irrelevant, they did so with no specific definition of biological relevance with respect to changes in the GM-fed animals."*
>
> - Robinson C. (2013)

Statistically significant effects were observed between rats fed the control diet and the test diet but were described as having occurred by chance and not of biological significance as the statistical analyses found these variations fell within the 5% significance level. The CRIIGEN report on NK603 outlined that biological variance can only be substantiated by referencing normal maize- fed rats with the GM-fed rats. Therefore when Monsanto used control diets from maize varieties not substantially equivalent to the GM maize isogenic control lines, then it would be difficult attribute changes to effects caused by the transgene. Furthermore the total GM-treated group and in some instances, **HISTORICAL DATA OF THE LAB CONDUCTING THE EXPERIMENT SERVED AS REFERENCES** for some of the effects observed: 40 rats per sex group were fed NK603 from a total of 400 rats and only half of these were analysed for biochemical parameters. In other words there were 80 experimental rats and 320 controls. Ordinarily there would be equal numbers of each. Of the 80 experimental rats only half (40) had their biochemical parameters analysed. In effect, therefore, the study only considered 40 experimental rats against 320 controls:

> *"This difference in size favours uncertainty and allows for questioning of **NOT BIOLOGICAL MEANINGFUL DATA**..."*

Although Roundup Ready® NK603 was approved for deregulation by FDA in 2002; safety evaluation by Monsanto (2005) showed some statistically significant data. However the significance was deemed not biologically meaningful or relevant. Blood changes observed in rats fed on MON863 were also deemed not to be of biological relevance. In some of these experiments large control groups of historical data were used. **To date no independent study of toxicity other than that by the developers of GM maize has been done. The safety of GM maize therefore remains controversial. Independent, longer, multigenerational experiments will be required to confirm the safety of GM maize.**

It is important to highlight the way GM foods (i.e. maize, soybean and canola) are used by both the producing and importing countries. In the USA, the largest GM food producer, the

industry puts refined products of GM crops into the market. These products go through lengthy and sometimes complicated processes before they are given to the consumers:

- The maize that is eaten directly makes up only 1.8% of the total crop but then it is eaten as a refined modified product in the form of cereals such as cornflakes, etc.
- The rest is consumed as corn oil, sweetening syrups for soft drinks and alcohol.
- In the case of GM soybean, the American consumer takes it as refined oils and proteins.

On the other hand, importing countries like Kenya use maize as the whole grain and soybean as the whole seed. Therefore any added proteins or pesticide residues will be found in the whole grain maize and in the soybean seed.

### 3.7 Conclusion

When reviewing the safety of GM foods, it is recommended to do so case-by-case. In this case study, a review of the production, safety and literature of three GM maize varieties was performed. **No clinical trials exist pertaining to GM food safety**. As maize is a very important staple in Kenya and the above mentioned GM events the most widespread worldwide, they were the preferred choice for review.

The case study highlighted serious concerns with the imprecise, unpredictable nature of the transformation event; **subjectivity of the concept of substantial equivalence** in determining safety; and the **inadequacy of the animal feeding procedures** as prepared by the GM food producers.

## 4.0 REVISITING CONTROVERSIAL RESEARCH PAPERS ON SAFETY ASSESSMENT OF GM FOODS

### 4.1 European Food Safety Authority Review

The European Food Safety Authority (EFSA) GMO Panel Working Group has extensively reviewed the safety and nutritional assessment of GM plants and derived food and feed, with a special focus on the role of animal feeding trials (EFSA, 2008). In the safety assessment, GM plants and derived food and feed are examined, in comparison to their non-GM counterparts, for intended and unintended (unexpected) characteristics, and are then assessed for their potential impact on the environment, safety for humans and animals, and nutritional quality in comparison with their non-GM counterparts. The modified plants and their derived products undergo molecular, compositional, phenotypic and agronomic analysis to identify similarities with, or differences from, their non-GM counterparts. The safety assessment looks for (i) the presence and characteristics of newly expressed proteins and other new constituents and possible changes in the level of natural constituents beyond normal variations, and (ii) the possible occurrence of unintended (unexpected) effects in GM plants due to genetic modification. **The OECD recommended 90-day feeding trials in laboratory rodents are used to assess potential unintended effects of toxicological and/or nutritional relevance, and to establish whether the GM food and feed is as safe and nutritious as their non-GM counterparts**.

It is noted that the approaches used to perform safety and nutritional assessment of whole food and feed in laboratory animals are borrowed largely from approaches used for testing other products meant for human consumption such as irradiated foods, novel foods, fruits and vegetables. These approaches are considered relevant for the safety and nutritional testing of whole GM food and feed. According to EFSA, numerous lab animal feeding trials have been undertaken on various GM foods including maize, soy beans, and potatoes for prolonged periods and in which parameters such as body weight, organ weights, histopathology, blood chemistry, feed consumption were measured, and majority of these trials did not indicate adverse effects or abnormalities. Nevertheless, in some studies adverse effects and abnormalities were observed in GM products-fed animals, but the results of these studies according to EFSA, were difficult to interpret due to shortcomings in the experimental design. EFSA considers laboratory animal feeding studies of 90-days duration to be sufficient to pick up adverse effects of diverse components that would also, give adverse effects after chronic exposure. **EFSA further suggests that in general, long term, chronic toxicity testing of whole GM food and feed is not expected to generate information additional to what is already known from the short-term testing**.

> *"In the present scientific report EFSA provides a commentary on OECD TG 453 with considerations on its applicability to support the safety assessment of long term consumption of a given food with respect to its chronic toxicity or carcinogenicity potential."*
>
> - *EFSA Journal 2013*

This is a dynamic area and is regularly updated as evidenced by a recent report by EFSA to the European Commission (July 29, 2013) recommending new issues to be considered in the design of laboratory **animal feeding trials that assess chronic toxicity and/ or carcinogenicity** of whole food or feeds (EFSA Journal 2013).

### 4.2 A 90-day Laboratory Animal Feeding Trial on Herbicide Tolerant and Insect Resistant GM Maize

Investigating the role of manufacturers in research *vis a vis* independent scientists has revealed some disconnects. De Vendômois et al. 2009 observed that although the 90-day laboratory rodents feeding trials are used for regulatory approvals of GM plants and their products, **these tests apparently are not compulsory, are not independently conducted, and the test data and the corresponding results are kept in secret by the companies developing the GMOs**. A re-analysis of regulatory raw data pertaining to three GM maize varieties (NK603, MON 810, and MON 863) by de Vendômois et al. (2009) led the authors to conclude that these products may cause hepato-renal toxicity, and therefore, recommended that longer testing was necessary. However, the results of these analyses were challenged by the company developing the GMOs in question and the regulatory bodies, mainly on the divergent biological interpretations of statistically significant biochemical and physiological effects.

### 4.3 The Pusztai Affair on Genetically modified potato

The controversial nature of research findings involving GMOs is exemplified by the Putszai affair. Dr Arpad Pusztai received a grant from the UK government, in the 1990s, to design the system for safety-testing genetically modified organisms (GMOs). Working with a group of other scientists at facilities that included Rowett Institute in Aberdeen, Scotland, the top nutritionist Dr Pusztai noted that, within just 10 days of feeding rats with GM potatoes, the animals developed potentially pre-cancerous cell growth, smaller brains, livers and testicles, partially atrophied livers, and damaged immune systems. These potatoes had been transformed with the *Galanthus nivalis* agglutinin (GNA) gene from the Galanthus (snowdrop) plant, allowing the GNA lectin protein to be synthesised. This lectin has been shown to be toxic to some insects.

The controversy surrounding these results led to termination of Dr Pusztai from his employment at Rowett Institute and a gag in respect to dissemination of research findings. Subsequent intervention from the Hungarian parliament lifted his gag order and his research was published in the prestigious Lancet (Ewen SW & Pusztai A, October 1999[23]). In 2005 Pusztai was given a whistleblower award from the (400-member) Federation of German Scientists. It is important to note the different ways the three EU member stated approached this issue.

[23] "Effect of diets containing genetically modified potatoes expressing Galanthus nivalis lectin on rat small intestine". Lancet 354(9187): 1353–4

### 4.4 Andres Carrasco Studies on Developmental Abnormalities in Parts of Argentina

Another example of the work of independent scientists is studies conducted in Argentina by Paganelli et al (2010[24]). This work showed that misregulation of the retinoic acid (RA) pathway caused craniofacial abnormalities (by misregulation of sonic hedgehog and otx2 expression) and posterior regression syndrome in all vertebrates tested including, humans.

This study followed after there were reports of people in Argentina who claimed escalating rates of birth defects and cancers after the introduction of genetically modified soy, which is engineered to tolerate huge amounts of glyphosate spray. The study of Paganelli et al (2010) confirmed similar findings by Benitez-Leite et al (2009[25]) that pointed to the correlation between malformations and exposure to pesticides in Paraguay, giving the outcome of heavy agrochemical use in Paraguay. This work identified that living near treated soy fields, dwellings located less than 1 km from treated fields, storage of pesticides in the home, and contact with pesticides were significantly associated risk factors for congenital malformations.

These South American studies bring concerns of expansion of industrialized crops cultivation which require the intensive use of glyphosate and human health.

### 4.5 Dr. Ignacio Chapela and Contamination of Corn Fields

Environmental concerns were investigated by Ignacio Chapela on indigenous corn varieties in Mexico which were contaminated through cross pollination with GM varieties. Although the Mexican government had a ban against GM corn to prevent this possibility, US corn imported for food had been planted nonetheless. This work published results regarding the flow of transgenes into wild Mexican maize[26].

Controversy over the accuracy of the claims and methodological concerns about the paper led to an editor's note saying there was insufficient evidence to justify the original publication. However, a more recent study published in the February 2009 issue of Molecular Ecology confirmed the presence of transgenic DNA in Mexican maize[27]. This study however did not confirm that the transgene-contaminated corn had replicated.

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[24] Paganelli et al. (2010), "Glyphosate-Based Herbicides Produce Teratogenic Effects on Vertebrates by Impairing Retinoic Acid Signalling" Chem. Res. Toxicol., 23, 1586–1595.

[25] Benítez-Leite, S., Macchi, M. A., and Acosta, M. (2009) Malformaciones Congenitas asociadas a agrotoxicos. Arch. Pediatr. Urug. 80, 237–247

[26] Quist, David; Ignacio Chapela. 2001. "Transgenic DNA introgressed into traditional maize landraces in Oaxaca, Mexico". Nature 414 (6863): 541–543

[27] Pineyro-Nelson A. et al 2009. "Transgenes in Mexican maize: molecular evidence and methodological considerations for GMO detection in landrace populations". Molecular Ecology 18(4): 750–761

### 4.6 Additional Toxicological Studies

In a study in which intestinal and peripheral immune responses were investigated for the GM maize MON 810 in mice, it was observed that in comparison to the controls, MON810 maize induced alterations in the percentage of T and B cells and of CD4(+), CD8(+), gamma-deltaT, and alpha-betaT subpopulations of weaning and old mice fed for 30 or 90 days, respectively, at the gut and peripheral sites (Finamore et al., 2008). Also, observed was an increase of serum IL-6, IL-13, IL-12p70, and MIP-1beta. These results suggest that age of the consumer of the GM product, and gut and peripheral immune response to the GM crop should be considered in the safety evaluation of GMOs.

In spite of assurance that GM products currently on the market have all gone through safety assessment, and that there are no indications of any risks to human health, it is worth noting that prior to 2006, the literature on toxicological studies on GMOs or safety assessment studies of GM products was very scanty (see Domingo, 2007). Even though the number of studies (mainly on GM maize and soybeans) suggest that GM products are as safe and as nutritious as their non-GM counterparts (Domingo and Giné Bordonaba, 2011), serious concerns continue to be raised regarding safety of GM products. Diverse groups including consumer and environmental Non-Governmental Organizations (NGO) have **suggested that all GM plants or products should be subjected to long-term animal feeding studies before approval for human consumption** (Domingo and Giné Bordonaba, 2011).

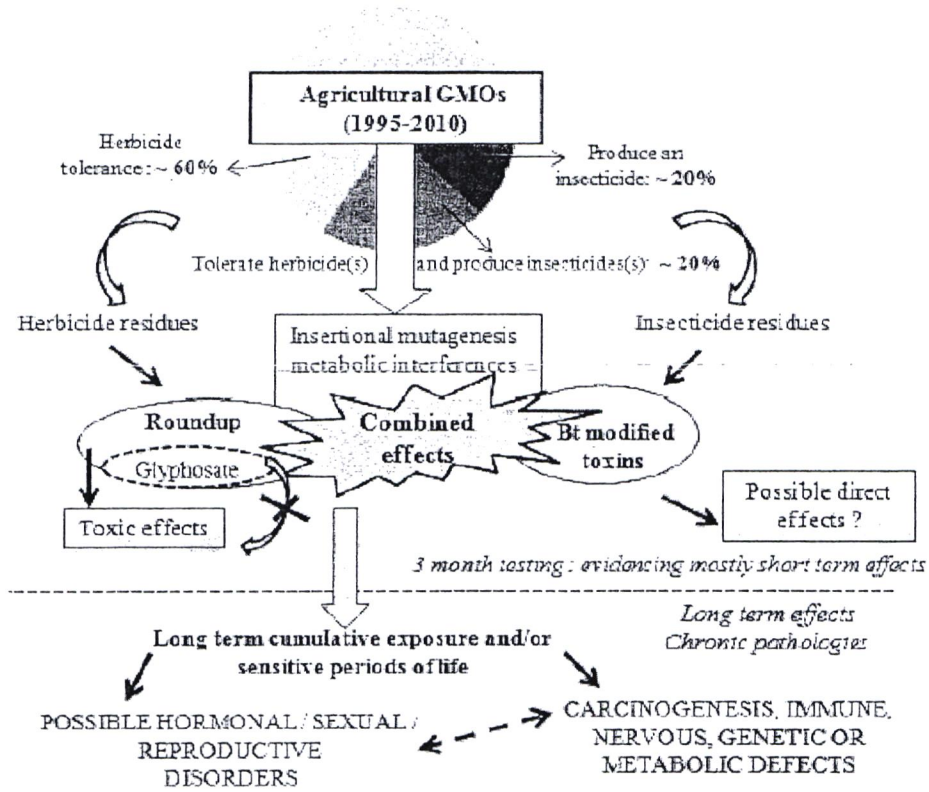
Although long-term lab animals feeding trials have been dismissed as not having value in safety assessment of GM products (EFSA, 2009), the recent study of Séralini et al., (2012), in which the long-term health effects of the Roundup-tolerant GM maize, NK603 were investigated in lab rats feeding trials over a 2 year period point to the value of long term toxicity studies. Further concerns are being raised about the herbicide Roundup and the chemical on which it is based, glyphosate, in view of the fact it has been shown to cause birth defects in frog and chicken embryos at dilutions much lower than those used in agricultural and garden spraying (see review by Antoniou et al., 2011). A recent study in which glyphosate and the Bt toxin Cry1Ab present in insect-tolerant GM crops, was detected in human serum is even more worrying (Aris and Leblanc, 2011).

#### 4.6.1 Claire Robinson (2013) review

A review by Robinson C. (2013) lists 19 animal feeding studies on GM maize and soy that revealed signs of toxicity; 5 additional studies on insect-resistant crops showing potential for harm in animal feeding trials; two further studies on herbicide-tolerant crops with adverse physiological effects – one such study being a multi-generational study in rats; and concludes:

> *"The evidence supports the American Academy of Environmental Medicine's (AAEM) statement on GM foods, which notes that they have not been properly tested for human consumption but that animal studies offer "ample evidence of probable harm". The AAEM recommends that physicians prescribe non-GM diets to patients."*
>
> - *Claire Robinson (2013)*

**Figure 4.1 Proposed modes of actions of agricultural GMOs and/or associated pesticides on health. (de Vendômois et al 2010)**




Almost all GMOs disseminated in the environment are plants, namely soy, maize, cotton, and oilseed rape (1995-2010). Their genetic and phenotypic modifications are herbicide tolerance and / or insecticide production (modified Bt toxins) in more than 99% cases. Thus they can be described as pesticidal plants. Consequently, two major health risks are described:

(1) due to mid or long term side effects, brought by new pesticide residues in food or feed, and directly due to the new genetic characteristic. The residues from herbicide(s) can be absorbed by tolerant plants.

(2) Insertional mutagenesis linked to the genetic modification, or post-genomic metabolic interferences or derivations. These are direct or indirect less specific effects independent from the toxicology assessment of the transgene product.

These unexpected possible consequences cannot be approached by gross substantial equivalence studies without metabolomic analyses. They can be invisible on the plant phenotype, but still able to induce long term toxicity after consumption, specific to each

genetic transformation (Fig 4.1). The possible combined effects between all these impacts cannot be excluded, inducing chronic pathologies after regular consumption.

### 4.6.2 Compositional Differences In Soybeans On The Market: Glyphosate Accumulates In Round Up Ready GM Soybeans; T. Bohn, M. Cuhra, T. Traavak, M. Sanden, J. Fagan, R. Primicerio

This work involved analysis of Roundup ready GM soybean, conventional non-GM soybean grown using usual agricultural chemical and organic soybean all from Iowa, USA. The Authors concluded that:

- Organic soybean had the healthiest nutritional profile i.e. had the more sugar content, more zinc and total protein and less fibre than both conventionally grown non-GM soy and GM- soy
- Organic soybean also contained less total saturated fat and omega-6 fatty acids than the other two soybeans
- GM-soy contained high residues of Glyphosate and AMPA (aminomethyl sulphoponic acid which is the major degradation product of glyphosate). But conventionally grow non-GM soy and organic soy did not have any of these residues.
- When the authors compared the three types of soy using 35 nutritional and chemical variables, they were able to differentiate each of these three types of soybean.

The authors therefore concluded that there was "**substantial non-equivalence**" in the compositional characteristics for 'ready-to-market' soybeans. This work calls to question the use of substantial equivalence between GM and non-GM products as a starting point in assessing GM product safety by the various regulatory agents at both the national and international levels.

### 4.6.3 Rat feeding studies with genetically modified maize - a comparative evaluation of applied methods and risk assessment standards. Harmut Meyer and Angelica Hilbeck (published by Springer)

The authors stated that a 2-year study with GM NK603 maize (the Seralini study) sparked an international scientific and public debate as well as policy responses by the European Commission. Following which "... *European Food Safety Authority (EFSA) evaluated the study as defective based on conceptual and methodological short comings by retrograde application of the recommendations, including a 90-day feeding study.*" The authors compared the rat feeding Monsanto studies that had shown that their NK603 GM-maize was safe and those of Seralini, which indicated opposite results. The authors concluded that their own "comparative analysis of the three relevant publications, including a 90 day feeding study of Monsanto, showed that all of them satisfy or fail to satisfy the EFSA evaluation criteria to a comparable extent; the rejection of only one of the papers (Seralini's) was, therefore, in the authors' opinion, "**not scientifically justified**". The authors further state that "We also show that EFSA's criteria are not standard practice in 21 other rat feeding studies

lasting a minimum of 12 months." These authors further claimed that their own review revealed "critical double standards in the evaluation of feeding studies submitted as proof of safety for regulatory approval to EFSA". The authors also argue that **"the current approach to declare statistically significant differences between genetically modified organisms and its parents as 'biologically irrelevant' based on additional reference controls lacks scientific rigor and legal justification in the European Union (EU) system**. Only recently, the EU authorities started building up an implementing system based on its own legislation and supportive of the approach to risk assessment in the context of technology assessment. They authors concluded in their abstract by saying that **"until these issues are resolved, we do not expect that neither the public nor the scientific debate will subside."**

These authors show the lack of universally acceptable scientific safety testing systems for food such as the ones that apply for medicines and medical products.

### 4.6.4 A long-term toxicological study on pigs fed a combined genetically modified (GM) soy and GM maize; Judy A Carman, Howard R. Vliger, Larry J. Ver Steeg, Verlyn E. Sneller, Garth W, Robinson, Catherine A. Clinch-Jones, Julie I. Haynes, John W. Edwards

These authors stated that they fed 84 pigs (42 males and 42 females) out of 168 weaned at the same age (isowean) on mixed GM maize and GM soy diet and the other 84 (42 males and 42 females) on an equivalent non- GM diet (containing both double and triple stacked events) for 22.7 weeks which is regarded, according to these authors, to be the normal life-span of a commercial pig from weaning to slaughter. For each of these pigs, the authors then measures:

- Food intake
- Weight gain
- Mortality
- Blood biochemistry

The authors found the following:

- GM fed pigs on gm uterus weight was 25% higher than that of the non-gm fed pigs.
- GM fed pigs had a higher rate (32%) of severe stomach inflammation that non-gm fed ones (12% at p=0.004)
- The severe stomach inflammation was worse in GM-fed males than in non-GM fed males by a factor of 4.0 (p=0.041)
- The severe stomach inflammation was worse in GM fed females than in non-GM fed females by a factor of 2.2 (p=0.034)

The authors found an association between GM fed pigs and the non-GM fed pigs with respect to the above results. This study should be repeated.

### 4.6.5 The recent banning and unbanning of glyphosate use in rice fields by the president of Sri Lanka; Posted on the internet in May 13 2014 - 11:26pm by Sustainable Pulse

Sri Lanka in March this year banned the sale of Monsanto's "Round Up" glyphosate weedicide after a study found that the weedicide is responsible for the increasing number of chronic kidney disease patients. But recently the Sri Lanka's Department of Agriculture announced that it has officially lifted the ban on glyphosate with the Registrar of Pesticides because no justifiable reason has been found to impose the ban **Source:** www.colombopage.com.

According to this source, "The decision to ban the weedicide sale was based on a directive of the President Mahinda Rajapaksa, who appointed a committee to look into the chronic kidney disease of unknown etiology (CKDu).

The research study conducted by Dr. Channa Jayasumana of the Rajarata University found that while the weedicide itself is not nephrotoxic, when it combines with hard ground water containing metals such as cadmium and arsenic, either naturally present in the soil or added through fertilizer, glyphosate becomes extremely toxic to the kidney.

However, since then the validity of Dr. Jayasumana's research had come under question as the manufacturer Monsanto and other agrochemical producers have raised objections to the findings saying that there is no evidence to suggest the conclusion that glyphosate is responsible for CKDu."

The source also claims that,

"A European glyphosate task force also has concluded that there is no true link to the kidney disease."

The source further goes on to state that the following:-

- **"GM Watch comment**: As for the "European glyphosate task force" mentioned in the article, which has "concluded that there is no true link" between glyphosate herbicide and chronic kidney disease, let's hope the Sri Lankan government recognises that this "task force" is entirely made up of the pesticide companies that make and sell glyphosate herbicide!"
- Starting in the mid-1990s, CKDu was discovered among the rice paddy farmers in the North Central Province (NCP) of Sri Lanka and over the years since then, the disease spread rapidly to the other farming areas of the country, especially in North Central, North Western, Uva and Eastern Provinces.
- A World Health Organization (WHO) reports estimated 15 percent of the population in North Central and Uva Province, about 60 000 people, had CKDu, and that 22,000 had died in the past 20 years in Anuradhapura alone from it.
- The Agriculture Department, while noting that they have not found conclusive evidence which relates the kidney disease to pesticides in general, say that a glyphosate ban will affect the tea plantations and also the paddy cultivation drastically

as it is the only effective weedicide for paddy and other commercial crops like, tea, coconut and rubber.

- The Department however, cautioned that any pesticide/weedicide use has adverse effects on health and advised the farmers to use them in a controlled manner, according to a report in *Ceylon Today*.
- Special officers will be deployed at Provincial Council levels to monitor and train farmers on the proper usage of glyphosate, the Department said.

### 4.7 Conclusion

In spite of the assurance that GM products are safe and do not cause harm to human health, convincing evidence is lacking. The 90-day lab rodents feeding test used in safety assessment of GM products is too short to assure food/feed safety, as this will only reveal the potential for acute or sub-acute harm. Therefore long-term, multi-generational lab animal studies might be more appropriate for food safety assessment.

90-days in a rat are equivalent to 7 to 8 years of age in a child. This is therefore an insufficient time frame for assessing the impact of food that could, in the case of maize, be consumed three times daily for an individual's lifetime. There is no data on the impact of reproductive ability, transgenerational effects or life-long impact of the consumption of the GM food.

## 5.0 THE INFRASTRUCTURAL CAPACITY TO HANDLE AND MONITOR GM PRODUCTS IN KENYA

### 5.1 The Legal Framework and Systems for Biotechnology on GM Foods in Kenya

The Government of Kenya (GOK) has begun to put in place control measures to assure and ensure that all GM activities or products approved in Kenya are safe. In 2006, the Cabinet approved the National Biotechnology Development Policy; in 2008, Parliament passed the Biosafety Bill, which then became law in 2009 – the Biosafety Act No 2 of 2009. The GOK has developed various regulations to implement the Biosafety Act No 2 of 2009. These include regulations on import, export and transit; the environmental release; contained use; and labelling.

### 5.2 Institutional Capacities to Handle and Regulate GMOs

### 5.3 The role of the National Biosafety Authority

The National Biosafety Authority (NBA) was created by an Act of Parliament, the Biosafety Act of 2009, to exercise general supervision and control over development, transfer, handling and use of genetically modified organisms (GMOs) so as to ensure safety of human and animal health and provide adequate protection of the environment as stipulated by the Kenyan law and under the Cartagena protocol on Biosafety. Any research on GM products in any institution within the country has to be approved by the National Biosafety Authority (NBA), the institution that has been mandated by law (Biosafety Act, 2009) to supervise and control transfer, handling and use of genetically modified organisms (GMOs). **The National Biosafety Authority (NBA) is in the process of reviewing Biosafety Act to align it with the Constitution and expand its mandate to include bio-security and other emerging issues in Biotechnology /Biosafety.**

The roles of the NBA are stipulated in the Biosafety Act No 2 of 2009 and include receiving, reviewing and making decisions on applications to introduce/develop biotechnology products for research or commercial purposes into the country. The NBA works in collaboration with the following regulatory agencies:

- Department of Public Health
- Department of Veterinary Services (DVS)
- Kenya Bureau of Standards (KEBS)
- Kenya Plant Health Inspectorate Services (KEPHIS)
- National Environment Management Authority (NEMA)
- Pest Control Products Board (PCPB)
- Kenya Wildlife Service (KWS)
- Kenya Industrial Property Institute (KIPI)

To enforce the Biosafety law, NBA collaborates with these regulatory agencies as specified in the Act, according to the mandate of each institution.

Department of Public Health: The Division of Food safety and Product Quality Control (Now called the Food Safety and Quality Control Unit) ensures safety of food meant for human consumption and protection of the consumer against foodborne diseases/illnesses.

Kenya Bureau of Standards (KEBS): Food and Agriculture Department is responsible for the development of standards covering food technologies, food safety, fertilizers, agricultural produce, livestock and livestock products, poultry and poultry products.

Kenya Plant Health Inspectorate Services (KEPHIS): provides surveillance of plant imports to ensure that ordinary plant permits are not used to import GMOs, monitors seed quality compliance to ensure unapproved genetic elements are not released to farmers, and to ascertain that varieties being released are tested for their genetic purity and conformance to biosafety guidelines, and also ensure that border surveillance is undertaken in collaboration with NBA.

National Environment Management Authority (NEMA): supervises and co-ordinates all matters relating to the environment, including rendering advice and technical support to entities engaged in natural resources management and environmental protection.

Department of Veterinary Service (DVS): mainly regulates animal GMOs in order to prevent introduction into the country of harmful foreign organisms, pests and diseases through adherence to strict quarantine regulations and procedures as well as through participation in institutional Biosafety Committees.

Pest Control Products Board (PCPB): The board regulates importation and exportation, manufacture, registration and use of pest control products.

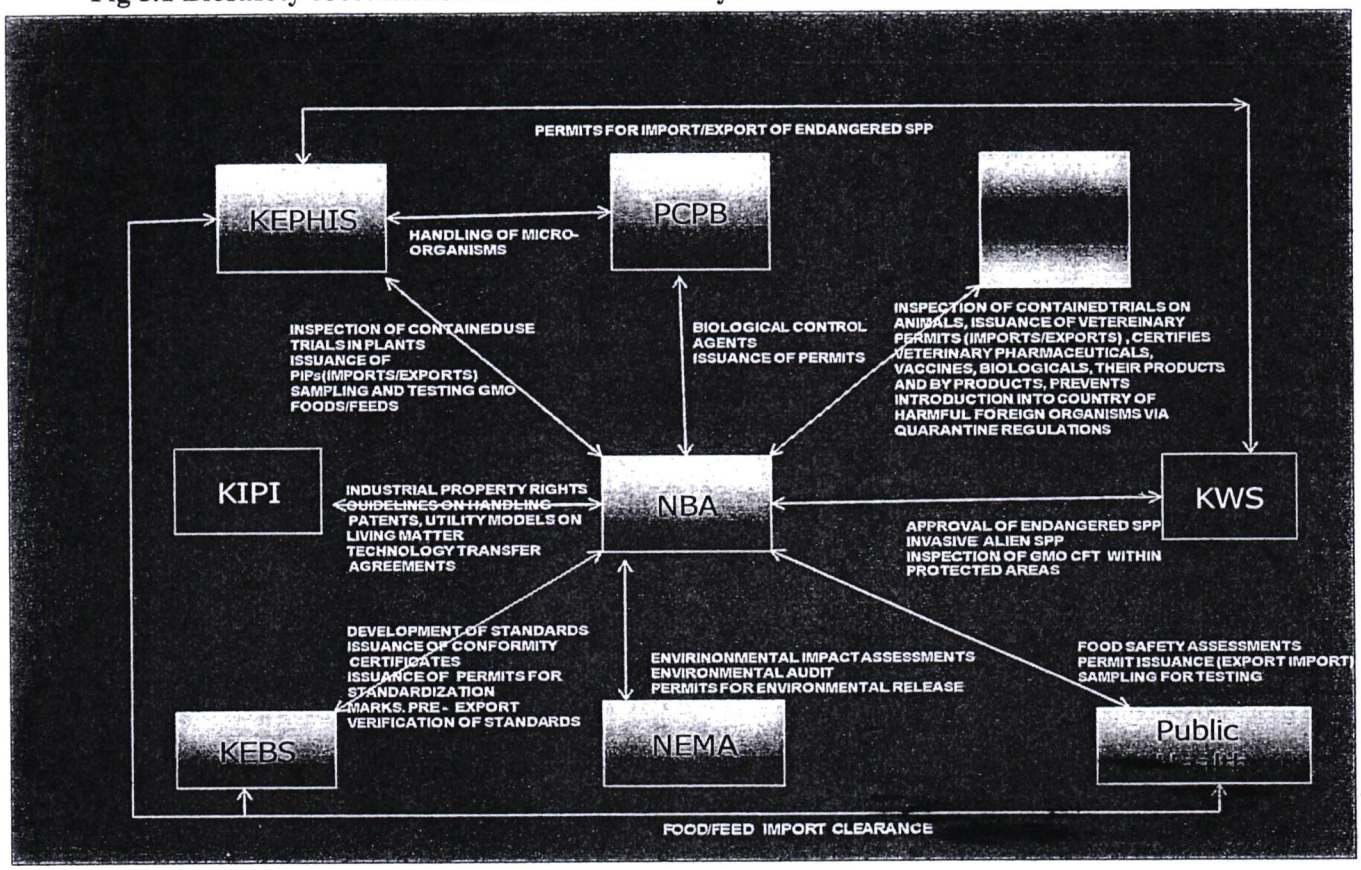
Kenya Wildlife Service (KWS): The Corporation focuses on biodiversity and biotechnology in wildlife and forestry related matters.

Kenya Industrial Property Institute (KIPI): The institute is responsible for addressing intellectual property issues arising from modern biotechnology.

## 5.4 Coordination of the Regulatory Agencies

Regulation of GMOs is undertaken by NBA pursuant to the recommendations of National Biotechnology Development Policy of 2006 and enactment Biosafety Act in 2009. NBA is the central coordinating and implementation body in regulating all aspects of modern biotechnology besides agricultural biotechnology (Figure 5.1). Depending on the type of GMO under consideration, Biosafety Act specifies the roles of the regulatory agencies which include: monitoring of approved projects for compliance; informing the Authority of any significant new scientific information or any unintentional or unapproved introduction of a GMO into the environment.

**Fig 5.1 Biosafety coordination framework in Kenya**




Key to Fig 5.1:
GMO CFT refers to genetically modified organisms in controlled field trials
Endangered and Alien spp refers to endangered and alien species

### 5.5 Institutional Research on GMOs in Kenya

To date, 16 laboratory/greenhouse applications and 9 confined field trials have been approved and are at different stages of implementation (refer to Annexes II & III respectively)

A number of National research institutions and Universities have embraced GMO research.

**It is important to recognise that:**

**Kenya Agricultural Research Institute** (KARI) is a lead player with highly trained personnel; molecular biology and biosafety level II laboratories; and transformation and field trial facilities. KARI research focus includes cassava, sweet potatoes, sorghum, maize and cotton. The KARI program has research at the laboratory, greenhouse and confined field trial stages.

The **Plant Transformation Laboratory** (PTL) at Kenyatta University (KU) is the only Biosafety Level II laboratory in East and Central Africa in a public University. Research at PTL focuses on food crops such as maize, sorghum, cassava, rice, sweet potato, groundnut and pigeon pea. Most of the work at KU is at the laboratory and greenhouse stage.

Other national institutions are also involved in GMO related activities as shown Table 5.1. Based on the criteria of institutional capability for GMO screening within the Southern African Network of GM detection Laboratories, Kenyan laboratories are ranked as shown in Table 5.2.

### 5.6 Institutional Biosafety Committee (IBCs)

Institutions with the intention of engaging in the purchase, construction, propagation or field release of GMOs or components must establish an Institutional Biosafety Committee (IBC) to serve as the administrative board on matters of biosafety. The composition and functions of IBC are stipulated in Regulations Reg. 6(1)-(5) of the Biosafety Contained-Use regulations (2011). For the IBC to be granted freedom to exercise the full extent of its powers in undertaking all of its functions and responsibilities, the parent institutions must appoint appropriate and qualified individuals to the IBC and be prepared to support the needs and demands of the committee. In addition to the IBC, institutions particularly those engaged in industrial-grade or other large-scale work, are encouraged to recruit a Biosafety Officer (BSO) to work in conjunction with various biosafety committees. For an IBC to be registered with NBA, the parent institution must submit for review a completed notification form, detailing the academic and professional history, discipline and qualifications attained by each member appointed and also detailing relevant operations within the institution. NBA specifically requests for the following information in reference to genetic manipulation field work:

- IBC membership (indicate Chairperson, Secretary and organizational structure);
- A designated Biosafety Officer, where applicable;
- An exhaustive list of current field work projects supported by the institution (specifications of the experimental organism field tested and detail results of risk assessment); and
- **A catalogue of the contingencies and occupational hazards affecting the health of personnel, the community or the environment - reasonably and directly attributed to genetic manipulation practices - throughout the time of establishment.**

There are four Institutional Biosafety Committees in place, two in national institutes of higher learning (Kenyatta University and University of Nairobi), one in a national research institute (Kenya Agricultural Research Institute) and one in an international research organisation (International Livestock Research Institute).

## Table 5.1 National Institutional capacity for handling GMOs in Kenya

| Institution | Mandate | Capacity | Handling GMO |
|---|---|---|---|
| **A) Research and training** | | | |
| **KARI - Kenya Agricultural Research Institute)** Focus crops: maize, cotton, sorghum, cassava, sweet potatoes | Research, Outreach | Personnel, molecular labs, Transformation facilities,<br>• Biosafety Level II Laboratory<br>• Biosafety Level II Greenhouses<br>• Confined field trial facilities in several sites<br>• Institutional Biosafety Committee in place | Yes |
| **KU – Kenyatta University**<br>Plant transformation laboratory.<br>Focus crops: maize, sweet potato, sorghum, cassava, rice, groundnut, pigeon pea | Research, Training | Personnel, Transformation facilities, molecular labs, greenhouse evaluation<br>• Biosafety Level II laboratory<br>• Biosafety Level II Greenhouses<br>• Institutional Biosafety Committee in place<br>Train ICGEB fellows on GM related research | Yes |
| ILRI - International Livestock Research Institute Focus crops: cassava, potato, yam, banana, sweet potato, pigeon pea (among others). A comprehensive list of approved contained research at ILIRI is listed in the appendix | Research, Training | Personnel, Transformation, molecular labs, greenhouse evaluation | Yes |
| MMUST – Masinde Muliro University of Science and Technology | Research, Training | Personnel, Molecular labs, greenhouse evaluation | Beginning |
| UoN – University of Nairobi | Research, Training | Personnel, Molecular labs | No |
| JKUAT – Jomo Kenyatta University of Agriculture and Technology | Research, Training | Personnel, Molecular labs | No |
| KEMRI - Kenya Medical Research Institute | Research | Personnel, Molecular labs | No |
| Moi University | Research, Training | Personnel, Molecular labs | No |
| University of Eldoret | Research, Training | Personnel, Molecular labs | No |
| **B) Regulatory** | | | |
| NBA – National Biosafety Authority | Regulatory | Personnel, Coordination, monitoring and surveillance | Yes |
| **Department of Public Health – Food Safety and Quality Control** | **Regulatory, Safety** | Personnel, monitoring, surveillance, coordination | Yes |
| KEPHIS – Kenya Plant Health Inspectorate Services | Regulatory, Service | Personnel, Molecular labs | Yes |
| NEMA – National Environment Management Authority | Regulatory | Monitoring | No |
| KEBS – Kenya Bureau of Standards | Regulatory | Standards, developing a molecular lab | Yes |
| KENAS – Kenya Accreditation Service | Regulatory | Personnel, molecular labs, standards | No |
| **C) Policy and awareness creation** | | | |
| NACOSTI –National Commission of Science, Technology and Innovation | | Policy | |
| KNAS – Kenya National Academy of Sciences | | Independent, unstructured reviews | |
| Ministry of Education Science and Technology | | Policy, legal and regulatory framework | |

Table 5.2 Self-Reported Institutional capacity for GMO screening within local Institutions of GM detection Laboratories

| No | Name of Institution | Status of Laboratory* | | | |
|---|---|---|---|---|---|
| | | Functional level of laboratory | Equipment | Quality management documents | Expertise of personnel |
| 1 | MMUST – Masinde Muliro University of Science and Technology | 2 | 1 | 1 | 2 |
| 2 | UoN – University of Nairobi-Kabete Campus | 2 | 2 | 1 | 1 |
| 3 | UoN – University of Nairobi-Chiromo Campus | 1 | 1 | 1 | 1 |
| 4 | KARI - Kenya Agricultural Research Institute-Biotechnology Center | 1 | 1 | 1 | 1 |
| 5 | KU – Kenyatta University | 1 | 1 | 1 | 1 |
| 6 | JKUAT – Jomo Kenyatta University of Agriculture and Technology | 1 | 3 | 2 | 1 |
| 7 | KEMRI - Kenya Medical Research Institute | 1 | 1 | 1 | 1 |
| 8 | Moi University** | 5 | 5 | 5 | 5 |
| 9 | University of Eldoret | 2 | 2 | 1 | 1 |
| 10 | KEPHIS – Kenya Plant Health Inspectorate Services | 1 | 1 | 1 | 1 |
| 11 | NEMA – National Environment Management Authority | 5 | 5 | 5 | 5 |
| 12 | KEBS – Kenya Bureau of Standards | 1 | 1 | 1 | 1 |
| 13 | NBA - National Biosafety Authority | 5 | 4 | 1 | 3 |

* See Table 5.3 is the Key

** Moi University is in the process of establishing a state of the art biotechnology facility

**Table 5.3 Laboratory status for GMO detection/ screening – A key to Table 5.2[28]**

| | FUNCTIONAL LEVEL OF LABORATORY | EQUIPMENT | QUALITY MANAGEMENT DOCUMENTS | EXPERTISE OF PERSONNEL |
|---|---|---|---|---|
| 1 | Laboratory can perform PCR-based GMO detection/ screening **AND** Real-time PCR GMO quantification | • Real-Time PCR<br>• PCR System<br>• Gel electrophoresis<br>• Gel documentation system<br>• Optional: ELISA Plate reader | • Quality system that includes<br>• Quality Manual,<br>• Safety manual and Standard operating procedures | Personnel are trained in PCR based GMO detection/ screening and GMO quantification |
| 2 | Laboratory can perform PCR-based GMO detection/ screening | • PCR System<br>• Gel electrophoresis<br>• Gel documentation system<br>• Optional: ELISA Plate reader | GMO detection/ screening is performed according validated methods | Personnel are trained in PCR based GMO detection/ screening |
| 3 | Laboratory can use strip and/or ELISA based testing to detect GMOs | • PCR System or ELISA Plate reader | Methods not validated | Personnel are trained in strip/ELISA testing |
| 4 | Laboratory not able to apply any form of GMO testing | • No specialized equipment | No methods | Personnel have no training |
| 5 | Without laboratories | Source services from accredited laboratories | | |

[28] Taken from SANGL http://gmo-crl.jrc.ec.europa.eu/capacitybuilding/docsworkshops/SouthAfrica-Feb-2012/2012-02-07%20SANGL%20update.pdf

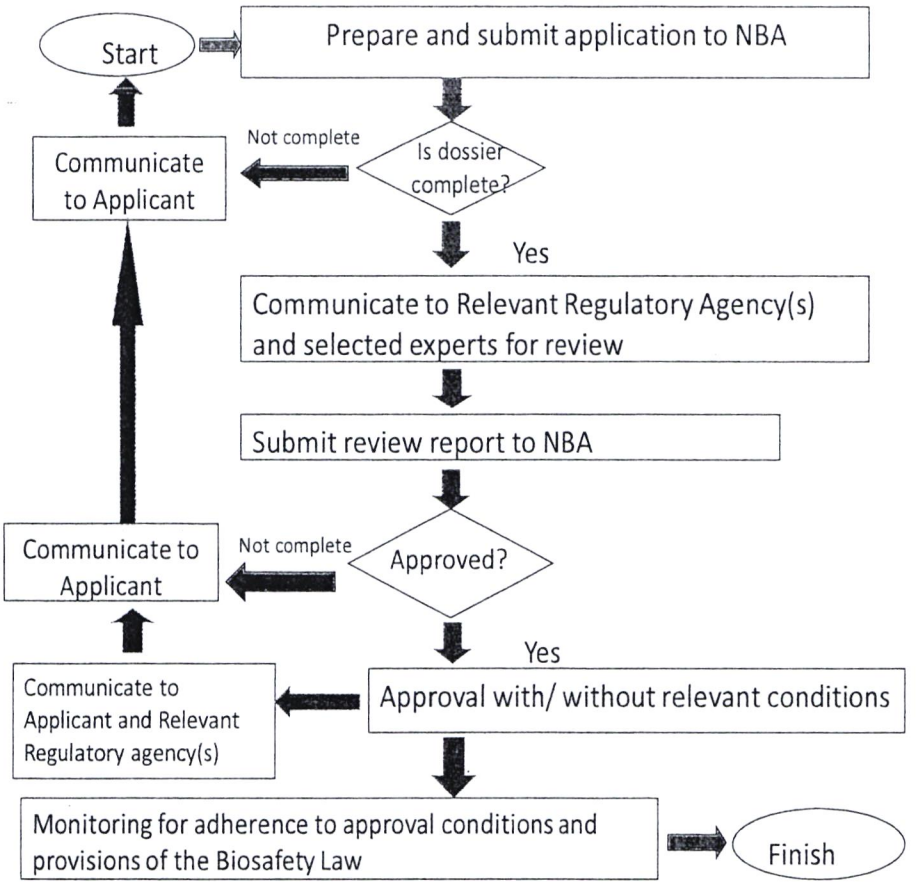
## 5.7 Accreditation of laboratories

The Kenya Accreditation Service (KENAS) is the body established by the government to ensure competence of laboratories. KENAS would then be able to accredit laboratories and personnel that handle GMOs.

## 5.8 Approval Procedures for Import of GM Foods by the Relevant Regulatory Agencies

Any GM food that is imported in to the country must first be given approval by NBA, as outlined in Figure 5.2.

**Figure 5.2 The Approval Procedure for GM crops in Kenya**



Applications for the introduction of GM foods intended for placement in the market or for environmental release are made to the NBA via relevant research institutions' biosafety committee (IBC) or by independent applicants. The NBA then assesses the application on the basis of the National Guidelines for the Release of Genetically Modified Organisms in to the Environment, as stipulated in the Biosafety Act. Approvals are based on a risk assessment process anchored on guidelines outlined by the Codex Alimentarius Commission (CAC) and the Organization for Economic Development and Corporation (OECD), as outlined in Fig. 5.2, above.

The NBA has established functional offices at points of entry and exit in Mombasa, JKIA, Namanga and Busia to monitor any movement of GM products. The officers at those points review import documents to ascertain whether they contain unapproved GMOs. They then enter the vessel and take a representative sample for GMO analysis. There are 2 methods that are currently used:

1. First is the rapid lateral-strip test based on ELISA to determine whether a given promoter and terminator is present. This is done in the points of entry.

2. Second is a quantitative detection method, whereby a sample is sent to Nairobi for qualitative and quantitative PCR based detection methods for GM, using NBA-approved laboratories.

The PCR method is the conclusive test which determines the GM status of the product so as to enable NBA to make a decision whether to release or destroy a consignment.

## 5.9 Adequacy of Qualified Human Resource Capacity to Monitor Research, Use and Review Importation of GM Foods into Kenya

In terms of human capacity, the NBA has yet to attain a critical mass of trained personnel for carrying out the its mandate including testing of GM products. The technical team lead by the CEO (a scientist with extensive experience in Biosafety), includes two PhD holders, ten officers with Masters of Science degrees in disciplines such as Ecology, Molecular Biology, Immunology, Molecular parasitology and Proteomics. The establishment at the NBA has a total of 77 available positions of which more than 50% have been filled. Out the 77 available positions, 21 are for biosafety officers, but only 50% of these are filled at present.

It is to be noted that since independent animal feeding food safety tests are not required under the present NBA regulations, NBA does not have such a capacity. However, there are laboratories and personnel in Kenyan universities, research institutions and other collaborating facilities who have the expertise and experience to carry out such tests should these tests be made mandatory.

## 5.10 Conclusion

Looking at the current situation, the country has some capacity to handle and monitor GM food imports. There are mechanisms in place for GM detection by the regulatory authorities, and institutions exist with varying levels of capability to handle GMOs. However, safety testing for human consumption has not been provided for in the regulations outlining the mandate of the NBA, nor within the approval procedures for the import of GM foods. Neither are there mechanism in place to assess the safety of GM foods and their products for human consumption.

Any chemical substances supposed to be taken by humans have to be cleared for safety by the Pharmacy and Poisons Board. The majority of the GM crops approved for commercial release worldwide contain traces of certain chemicals which they either produce or absorb. These chemical such as herbicides (glyphosate) and the different Bt toxins, have not yet been approved for human consumption by the Pharmacies and Poisons Board. Therefore the maximum toxicity levels of these chemicals in food destined for human use have not been established.

## 6.0 AN ANALYSIS ON FOOD SECURITY IN KENYA

### 6.1 What is food security?

Food security is defined as, "when all people, at all times, have physical and economic access to sufficient, safe and nutritious food to meet their dietary needs and food preferences for an active and healthy life" (FAO, 2010). It encompasses four main components namely **availability, accessibility, stability and utilization** (Ziervogel and Ericksen, 2010):

a) Food availability depends on production, storage, exchange of food or availability of social protection measures and transport infrastructure (Ericksen, 2008).
b) Accessibility refers to the affordability and allocation mechanisms (Ziervogel and Ericksen, 2010). It derives from the entitlements a household has to food, either through own-production of foodstuffs or through adequate purchasing power.
c) Food stability involves the guaranteed, sustained availability and access to food in the face of adverse climate or socioeconomic conditions (Devereux et al., 2004).
d) Food utilization refers to appropriate food use depending on personal needs (e.g. age and health) (Pelletier, 2002).

Food security is therefore dependent on farm production factors (land and capital assets, research, and extension), and non-farm factors including infrastructure and factors enhancing the purchasing power of the household.

Globally, around 900 million people are undernourished, meaning that they are under supplied with calories (FAO, 2012). Eradicating hunger is a central part of the United Nations' Millennium Development Goals (MDGs) (United Nations, 2012). But to achieve this MDG is still a major challenge for many developing countries especially in Sub-Saharan Africa. The challenge is to meet the rising food demand and changing food preferences in an efficient, environmentally, socially and economically sustainable manner.

It is estimated that food demand will grow by 50% by 2030 and 70% by 2050 (FAO, 2009). Economic drivers such as trade, land tenure, food markets and their volatility, supply and distribution, regulation, affordability and accessibility (particularly in the developing world) with associated globalization also affect the dynamics of global food security. Use of food commodities for biofuel production and other non-food industrial uses, coupled with falling yields of most food crops pose a great threat to food security.

To address food security concerns pro-poor programmes and safety nets are crucial for alleviating food insecurity in the short term, as well as for providing a foundation for long-term development. Investment in agriculture is critical to sustainable long-term food security. Irrigation, improved husbandry practices and quality inputs can reduce the production risks facing farmers, and reduce price volatility.

Notwithstanding the above, many arid (e.g. Israel) and semi-arid (e.g. South Africa) have shown that the constraints mentioned above can be surmounted. Outside Africa, some East

Asian countries, such as South Korea, Bangladesh, China and Japan, have shown that the same land can be tilled for thousands of years and still sustain large population densities. Some of these countries were able to overcome frequent famines by using sustainable agricultural practice and by educating their farmers on improved methods of food production and storage as well as addressing the other constraints listed above. Some of these countries achieved this in less than 25 years (such as South Korea).

### 6.2 Major Causes of Food Insecurity in Kenya

The major causes of food insecurity in Kenya are not peculiar to Kenya or sub-Saharan Africa alone. They are the causes found in any nation anywhere in the world, which is experiencing transformation from an agrarian (subsistent) economy to an industrial economy. These causes are:

#### i) Low Productivity

Kenyan agriculture sector is characterized by low crops and livestock yields. For example, despite extensive research, the national average maize yield has stagnated at about 19 bags per Ha for over 10 years while average milk yield per cow per day has been less than 10 litres compared to the national potential of 20 litres of milk per cow per day.

The low crops and livestock yields are attributed to inadequate access to affordable credit, low investment in farming, low inputs use, low adoption of modern technology, low levels of farm mechanization, inadequate extension coverage, poor management of endemic livestock diseases and tropical crops pests and diseases, among others.

#### ii) Post-harvest losses

There has been dominance of primary food production with little post-harvest management interventions in Kenya leading to high losses estimated at 21% in cereals, 11% of fruits and 8% of vegetables. These levels of losses are huge particularly for maize which is the staple food crop and has serious implications on the food security status. The pronounced post-harvest crop losses coupled with the low level of processing also translate into reduced incomes for farmers and less job opportunities for Kenyans.

#### iii) Over-reliance on rain fed agriculture

Most of the crop and pastoral systems in Kenya are heavily reliant on rainfall as the sole source of water. Seasonal rainfall variability leads to unpredictable production levels of food.

#### iv) Climate change

There has been increased occurrence of climate change-related challenges, such as frequent droughts, floods, frostbites, pest infestation (e.g. army worms, locusts, bollworms) and disease outbreaks, leading to serious food insecurity.

#### v) Increasing food prices

According to Kenya National Bureau of Statistics (KNBS) the Consumer Price Index (CPI) increased by over 19% from January 2010 to December 2011. This is also confirmed by 2011 World Bank report indicating prices of basic commodities in Kenya (flour, oil, sugar and wheat products) increased by 50 per cent in the last half of 2011. The main reasons for high food prices include poor food distribution mechanisms, unstructured markets, increasing cost of fuel, overdependence on few food commodities, and poor post harvest management. Global shortage of cereals combined with deterioration of international terms of trade with the major producing countries also affected Kenya's national food situation since Kenya's key staples such as maize, wheat, rice and beans are among the most globally traded food commodities

**vi) Land tenure and land use for agriculture production**

Prior to 2009, Kenya did not have a single and clearly defined National Land Policy. This has resulted in a complex system of land ownership, management and administration rendering many people landless and with limited access to land for food production. Continued land subdivision into uneconomic units has restricted farm mechanization, land degradation and reduced land available for farming due to the demand for individual settlement.

Therefore as Kenya develops into an industrial nation it will no doubt have to follow the well-tried out methods for eliminating the above causes, becoming not only food sufficient but a net exporter of food.

### 6.3 Food Security Interventions

Causes of food insecurity in sub-Saharan Africa include low agricultural productivity coupled with policy, institutional and technological challenges, high seasonal and year-to-year variability which is often linked to insufficient water for crop and livestock production. The food security initiatives can be categorized under short, medium and long term categories.

Current government short term initiatives include:

- Waiver of duty on some grains, mainly maize and wheat, to boost imports in order to meet production gaps;
- Support to farmers that experience periodic shocks such as drought through provision of relief seeds and subsidized inputs;
- Increasing levels of Strategic Grain Reserve (SGR) from current stocks to at least 6 million bags.

As this initiative is being pursued, the SGR is also expected to expand and to include other foodstuffs like rice, sorghums, millets, beans, powdered milk, hay for animal feed and change name to Strategic Food Reserve (SFR).

The medium to long term government interventions:

**i) Irrigation Expansion Programmes**

Kenya has an estimated irrigation potential of **1.3 million** hectares which can be developed. Of the available irrigation potential, **540,000 ha** can be developed with the available surface water resources and another **760,000 ha** through development of water storage facilities and ground water exploitation. Currently **140,600 ha** of irrigation has been developed which can be categorized into three main types namely: Smallholder schemes **49,000ha** (43%); Public/National schemes **44,600ha**, (18%) and Private schemes **45,000ha**, (39%). The remaining potential of 1.16 Million hectares can effectively be tapped by increasing funding into irrigation development in the various categories.

H.E President Uhuru Kenyatta launched the Galana/ Kulalu Food Security Project on 9th January 2014. In this project **one million acres** will be irrigated in 5 years. A total of **500,000 acres** will be put under **maize**, **200,000 acres** under **sugarcane** and the remaining acreage will be put under horticulture, livestock and aquaculture. A model farm of 10,000 acres is already being prepared with an initial 3,000 acres. Once successfully completed, this project is expected to provide the country with all its maize needs and also with surplus maize for export.

**ii) Agricultural Mechanization**

Appropriate agricultural mechanization will enable Kenyan farmers to increase food production to such a level as to feed, not only themselves, but also the country's growing urban population. Unfortunately, in Kenya, the rate of adoption and utilization of agricultural mechanization is slow. The use of motorized power stands at 30%, hand and animal draught (ADP) is 50% and 20% respectively. For the country to achieve the intended transformation, the Government has to embark on a national mechanization strategy to promote access to agricultural machinery for agricultural production. The program includes the availing of machinery and equipment and financial arrangement (Revolving Fund) that facilitates access of the machinery to farmers.

**iii) Reduction of Post-harvest losses**

The grain drying and storage project was initiated in 2010/ 2011 by the then Ministry of Agriculture to support the Economic Stimulus Project (ESP). The aim of the project was to:

- maintain high quality of stored grain by minimizing grain quality deterioration (post-harvest losses due to aflatoxin contamination and pests);
- ensure sustained grain market value through procurement of mobile grain driers;
- construct grain drying and storage facilities
- construct community-based medium capacity stores holding up to 10,000 bags of grain.

In 2011/2012, 36 mobile grain driers were procured and distributed to districts according to grain production and reported past aflatoxin contamination incidences. Regarding the construction of storage and drying structures, the construction in 13 project areas of Kirinyaga (Kirinyaga Central), Embu (Mbeere North), Makueni (Makueni), Narok (Trans Mara West), Trans Nzoia (Trans Nzoia East), Uasin Gishu (Eldoret East and Eldoret West), Tharaka Nithi (Meru South and Mara), Meru (Buuri), Kakamega (Navakholo and Lugari) and Nandi (Nandi South) is ongoing.

**iv) Fertilizer and Seed Subsidies**

Use of fertilizer is crucial in increasing agricultural production and its use has been increasing in Kenya in the recent past. To hedge off fertilizer price fluctuations across seasons, the Government has intervened by introducing fertiliser subsidies. The Government has also set up a seed and fertilizer subsidy fund to ensure that these inputs are accessible to small scale farmers so as to help them to boost their agricultural productivity.

### 6.4 The Role of GMOs in Fighting Food Insecurity

GMOs could play a role in addressing major challenges that face farmers in food production, such as pests, drought, weeds, disease pathogens, and nutritional security. It is anticipated that GM crops or their products would be produced at a relatively low cost, would have an improved yield, improved survival or shelf life, and possibly, also, have a better nutritional value. Because of these characteristics, they are considered to be more profitable as commercial products than the traditional varieties as they promise reduced farm inputs and increased crop yield and farm income.

The acreage under GM crops and the number of countries adopting GM crops for commercial purposes have continued to increase since 1996, when GM crops were first commercialized, and many resource-limited countries have since adopted the technology. In the last 15 years, GM crop producing countries have benefited from adoption of this technology in the form of improved crop productivity, food security, and the income to farmers and the GM multinationals.

It was perceived that GM crops had the potential to provide solutions to hunger, malnutrition and food security problems that plagued limited-resource countries, particularly, those in the sub-Saharan Africa, where agricultural productivity tends to be low. It was believed that production of certain GM crops especially those designed to have pest resistance traits would result in substantial decrease in the use of chemicals for pest control. GM crops were claimed to have more advantages than traditional varieties: they promised greater yield, superior quality than traditional varieties, and increased farm income.

### 6.5 The Reality of Product Yield and Pesticide Use

According to some researchers (Benbrook 2009) GM crops may not have necessarily delivered on the promises claimed of increased yield and reduced pesticide use. Gurian-

Sherman (2009) has evaluated in detail, the overall, or aggregate, yield effect of GM crops after more than 20 years of research, and 13 years of commercialization in the United States. The three most common GM crops in the US insect tolerant corn (maize), herbicide tolerant maize, and herbicide tolerant soybeans have been grown in the US for more than a decade, and so, there is a wealth of data on yield under real-world conditions.

A close examination of numerous studies of corn and soybean crop yields since the early 1990s provides a good gauge of how well GM crops are living up to their promise for increasing those yields. GM soybeans have not increased yields, and GM maize has increased yield only marginally on a crop-wide basis.

According to Gurian-Sherman (2009), overall, maize and soybean yields have risen substantially over the last 15 years, but largely not as a result of the GM traits. Most of the gains are due to traditional breeding or improvement of other agricultural practices. Thus according to Gurian-Sherman (2009) GM crops, hailed by some as critically important for ensuring adequate food supply in the future, have so far produced only small increases in yields in the United States.

> *"GM crops have increased overall pesticide use by 318.4 million pounds over the first 13 years of commercial use, compared to the amount of pesticide likely to have been applied in the absence of HT and Bt seeds. The 318.4 million pound increase represents, on average, an additional 0.25 pound of pesticide active ingredient for every GM trait acre planted over the first 13 years of commercial use. Bt maize and cotton have delivered consistent reductions in insecticide use totalling 64.2 million pounds over the 13 years. Bt maize reduced insecticide use by 32.6 million pounds, or by about 0.1 pound per acre. Bt cotton reduced insecticide use by31.6 million pounds, or about 0.4 pounds per acre planted. HT crops have increased herbicide use by a total of 382.6 million pounds over 13 years. HT soybeans increased herbicide use by 351 pounds (about 0.55 pounds per acre), accounting for 92% of the total increase in herbicide use across the three HT crops."*
>
> - *Source: Benbrook C (2009)*

In some cases GM crops have created unexpected problems including the creation of herbicide-tolerant "super weeds", Bt resistant pests, disrupted ecosystems, compromised soil quality, reduced diversity (Benbrook 2009). Lu et al (2010) investigated long-term ecological effects associated with adoption of Bt cotton in northern China over a period of 10 years, and observed that the wide-scale adoption of this GM crop resulted in progressive increases in populations of mirid bugs (Heteroptera: Miridae), non-target pests, and these increases were related to a decline in insecticide use in this crop. Alterations of pest management regimes in Bt cotton may have been associated with the appearance and subsequent spread of these non-target pests. Similarly, the susceptibility of the pink bollworm (*Pectinophoragossypiella*),

which feeds almost entirely on cotton in China to Bt toxin Cry1Ac has significantly decreased in the Yangtze River Valley of China in recent years (Wan et al., 2012).

In a recent report[29] outlining the status of agriculture in 16 African countries, the Alliance for a Green Revolution in Africa (AGRA), stated:

*"GM crops are unlikely to impact Africa food security in the near future given low marginal yield gains over conventionally bred seeds."*

### 6.6 Conclusion

Both GM and non-GM crops have their own challenges. Their advantages or otherwise depend on whether you are dealing with large-scale highly mechanised food production or small scale poorly mechanised or subsistence farming. The food security challenges identified in this report require a multi-faceted and multi-sectoral approach. However in all instances, there are key areas that affect agricultural productivity in Kenya, namely:

- Water availability
- Soil fertility
- Disease control
- Harvesting
- Storage
- Transportation and
- Marketing

None of the GM food crops currently on the international market can answer the above key challenges facing the food insecurity problems in Kenya.

[29] Alliance for Green Revolution in Africa (AGRA) (2013). *Africa Agriculture Status Report: Focus on Staple Crops*

## 7.0 INVESTIGATING OTHERS ISSUES PERTINENT TO GM FOOD SAFETY

### 7.1 The GMOs Development and Commercialization in the United States of America

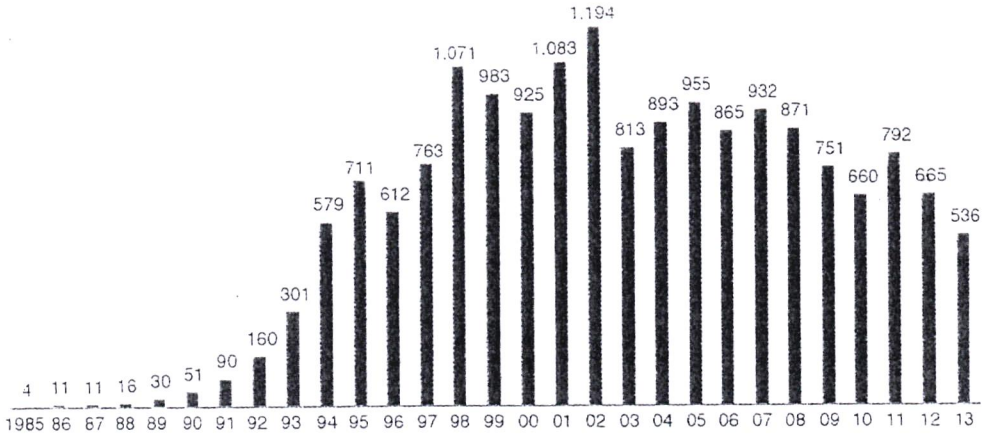
Genetic Modification also called Genetic Engineering is a key component of modern agricultural biotechnology. Commercial use of major genetically modified (GM) crops began in 1996. Genetically modified crop traits have been classified into one of three generations (Fernandez- Cornejo, 2004). The first generation features enhanced input traits such as herbicide tolerance, resistance to insects, and resistance to environmental stress (like drought). The second features value-added output traits such as nutrient-enhanced seeds for feed. The third generation of GM crops would include traits to allow production of pharmaceuticals and products beyond traditional food and fibre. Most GM crops planted in the United States have first-generation traits. Most of the GM crops planted in the USA have traits that provide herbicide tolerance (HT) and/or insect resistance.

HT crops are able to tolerate certain highly effective herbicides, such as glyphosate, allowing adopters of these varieties to control pervasive weeds more effectively. Commercially available HT crops include soybeans, corn, cotton, canola, sugar beets, and alfalfa. Insect-resistant or Bt crops contain a gene from the soil bacterium *Bacillus thuringiensis* (Bt) that produces a protein which is toxic to certain insects, protecting the plant over its entire life (Fernandez-Cornejo and McBride, 2002). Commercially available Bt crops include corn, cotton and soybean.

More than 15 years after commercial introduction, adoption of first-generation GM crop varieties by U.S. farmers has reached about 90 percent of the planted acres of corn, soybeans, and cotton. U.S. consumers eat many products derived from these crops—including cornmeal, oils, and sugars— largely unaware of their GM origins. Despite the rapid increase in adoption rates for the GM corn, soybean, and cotton varieties by U.S. farmers, some continue to raise questions regarding the potential benefits and risks of these crops.

According to USDA (2014), the number of field release permits and notifications issued by APHIS for GMO (mostly plant varieties) grew from 4 in 1985 to 1,194 in 2002 and then averaged around 800 per year (Fig. 1). The cumulative number (beginning in 1985 and ending in September 2013) of releases for field testing increased from 10,700 in 2005 to more than 17,000 in 2013. Field releases approved for corn increased from close to 5,000 in 2005 to 7,800 in 2013. Approved releases for GM varieties with herbicide tolerance traits increased from 3,587 in 2005 to 6,772 in 2013; insect resistance from 3,141 to 4,909; and product quality such as flavour and nutrition from 2,314 to 4,896. The numbers of field releases of GMOs varieties in USA approved by APHIS are shown in Figure 1.

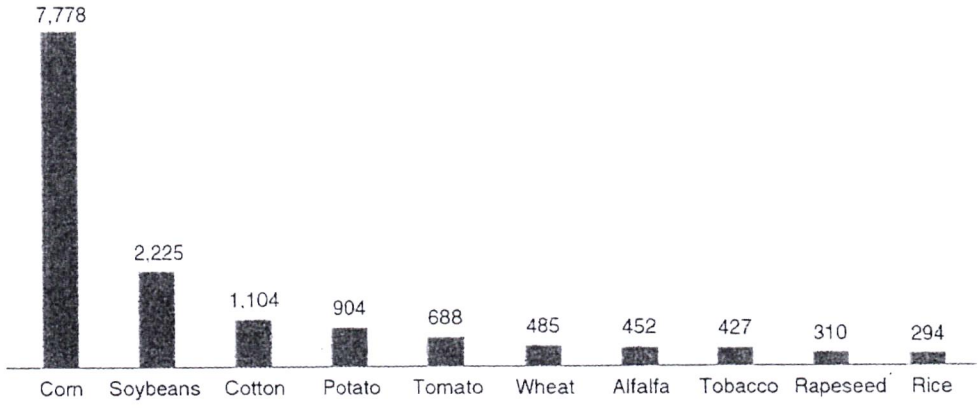
Figure 1
Number of releases of genetically engineered (GE) organisms varieties approved by APHIS, 1985-2013* (Includes permits and notifications)




*As of September 24, 2013.
Authorizations for field releases of GE organisms (mostly plant varieties) are issued by USDA's Animal and Plant Health Inspection Service (APHIS) to allow technology providers to pursue field testing.
Source: Information Systems for Biotechnology (ISB, 2013).

Most field releases have involved major crops, particularly corn, which had about 7,800 field releases approved as of September 2013. More than 2,200 field releases were approved for GM soybeans, more than 1,100 for GM cotton, and about 900 for GM potatoes (Fig. 2).

Figure 2
**Number of releases approved by APHIS: Top 10 crops (includes permits and notifications)***

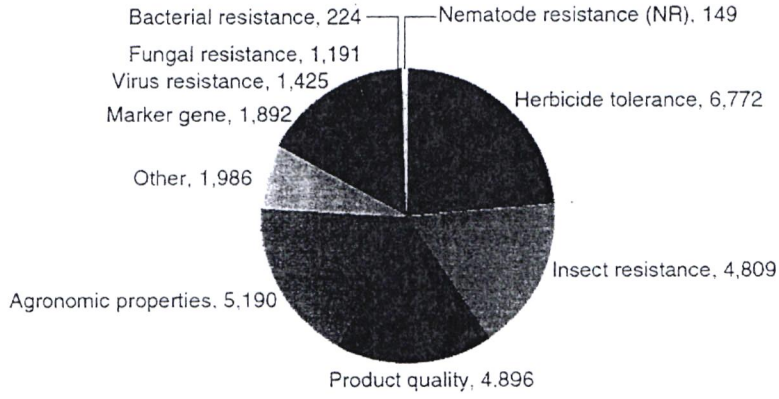



*As of September 24, 2013.
Authorizations for field releases of GE plant varieties are issued by USDA's Animal and Plant Health Inspection Service (APHIS) to allow technology providers to pursue field testing.
Source: Information Systems for Biotechnology (ISB, 2013).

Releases approved between 1985 and September 2013 included GM varieties with herbicide tolerance (6,772), insect resistance (4,809), product quality such as flavor or nutrition (4,896),

agronomic properties (like drought resistance) (5190), and virus/fungal resistance (2,616) (Fig. 3).

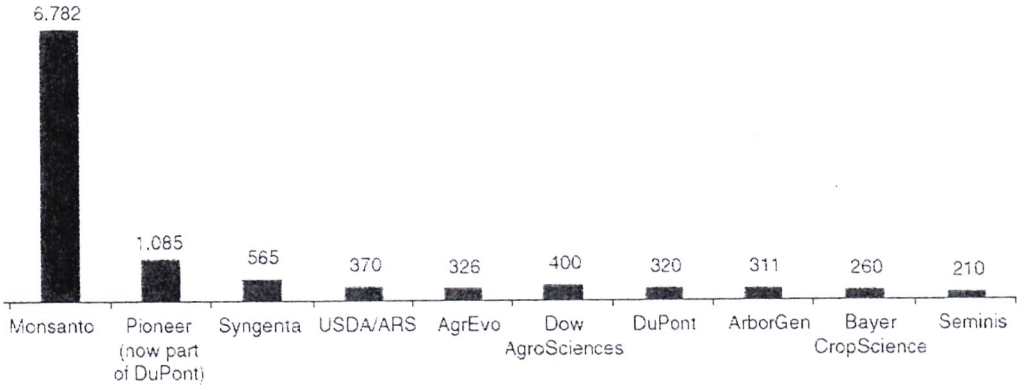
Figure 3
**Number of releases approved by APHIS by GE trait (includes permits and notifications)***




*As of September 24, 2013.
Authorizations for field releases of GE plant varieties are issued by USDA's Animal and Plant Health Inspection Service (APHIS) to allow technology providers to pursue field testing. Counts refers to the actual number of approved release locations per phenotype category. http://www.aphis.usda.gov/biotechnology/status.shtml
Source: Information Systems for Biotechnology (ISB, 2013).

The top release permit-holding institutions include Monsanto (6,782 permits/notifications held), Pioneer/DuPont (1,405), Syngenta (565), and USDA/ARS (370) (Fig. 4).

Figure 4
Institutions having the most authorized permits and notifications (number held)




*As of September 24, 2013.

Authorizations for field releases of GE plant varieties are issued by USDA's Animal and Plant Health Inspection Service (APHIS) to allow technology providers to pursue field testing.

Source: Information Systems for Biotechnology (ISB, 2013).

## 7.2 Adoption of GM Crops by U.S.A. Farmers

According to USDA (2014), GM crops were commercially introduced in the United States in 1996 and were rapidly adopted. In 2013, USA farmers planted about 169 million acres of GM corn, soybeans, and cotton, accounting for almost half of the estimated total land used to grow all U.S. crops. On a global scale, approximately 420 million acres of GM crops were planted in 28 countries in 2012 (James, 2012). USA acreage accounted for approximately 41 percent of acres planted with GM seed, Brazil accounted for 21 percent, Argentina for 14 percent, Canada for 7 percent, India for 6 percent, and China, Paraguay, South Africa, and Pakistan each for roughly 2 percent.

Planting of GM crops (measured in acres) increased by 68 percent between 2000 and 2005 and grew by 45 percent between 2005 and 2013. Three crops (corn, cotton, and soybeans) make up the bulk of the GM crops planted in USA, mostly for herbicide tolerance (HT) and insect resistance (Bt). Including varieties with HT and/or Bt traits, GM crops accounted for 90 percent of all planted cotton acres, 93 percent of soybean acres, and 90 percent of corn acres in 2013.

## 7.3 GM Crop development in South Africa

In Africa, the use of GM technology and its products is still in its infancy. Only four countries produce commercialised GM crops (Fig 7.5). These are South Africa, Burkina Faso, Sudan and Egypt. The GM crops that are under commercial production in Africa are cotton

maize and soybean. South Africa is the only country that is growing GM food crops (maize); Burkina Faso, Egypt and Sudan all grow Bt cotton (ISAAA brief, 2014). Egypt is approaching commercialization of four GM crops; these are potatoes, squash, yellow and white maize, and cotton.

In South Africa, under the Genetically Modified Organisms Act of 1997, three transgenic crops – insect or herbicide resistant cotton, maize and soybean – have been approved for commercialization (Department of Health undated). GM crop plantings are growing: in 2004 South Africa had 500,000 ha under GM crops and growth continued in white maize used for food and yellow maize used for feed; soybean plantings increased from 35 percent adoption rate in 2003 to 50 percent in 2004, whilst *Bacillus thuringiensis* (Bt) cotton stabilized with about 85 percent of producers adopting it.

According to the International Service for the Acquisition of Agri-biotech Applications (ISAAA) in 2011, South African farmers planted a total of 2.3 million hectares of GM crops. The South African National Seed Organization (SANSOR) indicates that in 2011, 77% of seed sales for maize, 100% cotton and 78% soybean were genetically modified (African Centre for Bio-safety, 2012).

According to African Centre for Bio-safety, between Jan 2008 and Feb 2012, a total of 1458 GMO permits were granted in South Africa, nearly 1200 for maize alone (for commercial growing, field trials, imports and exports). The three largest companies, namely Monsanto, Pioneer Hi-Bred and Panner Seed, were granted 76% of these permits. In the case of GM maize the three companies own 84% of all registered varieties though virtually all GM seeds sold in South Africa contain Monsanto's patented traits. These companies therefore control the GM market in South Africa estimated to be over 1.5 billion rand.

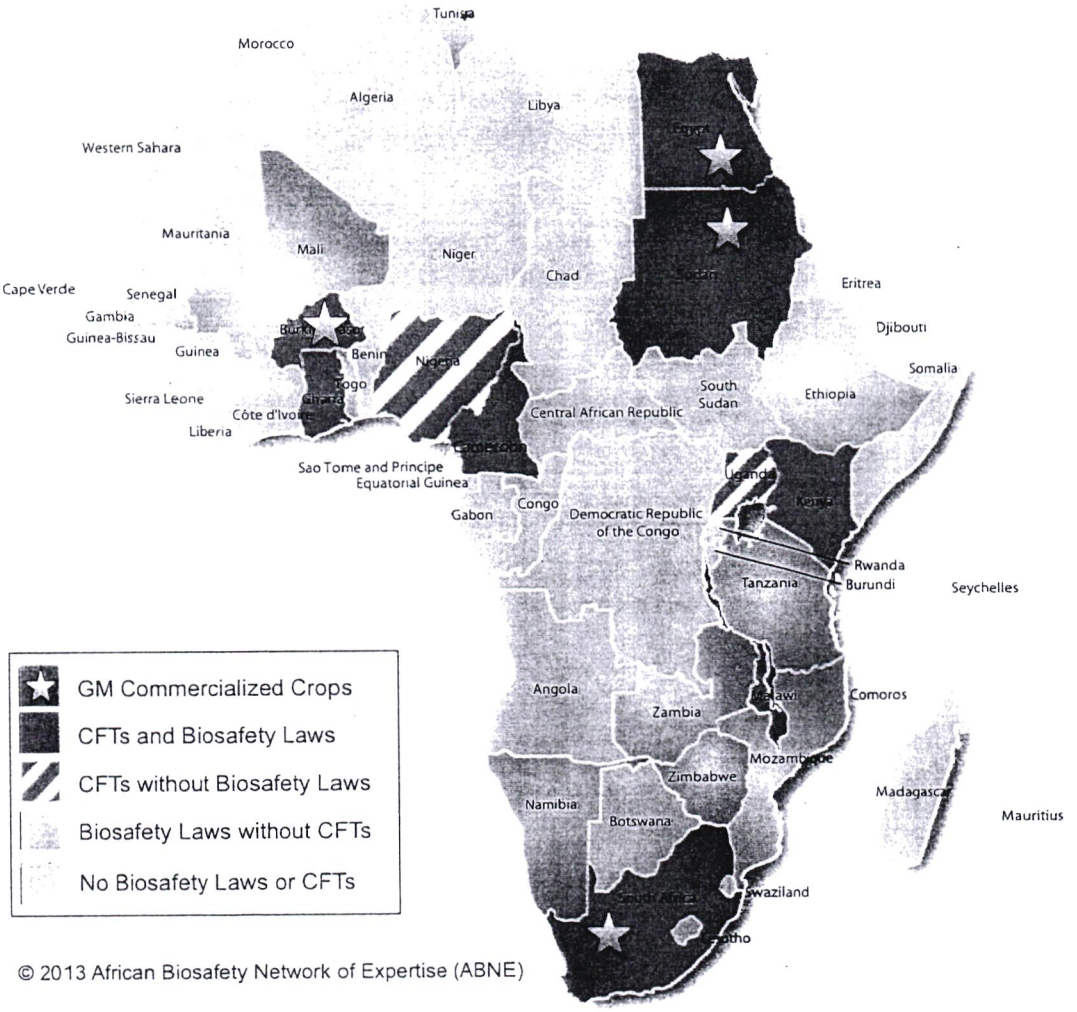
### 7.4 Consumption and use of Maize in America and in Sub Saharan Africa

According to the International Institute for Tropical Agriculture (IITA), maize is the major staple food in Sub Saharan Africa and in some Latin American countries for a total population of 1.2 billion people. In East and Southern Africa 30 to 50% of household incomes is spent on buying maize. IITA reports that:

> *"Worldwide production of maize is 785 million tons, with the largest producer, the United States, producing 42%. Africa produces 6.5% and the largest African producer is Nigeria with nearly 8 million tons, followed by South Africa. Africa imports 28% of the required maize from countries outside the continent."*[30]

[30] Accessed from IITA http://www.iita.org/maize

Figure 7.5 The Status of Crop Biotechnology in Africa (ABNE, 2013)[31]




[31] African Biosafety Network of Expertise (ABNE)
http://www.nepadbiosafety.net/abne/wp-content/uploads/2014/03/Africa-CFTs-and-Laws1.png

South Africa has recently overtaken Nigeria. South Africa produces both GM and non-GM maize but according to surveys on preferences, about 30% of South Africans still opt for non-GM maize. Maize is taken with vegetables and with meat, milk, sugar and tea. For the Black South Africans, maize is the staple food and is eaten at all meals. The non-black South African population consumes more wheat products than maize.

In the USA, the major world producer of GM maize production is distributed thus:

Animal feed/residue 39.5 %

Fuel ethanol 30.8 %

DDGs 9.2 %

Export 8.4 %

High-fructose corn syrup 4.3 %

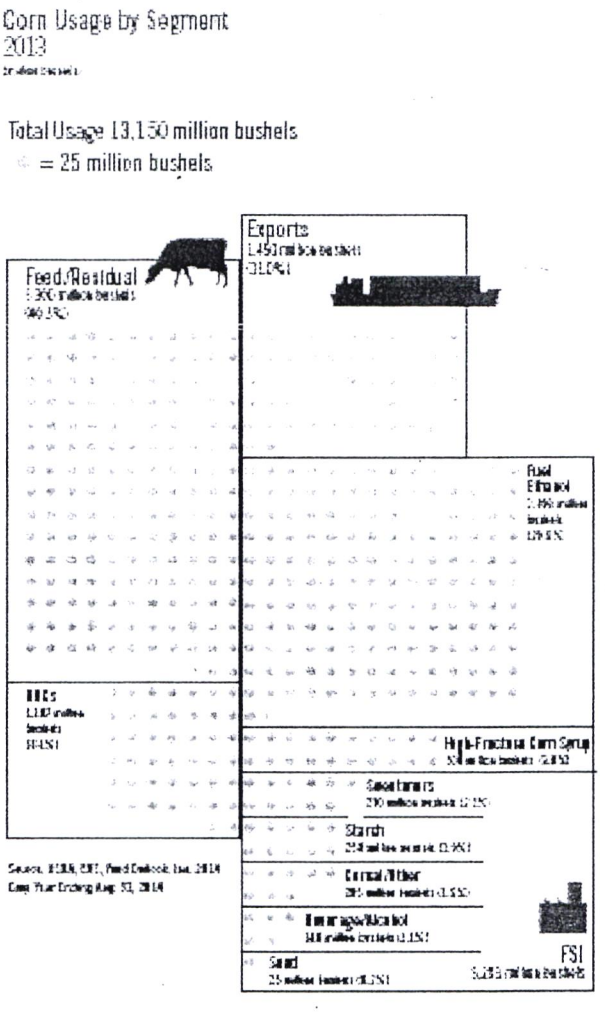
Sweeteners 2.5 %

Starch 2.1 %

Cereals/other 1.8 %

Beverage/Alcohol 1.2 %

Seed 0.2 %




The total acreage of 97,155 used for different maize varieties in the US is distributed thus: Non-GMO 11,659; Insect resistant 14,573; Herbicide resistant 20,403; and stacked traits 50,521[32].

In the USA the annual production of maize used for human food is between 1.8 and 2.5% while Africa as a whole uses up to 95% of its annual production as food, with East and Southern African nations using 85% of its production as food[33]. Maize is an important staple food for sub-Sahara African countries, feeing more than 300 million people. This contrasts with many Asian countries where maize is an important feed crop; and in many developed countries, such as the USA, where it is used largely as either livestock feed or for industrial products.

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[32] National Corn Growers Association (2013)
http://www.ncga.com/upload/files/documents/pdf/WOC%202013.pdf

[33] https://www.integratedbreeding.net/maize-facts-figures

## 7.5 Epidemiology Informing Policy Regarding Human Health

Epidemiology is the study of diseases, their patterns, causes, effects as well as factors determining and influencing their frequency and distribution for the purpose of development of evidence based control strategies. Several research designs to determine relationships between disease and various factors exist, the gold standard being prospective, randomized, long-term clinical trials. In these trials, the safety in respect to human health is paramount.

Protocols and guidelines for such trials are developed and constantly updated and have been informed by expensive mistakes encountered in the past. An example is the thalidomide tragedy a situation that influenced protocols in respect to clinical trials. Thalidomide was developed by German pharmaceutical company Grünenthal GmbH, who obtained a patent for it in 1954. Though initially marketed as a sedative and hypnotic, it was also found to be an effective antiemetic particularly in cases of morning sickness in pregnant women. Thalidomide was feted as "completely safe" for everyone, including mother and child, "even during pregnancy," as its developers "could not find a dose high enough to kill a rat." By 1960, thalidomide was marketed in 46 countries, with sales nearly matching those of aspirin.

In the United States however, FDA inspector pharmacologist Frances Oldham Kelsey M.D., prevented the drug's approval within the United States despite pressure from the pharmaceutical company and FDA supervisors. She felt that there was incomplete and insufficient data on its safety and effectiveness particularly data indicating whether the drug could cross the placenta, which provides nourishment to a developing fetus. Even where data was available, however, she felt that it may not have been entirely reliable and further studies were needed before approval.

By 1961 Dr. McBride and Australian Obstetrician began to associate this so-called harmless compound with severe birth defects in the babies he delivered. It was soon confirmed that Thalidomide interfered with the babies' normal development, causing many of them to be born with phocomelia, resulting in shortened, absent, or flipper-like limbs. These birth defects were reported in other countries where the drug was used. Initially, the makers of the drug ignored and denied these reports but overwhelming observational epidemiological data clearly showed an association and they finally stopped distribution in Germany. Other countries followed suit and, by March of 1962, the drug was banned in most countries where it had been previously sold.

The tragedy surrounding thalidomide and Kelsey's wise refusal to approve the drug helped motivate profound policy changes in the regulatory framework of the USA. The approval process for drugs, for instance, requires manufacturers' proof that the product is both safe and effective by involving animal testing and a tightly regulated long-term human clinical trial producing reliable epidemiological data.

Another example of epidemiological studies informing policy regards is the relationship between trans-fats and human disease. In the late 1890s, Nobel laureate Paul Sabatier worked to develop the chemistry of hydrogenation, which enabled the making of hydrogenated fats

such as margarine. The German chemist Wilhelm Normann showed in 1901 that liquid oils could be hydrogenated and hence solidified, and then patented the process in 1902. With a higher melting point and its being less prone to rancidity, hydrogenated fats or trans-fats such as margarine were celebrated as a healthy cheaper alternative to butter.

However, what was observed in fact was evidence emanating from epidemiologic, clinical trials, animal, and in vitro studies that demonstrated adverse consequences of industrially synthesized trans-fatty acids (TFA). Trans-fats increase the risk of coronary heart disease and actually appear to increase the risk of coronary heart disease more than any other macronutrient. In the meta-analysis of four prospective cohort studies involving nearly 140,000 subjects, a 2% increase in energy intake from trans-fats was associated with a 23% increase in the incidence of coronary heart disease (UK Food Standard Agency).

Furthermore, a growing database of more recent research from virtually all experimental models demonstrates evidence of detrimental consequences of TFAs on the risk of diabetes. Other studies suggest relationships between consumption of trans fats and Alzheimer's Disease, Cancer, Obesity, Liver Dysfunction, Infertility in women, Major depressive disorders as well as behavioral irritability and aggression.

It is however unethical to conduct prospective, randomized, long-term trials on the effects of trans-fat intake on the incidence of cardiovascular events such as heart attacks and strokes. The food industry likes to use the fact that this type of study does not exist to further their claim that the trans-fats are not harmful. However evidence from laboratory experimental studies, dietary trials, and prospective observational studies have informed policy leading to policy change where by countries such as Austria and Iceland have banned the marketing of trans-fats. Other countries such as USA have enacted strict laws such as mandatory labeling regulating production and sale.

It was thus prudent for the government to take a precautionary approach and effect a ban when there were concerns raised over the safety of GM foods. This ban would thus provide an opportunity to review literature and investigate the suitability study designs that would have an impact on the reliability of the data produced and the validity of inferences thereof. The association of GMOs on human health or absence thereof is an important matter of national concern requiring a rational and thorough scientific evaluation to inform policy. This is particularly important in respect to unhealthy diets and environmental factors among others identified as factors associated to an increase in the incidence of non-communicable diseases such as cancer, which is third leading cause of death in Kenya after infectious and cardiovascular diseases (Ministry of Public health and sanitation, 2011[34]; Henley, 2012.)

[34] National Cancer Control Strategy http://www.ipcrc.net/pdfs/Kenya-National-Cancer-Control-strategy.pdf

### 7.6 Procedures for Clinical Trials

There are comprehensive procedures set up for clinical trials for products involving human beings. The first steps involve non-clinical safety studies to support the different stages of clinical development. These initial studies evaluate the product for any toxic effects with respect to target organs, dose-dependence, and potential reversibility and are meant to form the basis for determining the initial safe starting dose in humans.

The second steps involve the single- and repeated-dose toxicity studies in two animal species before human exposure. These steps review reproduction toxicity studies in two mammalian species of which one is non-rodent, and determines genotoxicity, mutagenicity, allergenicity, local tolerance, carcinogenicity potential, reproduction toxicity as well as teratogenicity. Pharmacologic safety is then determined through pharmacokinetic and toxico-kinetic studies where the product is studied in respect to absorption, distribution, metabolism, excretion. The effect on vital functions such as the cardiovascular, central nervous and respiratory systems are also investigated in animals.

This then leads to tests in humans where in the first phase, human pharmacological studies are carried out usually in healthy volunteers to establish safety of the product. Phase two therapeutic exploratory studies then follow a limited number of subjects to demonstrate therapeutic activity, assess short-term safety and determine appropriate dose range or regimens.

In the third phase, therapeutic confirmatory studies in larger patient groups are carried out to establish short- and long-term safety and efficacy. In this phase, the overall therapeutic value is observed taking into account any adverse effects.

The fourth and final phase of the clinical trials is post-marketing surveillance to evaluate the product in circulation as a therapeutic agent. This provides opportunity to determine product's usefulness and any other effects that may not have been seen during the earlier studies.

It is only when these trials have been completed, that a product can be considered for production and marketing in respect to its safety and efficacy in humans.

### 7.7 Perceived Short-Falls of the Current Safety Assessment Standards

There is a significant characteristic of the transformation process that needs to be underlined: Plant transformation is a random, highly imprecise event resulting in a genetically unique transformant or 'event' that is virtually impossible to replicate especially with regards to the nature of the genetic pattern in the host plant genome (Lotter, 2007).

Mutations in the host DNA may arise at the insertion site of the transgene that result in disruption or rearrangement of the host chromosomal DNA (Lotter, 2007). In addition, results from the human genome project revealed that the human genome had vastly fewer genes than

had been anticipated, undermining the one-gene-one-protein doctrine and thus within the human genome and that of other higher organisms, including plants:

> *"...genes appear to operate in a complex network, and interact and overlap with one another and with other components in ways not yet fully understood."*
> - *ENCODE Project Consortium, 2007- on the results of the Human Genome Project from the US national Human Genome research Institute*

Therefore the edict that a GM event is similar to the conventional counterpart with the exception of the addition of the transgene is fatally flawed as consequences of the transformation event alone have not been determined. Further when a GM plant is created by hybridization of two separate GM events, resulting in the so-called 'stacked traits' even less information on unintended consequences become available. Indeed, for GMOs with "stacked traits" the 90-day *in vivo* feeding trials have not been performed and yet receive worldwide commercial authorisation, with no real knowledge of the cocktail effect of producing one or several insecticides and/ or the tolerance of one or more herbicides (de Vendemois, 2010).

> **POTENTIAL ACCUMULATION OF SUBSTANCES SIGNIFICANT TO HUMAN HEALTH**
> 25. *"Some recombinant-DNA plants may exhibit traits (e.g. herbicide tolerance) which may indirectly result in the potential for accumulation of pesticide residues, altered metabolites of such residues, toxic metabolites, contaminants, or other substances which may be relevant to human health. In certain cases of foods from recombinant-DNA plants (e.g. those that are commonly consumed whole and undiluted), the risk assessment should take this potential for accumulation into account. Conventional procedures for establishing the safety of such compounds (e.g. procedures for assessing the human safety of chemicals) should be applied."*
> *- CAC/GL 45-2003; Section 5, Article 54 – Potential accumulation of substances significant to human health*

Biotechnology industries review the transformation by sequence analysis of the DNA flanking the insertion site, the transgene sequence and reviewing sequence information at the junction to ensure that no new Open Reading Frames (ORFs) for known toxins or allergens have been created. In other words, the purpose of the current risk assessments is to determine whether any known or predicted hazards arise from transgene, when transformation-induced mutations are more likely to have unpredictable effects on the GM plant's phenotype (Latham, 2006).

A large proportion of the transformation events that are commercially available have the transgene expression under the control of the constitutive Cauliflower Mosaic Virus 35S promoter gene, which forces continual expression of the transgene in every cell of the host plant. This means that the foreign gene is continually expressing its product, acting

independently of the host plant's cellular control mechanisms and is wholly uncorrelated with the other plant genes. This is in stark contrast with the normal coordination that exists among the native genes. Furthermore the transgene produces a protein that has never existed in that species and is expressed in an essentially unregulated manner, uncoordinated with the natural functions of the host plant.

Biotechnology companies rarely test the transgenic protein within the plant system because of the low levels of expression within the tissues. Instead they make use of bacterial surrogate proteins for testing purposes (Fresse and Schubert, 2004). The surrogate protein is extracted from bacteria and then employed for *in vitro* allergenicity studies such as acute oral toxicity tests, *in vitro* digestibility studies and short term animal feeding trials.

> *"....As a result, animal feeding studies and allergenicity assessments that make use of bacterial surrogate proteins or their derivatives may not reflect the toxicity or allergenicity of the plant-produced transgenic protein to which people are actually exposed.... [and] given the use of bacterially produced surrogate proteins as the norm for testing, one cannot avoid the conclusion that the plant-produced transgenic proteins we actually eat are virtually untested."*
>
> - *Fresse and Schubert, 2004*

Currently, no harmonized animal feeding trial exists to test the safety of genetically modified foods (Kuiper et al 2001). It is impossible to determine if a protein product is safe unless it is tested in an animal: No amount of *in vitro* data can reliably attest to the safety of the protein product (Fresse and Schubert, 2004). Animal studies are necessary to assess the characteristics of the newly expressed protein. The minimum requirement to demonstrate the safety of the consumption of a food over a long term is a sub-chronic 90-day feeding trail. The failings of the ability to fully assess safety of GM foods in sub-chronic animal feeding trails have been outlined earlier in this report. It may therefore be prudent to consider lifelong, multigenerational studies for laboratory animals:

*"...Such tests could be associated to transgenerational, reproductive or endocrine research studies." de Vendemois et al. (2010).*

### 7.8 Conclusion

Maize is the most important cereal crop in sub-Saharan Africa. However, the continent as a whole produces only 6.5% of the world output, in comparison with US which produces 42%. Sub-Saharan African countries are net importers of maize and consume over 20% of the worldwide production of maize. Before considering importing and or consuming GM maize, necessary studies must be put in place for testing the safety of this GM product.

In order to produce results that are objective, a study on the safety of such products intended for human consumption in Kenya should be carried out by local, independent scientists within national institutions using government funding. In this regard, this study should be

among the priority research areas identified by the relevant regulatory and research authorities in the country that have been availed with the necessary resources.

This could be an example of national strategic research as was envisioned by The Science, Technology And Innovation Act, 2013, whose national research fund was increased from 0,5 to 2% of the GDP in Kenya.

## 8.0 ANALYSIS OF POSSIBLE REASONS AND UNDERLYING FACTORS FOR THE BAN OF GMO IMPORTATION, CULTIVATION AND/OR TRADE BY SOME COUNTRIES

### 8.1 Updated List of Countries That Have Banned or Restricted GMOs

#### 8.1.1 Situation in Africa

In most African countries, like many other poor countries, GM crop research infrastructures are still weak, mainly because of absent or inadequate national policies or regulatory systems to deal with safety requirement for approving general use of GMOs. As such, many African countries have not introduced genetically modified (GM) crops. Indeed, a number of countries have at one time or another, imposed bans and/or restrictions on GM imports, as indicated in the ***Table 2*** below.

| **Country** | **Nature of Ban or Restriction** | **GMO Affected** | **Year Effected** |
|---|---|---|---|
| Algeria | Import, distribution, commercialization | Any GM plant material | December, 2000 |
| Angola | Import | Unmilled GM food aid | April, 2004 |
| Benin | Import, moratorium until national legislation comes into force | GM food aid | 2002<br>Extended 2008 |
| Egypt | All crops imported from abroad and exported from Egypt be accompanied by a certificate from the country of origin stating they are free of genetically modified materials. | All imports | 2009 |
| Kenya | Imports due to health concerns | All | 2012 |
| Lesotho | Banned GMO food imports unless they are already processed or milled, citing concerns over environmental contamination.<br>Distribution permitted with public warning that grain should be consumed and not cultivated | Non---milled GM food aid | |
| Malawi | Import | Unmilled GM crops | 2002 |
| Mozambique | Import and distribution | Unmilled GM crops | |
| Namibia | Import (rejected GM maize but accepted wheat for aid) | GM maize | 2002 |

| | | | |
|---|---|---|---|
| Nigeria | Import and distribution | Unmilled maize | |
| Sudan | Import(later issued temporary waivers under pressure by the US) | GM food aid | 2004 |
| Swaziland | Distribution permitted with public warning that grain should be consumed and not cultivated | | |
| Zambia | Food aid | GM maize | 2002 |
| Zimbabwe | Import and distribution | Unmilled GM food aid | |

### 8.1.2 Situation in Europe and Asian counties

As of August 2012, the European Union had authorised 48 GMOs most of which were for animal feed or for feed and food processing. Of these, MON 810, a Bt expressing maize conferring resistance to the European corn borer and a potato called Amflora have approval for cultivation in Europe. The EU however has a provision that Member States may invoke to temporarily restrict or prohibit the use and/or sale of a GMO within their territory if they have justifiable reasons to consider that the approved GMO constitutes a risk to human health or the environment. As shown in the following table, this may include regulations for designation of GM-free zones as well as buffer zones and isolation distances between the GM and non-GM crops. Furthermore, these regulations provide for freedom of choice to the farmers and consumers in respect to imports and sale of GMOs for human and animal consumption grown outside the EU. In addition all food (including processed food) or feed which contains greater than 0.9% of approved GMOs must be labelled.

In respect to implementation, 56% of all EU member states including Austria, France, Germany, Hungary, Luxembourg, Greece, Bulgaria and Italy have imposed bans on the cultivation of GM crops approved by the European Food Safety Authority (EFSA) as safe. These bans reinforced EU member states right to make such decisions at the national level thus **the possibility of Member States to nationalise restrict or prohibit the cultivation of GMOs in their territory**. In exercise of this provision of nations, there are examples where EC unapproved products arriving in the EU were forced to return to their port of origin. The first in 2006 involved a shipment of rice from America containing an experimental GM variety (LLRice601 at Rotterdam and the second in 2009 when trace amounts of a GM maize approved in the US were found in a "non-GM" soy flour cargo. (Davison, J. (2010). "GM plants: Science, politics and EC regulations". *Plant Science* **178** (2): 94–98.)

Outside Africa, countries such as Sri Lanka, Thailand, China, Japan and the Philippines have laws limiting GM foods. In Europe, Norway, Austria, Germany, the United Kingdom, Spain, Italy, Greece, France, Luxembourg and Portugal have put in place restrictions on GM crops. The European Union is considering a Europe-wide banning of GM foods. In the Middle East, Saudi Arabia has banned GM foods and importation of GM wheat. Russia has recently (**in**

**April 2014)** issued a ban on use and import of Monsanto's GM corn following the study by the French scientists, which showed massive tumours and direct organ failure in mice put on the GM corn for two years. The implication of a major GMO producer in the controversy behind the retraction of this paper **in November 2013** is elucidated in this report.

**It is noteworthy that the Russian ban came after the paper was retracted. While announcing the ban the Russian government stated that Russia had enough resources for growing organic maize (corn).** On announcing the ban, Prime Minister Dmitry Medvedev said that Russia would no longer import GMO products and stated that the nation had enough space, and enough resources to produce organic food.

The following table shows the GMO status of various Asia/Pacific and European countries

| Region | Country | Status | Date | Remarks |
|---|---|---|---|---|
| Asia/ Pacific | Australia | Regional bans | **2013** | State of Tasmania banned GE rapeseed as weed; Western Australia has banned commercial GE plant. Some communities (e.g. Bondi/Sydney, West Wimmera Shire) declared themselves GE free. |
| | New Zealand | bans | **2013** | growing of any GMO food in the country.<br>Some local bodies in Auckland and Wellington have declared themselves GM free.<br>Trials with GE salmon have been blocked by the government. |
| | China | restriction | **2013** | Shipments of corn containing GMO or residues after discovery of the MIR162 corn strain not been approved for import in US shipments. |
| | India | moratorium | **2010** | Bt Brinjal variety was banned due to concerns of the seeds contaminating other self-sustaining crops |
| | Thailand | ban | **2001** | imports of 40 GE crops for commercial planting, but not for research purposes. |
| | Philippines | Regional moratorium<br>ban | | Valencia GE food and GE crop trials and commercialization<br>Bt eggplant ban |

| | | | | |
|---|---|---|---|---|
| | | | **2013** | |
| | South Korea | ban | 2013 | Follows an announcement by the U.S. Food and Drug Administration of contamination of commercial wheat grown in the USA with Monsanto's genetically engineered wheat |
| | Japan | ban | 2013 | importation of Thailand papayas (as well as papayas from Hawaii – which are now predominantly genetically modified). |
| | Russia | ban | 2014 | Banned all imports of GM corn, following an earlier study by French researchers which showed that rats grew massive cancer tumours when fed a lifetime of Monsanto's genetically modified corn |
| | Georgia | restriction | 2013 | importation of genetically modified seeds into the country without a specific license to do so |
| | Ireland | ban | 2009 | growing in Ireland, and Ireland has a voluntary GM food lab |
| | Luxembourg | Regional bans | 2009 | MON810 in 2009.<br>80 municipalities (out of 116 in Luxembourg) have declared themselves as "GE free" |
| | Bulgaria | ban | 2010 | Cultivation and sale |
| Europe | France | Moratorium<br>ban | 2013<br>2014 | Cultivation of Monsanto's genetically modified corn.<br>sale, use and cultivation of Monsanto's MON 810 on the basis of environmental risks |
| | Norway | restriction | 1997 | Banned the import of several GE crops and products which contain antibiotic resistance genes.<br>12 GMOs approved for sale in Norway: |

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|---|---|---|---|---|
| | | | | Varieties of tobacco and ornamental flowers<br>5 GMOs banned in Norway: 3 types of oil seed rape, one corn variety and one chikory.<br>No GMOs are approved for feed use so far |
| | Sweden | Restrictions<br><br><br><br><br><br><br>Regional bans | 2012 | No GMO crops for commercial cultivation<br>No GMO crops derived animal feed is used in Sweden. Dairy producers, beef producers, egg and chicken producers GMO free.<br>No GMO crops for commercial cultivation.<br>Supermarkets do not sell GMO containing products.<br><br>Jämtlands län County<br>Municipalities: Östersund kommun, Åre kommun, Krokoms kommun, Borlänge kommun, Uddevalla kommun, Kalmar komm un, Kumla kommun and Lindesbergs Kommun<br><br>Total: 34 GMO free zones (Including schools, restaurants, food shops, farms, churches |
| | Finland | allows | | No commercial cultivation of GMO<br>No GM labeled food for sale<br>One field trial with birch trees that are supposed not to make pollen.<br>some GM plants at university labs (gerbera flowers)<br><br>Finnish government and the Finnish people |

| | | | | |
|---|---|---|---|---|
| | | | | are largely open to the idea of GMOs. To date, no significant commercial cultivation has occurred due to incompatibility with Finland's climate |
| | Latvia | Restriction<br><br>Regional bans | 2012 | No GMO cultivation and no field trials<br>Law requires shops to separate labeled GMO products from other products<br>GM soy and corn widely used in animal feed<br>110 GMO free municipalities GM crop<br>Cultivation or mandatory rules on the cultivation of genetically modified plants on their territory<br>Municipalities<br>have such a right to declare GMO free zones |
| | Switzerland | ban | 2005 | growing of all genetically modified crops |
| | Lithuania | Restriction | 2012 | No GMO cultivation and no field trials<br>GMO advertisement law<br>GM soy and corn widely used in animal feed<br>Illegal GM canola seeds contamination scandal<br>in 2012 (near Latvian border) |
| | Estonia | Restriction | | No GMO cultivation and no field trials<br>GM soy and corn widely used in animal feed<br>GMO containing products sold in shops (mainly GM soy oil) |
| | UK | Restriction | | The Church of England has refused permission for GE crop trials on 60,000 hectares of its land<br>House of Commons banned GE foods for its catering. |

| | | | | |
|---|---|---|---|---|
| | Belgium | Regional ban | | Entire Wallonia GMO free |
| | Poland | ban | 2013 | Cultivation of GM crops expressing concerns that these crops may cross-pollinate with non-GM crops and Monsanto's MON810 maize pollen may find its way into honey<br><br>Amflora potatoes |
| | Luxembourg | ban | | Novartis Bt maize. |
| | Portugal | ban | | Novartis Bt maize. |
| | Spain | allows<br><br>Regional bans | | In 2012, over 120 thousand hectares of *Bt* maize cultivated 90 % of GM crops in the EU<br><br>GMO-free: Asturias, Basque Country, Balearic Islands and Canary Islands<br><br>The provinces of Málaga, Álava and Vizcaya Islands of Menorca, Mallorca and Cabildo Insular de Lanzarote<br><br>117 Spanish municipalities in 14 regions have sided against GMOs, representing about 20 percent of the country's population. |
| | Germany | ban | 2009 | cultivation of the MON810 maize for potential hazard to the environment; non-target arthropods which economically important in the ecosystem in pollination of fruits and vegetables |
| | Austria | ban | 2010 | growing and importation of the Monsanto's maize MON 863 on health safety grounds. |
| | Italy | ban | 2013 | cultivation of a type of genetically modified maize, citing environmental concerns and the crop's "negative impact on biodiversity after contamination from illegally cultivated MON810 corn |
| | Greece | Prohibition | 2006 | cultivation, commercialization and usage of GMO hybrid corn seed varieties of the MON |

| | | | | |
|---|---|---|---|---|
| | | Extension<br><br>Ban<br><br>moratorium | 2008 | 810. Noted potential threat to human health and to the beekeeping industry (Greece accounts for an estimated 16 percent of European Union honey production).<br><br>AgrEvo HR rapeseed,<br><br>GE crop trials |
| | Austria, Bulgaria | New guidelines | 2010 | 1. New guidelines in 2010 regarding the co-existence of GM and non-GM crops<br><br>2. Joint paper requesting that individual countries should have the right to decide whether to cultivate GM crops. **This underlines national sovereignty** |
| | Cyprus, Hungary, Ireland, Luxembourg Lithuania, Poland, Slovenia, Netherlands | | | |

### 8.1.3 Situation in the Americas

In the Americas, Brazil and Paraguay have restrictions on GM foods. IN the U.S. there are a growing number of states holding moratoria on GM foods, with the state of California proposing to label GM products.

| Region | Country | Status | Details | Date | Remarks |
|---|---|---|---|---|---|
| North America | Canada | Allows | | 1994 | 11.6 million hectares, 81 GM foods approved. Third largest producer of GM crops: corn, canola, soya, sugar beet. All Canadian canola is GM Imports cottonseed oil, papaya, and squash. No labelling required |
| | USA | allows | | | About 75% of processed foods with GM ingredients, 40 plant varieties have completed all of the federal requirements for commercialization **No labelling** |

| | | | | | |
|---|---|---|---|---|---|
| | | | | | **required** |
| | | Regional bans | California counties: Mendocino, Trinity Marin | 2004 | first to ban cultivation, production and/or distribution |
| | | | Washington: San Juan County | 2012 | bans growth |
| | | | North Dakota, Montana | | bans of GE wheat |
| | | | Burlington/Vermont | | moratoria on GE food This is the first state to impose mandatory labelling from July 2014 |
| | | | City of Boulder/Colorado | | Ban on GE crops |
| | | | Oregon: Jackson County | | unlawful for any person to propagate, cultivate, raise, or grow |
| | | | Big Island of Hawaii | 2013 | Exempts papaya |
| South America | Brazil | Allows | | | 21.4m Ha under GM crops cultivation<br>States of Rio Grande do Sul and Mato Grosso do Sul have declared their intentions to remain GM-free, 18 States called upon the Central government to block commercial GE crop planting. |
| | Argentina | allows | | | 21.3m Ha under GM crops cultivation |

| | | | | | |
|---|---|---|---|---|---|
| | Mexico | Partial ban | | 2013 | Planting and selling corn, multinational corporations releasing genetically modified corn in the countryside |
| | Peru | ban | | 2012 | |
| | Ecuador | ban | | 2008 | |
| | Venezuela | ban | | 2006 | |

**8.2 Conclusion**

Nations with bans, restrictions and moratoria to GM cultivation, import and/or sales have cited various concerns. Some have been the precautionary principle in view of inconclusive available evidence whereas others have been more specific. Health risks (toxicity, fertility and risk of inducing cancer) and environmental issues including long term effects on genetic diversity including contamination of non-GM plants through cross-pollination are the most common. There are however those that have reasoned that there is adequate fertile land available for conventional plants food production and thus GMOs would not be necessary.

## 9.0 PUBLIC HEARING & SUBMISSIONS

### 9.1 Introduction

The Gazette notice that established this taskforce indicated that "in the performance of its functions, the taskforce shall hold such number of meetings in such places and at such times as the taskforce shall consider necessary for the proper discharge of its functions". In this regard, the taskforce invited the public through an advertisement in the Daily Nation (page 20) and East African Standard (page 29) of 17th April 2014 to present their oral or written views regarding the safety of GMO foods. This is as per the Constitutional requirement of providing opportunity for public participation in article 10 (2) (a) which states:

> *"The national values and principles of governance include patriotism, national unity, sharing and devolution of power, the rule of law, democracy and participation of the people..."*

The advertisement also provided information of a public hearing forum to be held at the Louis Leakey Memorial Hall, National Museum of Kenya on Friday 25th April between 9 AM and 5 PM. A copy of this advertisement is in the annexure.

### 9.2 Set Up and Procedures

On the appointed day, 110 people attended the public hearing forum with 24 giving oral presentations and 19 written submissions. Most of the oral submissions were also accompanied by written submissions presented prior or during the forum. Each oral submission was presented within an 8 to 10 minute session electronically recorded as well as individually documented by taskforce members. The public hearing session was moderated by Amb. Mary Khimulu.

The hearing was attended by a cross section of Kenyans with varying interests in the matter at hand such as; industry, civil society, consumers, farmers, lawyers, academicians and clinicians. All who wanted to participate were given the opportunity to and their views documented. A list of all those who gave submissions is in the annexure.

### 9.3 Public Views

All presenters welcomed and appreciated the composition of the Task Force and expressed their gratitude for the Government giving them the opportunity to present their views publicly. The views of the submissions can be divided into four broad areas of concern: scientific tests and procedures to ensure safety; regulatory framework and its implementation; biotechnology training, education and career development and consumer rights.

In regard to scientific tests and procedures to ensure safety, there were submissions that this was comprehensively done and thus GMOs were safe for food. Some presenters said that all commercialized GM foods were tested for allergenicity and toxicity and those that failed

(such as the Brazilian nut allergy-like symptoms in GM soya) were not released into the market. The large acreage of GM crops worldwide and the high uptake of this technology was further quoted as evidence of safety. In addition, there were those who presented the view that there were no documented deaths or adverse human health effects directly attributed to consumption of GM foods after 20 years since their commercialization. One presenter said there were 30 tons of GM food imports into the country with no reported adverse effects. Some of the presenters also stated that they had consumed GM foods and are well to date. In addition, some presented, the fact that other countries as well as international bodies such as FAO, WHO and EFSA had approved GM foods provided proof that they were safe. However there were some submissions drawing attention of the taskforce to the merits and demerits of the scientific studies published so far regarding the safety of GMOs both as food and feed as well as in the environment. Some pointed to the retraction of publication by Séralini et al. (2012) adding that the findings of this study were no longer scientifically valid. There were submissions raising the issue of conflict of interest regarding funding of researchers and posited that many of the papers analyzed, the studies had been financially supported by industry or industry related donors.

The second group of submissions was concerned with the legal and regulatory framework and its implementation. The majority submitted that the current laws mainly the Biosafety Act 2009, the accompanying regulations and particularly the establishment of the National Biosafety Authority provided adequate framework for ensuring GM safety. This, one presenter stated, was informed by the fact that there were 11 GM events in ILRI and 8 at KARI that were regulated before the ban. Some however submitted that the Biosafety Act hadn't comprehensively dealt with issues of consumer redress and compensation as well as restoration of the environment in case of unintended harm. Of special notice were submissions that stated that the ban had not followed requisite legal procedure and should have been through a legal notice with another presenter concluding that in this case the ban was null and void. A number of presenters however believed that the implementation of the relevant laws and regulations was insufficient due to inadequate infrastructural and human capacity; wide scope regarding entry points into the country; coverage in regard to policing and random sampling as well as what they termed corruption. Thus, according to some, requisite risk assessment mechanisms and capacity was inadequate and called upon capacity building to strengthen institutions such as NBA. Regarding the international arena, one presenter said that Kenya was the only country worldwide to ban GMOs while another added the following countries to the list those who had banned GMOs: Poland, Germany, France, Italy, Bulgaria and Russia. Some submitted that Kenya being a signatory to international agreements such as the Cartagena Protocol was obligated in respect to allowing GMO technology into the country. On the other hand there were those who noted that seed and germplasm was owned by multinationals and most had genetic use restriction technology that caused second generations seeds to be sterile requiring repeated purchase and thus foreign dependency. They noted that the GMO issue was a matter of National sovereignty and Kenya should consider the matter without considering other countries or organizations and make the best decision which in their view was best for Kenyans.

The third lot of submissions was concerned with the effect of the ban on training and career opportunities. The majority of these submissions stated that the ban had a negative impact for biotechnology training institutions. Adding that such institutions would experience a decline of student numbers applying for biotechnology training since such students would feel that their career paths were curtailed because there would be no biotechnology opportunities for them in Kenya. Similarly many in this group of presenters stated that researchers would be discouraged from carrying out research and innovation in an area where a ban was in place. A decrease in funding opportunities was envisioned and in some cases reported for according to presenters, donor organizations were apathetic and withdrawing funding biotechnology when a ban was in place. One presenter (assuming that the ban on importation was tantamount to a ban on all GMO/ biotechnology research) noted that there was a contradiction because the same government that was declaring the ban was funding GMO research through NACOSTI. The majority in this group of submissions stated that GM technology like any other technology was inevitable and thus research and implementation of results thereof would have to be adopted in the country otherwise Kenya would be left behind.

The last group of submissions referred to consumer rights in regard to consumers of the technology and the products thereof. Some submissions stated that biotechnology industry had provided the competitive advantage that led to increased yields, reduced pesticide and fuel use as well as reduced erosion. In this regard, since Kenya has a maize production deficit, without GM maize it would be a challenge to get non GM maize to bridge the deficit and thus the ban takes Kenya back regarding progress made on food security and poverty reduction. Several presenters quoted examples of Bt cotton in Burkina Faso as a success story. There were however others who quoted the case of India where farmers committed suicide due to Bt cotton failure. One presenter however remarked that biotechnology could not be considered as a panacea to farmers' problems and thus should be rotated with conventional crops. There were presenters who submitted that GM technology was not informed by challenges Kenyan farmers experienced. They said increased yields and pests targeted by GM technology were not their main challenges but water, soil quality and marketing should be the focus. Some of the submissions indicated that there is no evidence that GM technology increased yields but benefited the multinationals not farmers. In addition, one submission said that the burden of proof of safety should lie with industry. Furthermore, some presenters said that GM crops contaminated conventional crops in the field leading to loss of market as was the case of Hawaiian Papayas. In addition, that contamination could lead to litigation against farmers like in Canada where a GM producer (Monsanto) won a case against a farmer whose field had been contaminated with GM canola and thus the farmer was considered to have violated the intellectual property of the GM producer. Consumers of products of GM technology submitted that the Kenyan Constitution had comprehensively provided for their rights such as those of information, traceability, redress and compensation. The government thus had a right to ensure that products were safe and there is need for legal mechanisms for enforcing redress and compensation in case of harm. Furthermore, labelling of GM foods contained in the gazette regulations would

provide information to consumers allowing them to make informed choices. One of the presenters wondered whether it was possible that consumers were still being exposed to GM food despite the ban due to inadequate monitoring and policing. One presenter noted that despite labelling regulations a survey found GM presence in unlabeled cereal, baby food and imported sausages found in the supermarket shelves in the country. Furthermore, the presenter stated that the traceability of GM foods and the capacity of institutions to trace GMOs from the consumers to their origin was questionable. One submission pointed out that the Biosafety Act contemplated imminent danger of GM technology products and thus provided for compensation and environmental restoration in cases of unintended harm. Another presenter highlighted the lack of comprehensive answers to the questions regarding the ban; and also added that the fact that many people may be taking certain action does not mean that particular action is right. Commenting on food security, this presenter stated:

*"National sovereignty is on the seed whoever controls the seed controls food..."*

**9.4 Comments on The Submissions**

The taskforce members observed that the terms GMO and biotechnology were used interchangeably. An example is when a presenter referred to GMOs, biotechnology and tissue culture technology interchangeably in his submission. This was in both oral and written submissions at times implying that the current ban on importation of GMOs also extended to products of biotechnology. In addition, the members noted that there was a general perception that the scope of the ban was not only on importation but also on research in the area of GMOs. Such presenters stated that the ban would affect biotechnology research, training and career development. This taskforce notes that the ban was specifically on the importation of GM foods.

In summary, the submissions fell into the following groups:

1. The first group was those that called for a lifting of the ban mainly those associated with the GM industry, some academicians, some from civil society, and some farmers.
2. The second group was those who called for the maintenance of the ban mainly from some civil society organizations and consumer groups.
3. The third group was those who called for lifting of the ban provided that certain conditions were met. This group was made up of presenters from the legal, medical and academic professions; some civil society members, some farmers and some consumer groups.
4. The fourth group stated that the GMO ban should be applied on a case by case basis, depending on the assessment of the benefits, risks and safety of each GM product.

## 10.0 CONCLUSIONS OF THE TASK FORCE

### 10.1 Preamble

The Kenyan agricultural industry is dominated by small-scale farming, whose production is highly dependent on rainfall. The lowest national output for agriculture over the past decade has been almost entirely attributable to low rainfall and disease outbreak. Farmers and consumers alike are also plagued by increased costs of fertilisers, high global food prices and low purchasing power. Global GM crop production has focussed on two key traits: herbicide tolerance and insect-pest resistance. Food assurance in Kenya, whichever the source, will arise predominantly from access to safe, affordable foods in spite of changing weather patterns.

### 10.2 GMOs and Food Safety

The Government of Kenya (GOK) has put in place control measures to assure and ensure that all GM activities or products approved in Kenya are safe. In 2006, the Cabinet approved the National Biotechnology Development Policy; in 2008, Parliament passed the Biosafety Bill, which then became law in 2009 – the Biosafety Act. The GOK has developed various regulations to implement the Biosafety Act No 2 of 2009. These include the following regulations on:

- Contained use – covers any GMO-related activities or research under containment and/or confinement such as within laboratories, glasshouses and confined field trials
- Environmental release – covers activities during the commercialisation of GMOs and that involves environmental release and marketing
- Import, export and transit – cover the movement of GMOs into and out of the country and the safe transit within the national borders, in conjunction with the above regulations on release
- Labelling – cover aspects of traceability of the GMO and consumer awareness of products containing GMOs
- Currently under preparation is a draft regulation on handling, packaging, storage, and transportation of GMOs.

Within these regulations the assessment of safety of the GMO for human consumption is determined

> *"...in accordance with Kenyan standards and laws prior to Environmental Release and/or placing in the Market and Import, Export or Transit."*
> - Source NBA: SOP for Food Safety Assessment Procedure

**However, the regulations contained within the National Biosafety Act fail to directly address the assessment of safety of GM foods for human consumption.** The law that addresses human safety refers to occupational health. The Fourth and Fifth Schedules describe approval for contained use and contingency plans, respectively.

The current safety regulations of Kenya make no reference whatsoever to the safe consumption of GM foods.

## 10.3 Food Safety Assessment of GM Maize

When reviewing the safety of GM foods, it is recommended to do so case-by-case. In this case study, a review of the production, safety and literature of three GM maize varieties was performed. No clinical trials exist pertaining to GM food safety. As maize is a very important staple in Kenya and the above mentioned GM events the most widespread worldwide, they were the preferred choice for review.

The case study highlighted serious concerns with the imprecise, unpredictable nature of the transformation event; subjectivity of the concept of substantial equivalence in determining safety; and the inadequacy of the animal feeding procedures as prepared by the GM food producers.

## 10.4 Food Safety Assessment by Animal Feeding Trials

In spite of the assurance that GM products are safe and do not cause harm to human health, convincing evidence is lacking. The 90-day lab rodents feeding test used in safety assessment of GM products is too short to assure food/feed safety. This will only reveal if there is the potential for acute or sub-acute harm. Therefore long-term, multi-generational lab animal studies might be more appropriate for food safety assessment.

90-days in a rat are equivalent to 7 to 8 years of age in a child. This is therefore an insufficient time frame for assessing the impact of food that could, in the case of maize, be consumed three times daily for an individual's lifetime. There is no data on the impact of reproductive ability, transgenerational effects or life-long impact of the consumption of the GM food.

## 10.5 GMOs and Food Security

Maize is the most important cereal crop in sub-Saharan Africa. However, the continent as a whole produces only 6.5% of the world output, in comparison with US which produces 42%. Sub-Saharan African countries are net importers of maize and consume over 20% of the worldwide production of maize. Before considering importing and or consuming GM maize, necessary studies must be put in place for testing the safety of this GM product.

**In order to produce results that are objective, a study on the safety of such products intended for human consumption in Kenya should be carried out by local, independent scientists within national institutions using government funding.** In this regard, this study should be among the priority research areas identified by the relevant regulatory and research authorities in the country that have been availed with the necessary resources.

Both GM and non-GM crops have their own challenges. Their advantages or otherwise depend on whether you are dealing with large-scale highly mechanised food production and water management or small scale poorly mechanised or subsistence farming. The food security challenges identified in this report require a multi-faceted and multi-sectoral

approach. However in all instances, there are key areas that affect agricultural productivity in Kenya, namely:

- Water availability
- Soil fertility
- Disease control
- Harvesting
- Storage
- Transportation and
- Marketing

None of the GM food crops currently on the international market can answer the above key challenges facing the food insecurity problems in Kenya.

### 10.6 Countries with Bans and/or Restrictions

Nations with bans, restrictions and moratoria to GM cultivation, import and/or sales have cited various concerns. Some have been the precautionary principle in view of inconclusive available evidence whereas others have been more specific. Health risks (toxicity, fertility and risk of inducing cancer) and environmental issues including long term effects on genetic diversity including contamination of non-GM plants through cross-pollination are the most common. There are however those that have reasoned that there is adequate fertile land available for conventional plant food production and thus GMOs would not be necessary

**56% of the European member states have put various restrictions on the importation of GM foods (especially GM maize varieties), with only one member state (Spain) that is cultivating GM seed**. Most of the GM approvals by the EFSA are restricted to consumption (feed) and processing but not for cultivation and or research. Therefore within the European Union there is limited importation and virtually no cultivation of GM crops. **Each country is granted the right to make its own laws under the principles of National Sovereignty in relation to the CAC guidelines of GM food safety.**

**Therefore Kenya is not alone in seeking reassurance on the safety of GM products for human consumption.**

### 10.7 Infrastructure

Looking at the current situation, the country does not have adequate capacity to handle and monitor all GM food imports. There is a lot of overlap and duplication at the border points and not enough technological know-how or in-house laboratory support and the key GM regulatory agencies.

Any chemical substance which is supposed to be taken by humans has to be cleared for safety by the Pharmacy and Poisons Board. The majority of the GM crops approved for commercial release worldwide contain traces of certain chemicals which they either produce or absorb. These chemicals such as herbicides (glyphosate) and the different Bt toxins, have not yet

been approved for human consumption by the Pharmacy and Poisons Board. Therefore the maximum toxicity levels of these chemicals in food destined for human use have not been established. In other words, new maximum residue levels for GM foods either producing or absorbing chemicals that can be tolerated by human beings must be determined.

This would need the joint collaboration of the Pest Control and Produce Board and the Pharmacy and Poisons Board with the NBA. In addition the networking system between the standards and regulatory bodies needs to be improved and the role of each partner in this network clearly defined.

**The Government should adapt the new mandatory EFSA (2013) regulations of the 90-day animal feeding trials with extension to life-long multigenerational trials in laboratory animals.**

Government funding of KARI is needed in order to strengthen biotechnological research which has been and is still producing crops which answer Kenya's agricultural and nutritional needs; and whose safety for human consumption is already proven. By the same token Government should fund KARI to produce GM crops which meet the local food security and farming industry needs at all geoclimatic zones in all counties.

All GM and novel non-GM plants should meet all the safety requirements for human consumption.

### 10.8 The GM Task Force Recommendations on the Ban:

The Task Force is fully aware that GM technology is one of the biotechnological developments whose aim is to solve food availability and nutrition issues; in the context of an expanding global population and climate change. The Task Force would therefore urge government to encourage and support the development of this technology while at the same time as for all other technologies, putting in place safety measures so as to ensure that the GM technology delivers the promises it offers to humanity.

#### 10.8.1 Key Questions Considered By the Task Force Regarding GM Foods

- Are GM foods safe for human consumption? – Not Proven
- Are GM foods the only answer to food security in Kenya? - No
- Is the necessary legislation to assess the safety of GM foods for human consumption in place? – No
- Is there adequate infrastructure in place in Kenya at present available to assess, approve, monitor, trace, recall, inform on all matters relating to GM foods and food safety for human consumption? – No

**In view of the above, the GM Task Force recommends that the ban on GM imports be lifted on a case-by-case basis subject to the fulfilment of the conditions below:**

### 10.8.2 Need for New Legislation on The Safety of GM Food For Human Consumption

Noting that no GM product has so far been tested for safety for human consumption in Kenya, a new screening system which will require new legislation will have to be put in place. The present Biosafety Act has no specific provision for testing GM products for safety for human consumption.

### 10.8.3 Requirement For Acute And Sub-Acute Toxicity Testing

All GM products must pass a preliminary, independently verified, 90-day animal feeding study, which cover the acute and sub-acute phase of testing for human consumption. The 90-day feeding tests will qualify the GM producer for the issuance of a Class A permit from the Food Safety and Quality Control Unit of the Ministry of Health. This permit should be for a limited period not exceeding two (2) years.

### 10.8.4 Requirement for Chronic Toxicity Testing

All GM products must pass an independently verified 2-year animal feeding chronic toxicity test. This test will rule out carcinogenicity, teratogenicity, etc. The Chronic toxicity tests will qualify the GM producer for the issuance of a Class B permit from the Food Safety and Quality Control Unit of the Ministry of Health. This permit should be for a period not exceeding five (5) years.

### 10.8.5 Requirement for Long-Term and Epidemiological Surveillance Testing

The long term tests will involve animal testing for at least three generations to rule out any transgenerational harm. The epidemiological tests will take the form of surveillance by the Ministry of Health on human populations for at least two generations i.e. from childhood to adulthood for the first generation and their offspring. This testing will use the usual epidemiological tools for surveillance. The long term and epidemiological surveillance testing will qualify the GM producer for the issuance of a Class C permit declaring the product safe for human consumption and needing no further tests.

### 10.8.6 Responsibility for Reparation

Any GM producer whose product causes harm as confirmed by metabolomics, by animal and human testing and or through accepted new technologies involving *in silico* (computer) modelling will be held fully responsible for making good the harm and for reparation.

The issuing authority may withdraw any permit if later testing including chronic testing and surveillance reveals harm.

### 10.8.7 Definition of the Role of the Food Safety and Quality Control Unit of The Ministry Of Health

The specific role of GM food safety evaluation for human consumption is a State Department of Health issue. Therefore they should be responsible for issuing the permits after consultation with the appropriate regulatory agencies and the Pharmacies and Poisons Board.

In case of severe famine where there is threat of loss of life, the President on the advice of the Cabinet, may instruct the Food Safety and Quality Control Unit to issue a special permit for the importation of life-saving food for a limited period provided that such cannot be used as seed for cultivation and has been declared fit for human consumption.

Notwithstanding this, every effort will be made to source the food from non-GMO sources, failing which emergency GM food may be allowed in.

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## Annex I: Letter by Food and Agriculture Administration, USA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

October 18, 2000

Kent A. Croon
Regulatory Affairs Manager
Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198

Dear Dr. Croon:

This is in regard to Monsanto 's consultation with the Food and Drug Administration (FDA) (Center for Veterinary Medicine and Center for Food Safety and Applied Nutrition) on its genetically modified Roundup Ready® NK603 corn. According to Monsanto , this new line is modified for herbicide tolerance through the expression of the 5-enolpyruvylshikimate-3-phosphate synthase gene (EPSPS) isolated from *Agrobacterium tumefaciens* sp. CP4. The CP4 EPSPS gene encodes the 5-enolpyruvylshikimate-3-phosphate synthase, which confers tolerance to glyphosate (Roundup®) herbicide.

As part of bringing the consultation regarding this product to closure, Monsanto submitted a summary of its safety and nutritional assessment of the genetically modified Roundup Ready® NK603 corn on February 28, 2000. This communication informed the FDA of the steps taken by Monsanto to ensure that this product complies with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment Monsanto has conducted, it is our understanding that Monsanto has concluded that the Roundup Ready® NK603 corn grain and forage derived from the new variety, are not materially different in composition, safety, and other relevant parameters from corn grain and forage currently on the market and that it does not raise issues that would require premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF 0071. This file will be maintained in the Office of Premarket Approval.

Based on the information Monsanto has presented to FDA, we have no further questions concerning grain and forage from the Roundup Ready® NK603 corn at this time. However, as you are aware, it is Monsanto 's continued responsibility to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Sincerely yours.

/s/
Alan M. Rulis. Ph.D.
Director
Office of Premarket Approval

**Annex II: Approved Contained Use Research Activities of Genetically Modified Organisms at ILRI**

| NO | NAME OF APPLICANT | TITLE OF APPLICATION | LOCATION/SITE OF FACILITY | DESIRED TRAIT | DATE APPROVED | REMARKS |
|---|---|---|---|---|---|---|
| 1 | International Livestock Research Institute (ILRI) | Application to carry out genetic modification of banana for disease resistance under laboratory and greenhouse conditions in Kenya | ILRI facility-Nairobi | Bacterial wilt disease resistance | 11th March 2011 | Approval was given after a thorough risk assessment and the risk management measures put in place were found acceptable. |
| 2 | International Livestock Research Institute (ILRI) | Application to carry out genetic transformation of pigeon pea for insect resistance under laboratory and greenhouse condition in Kenya | ILRI facility-Nairobi | Insect resistance | 11th March 2011 | Approval was given after a thorough risk assessment and the risk management measures put in place were found acceptable. |
| 3 | International Livestock Research Institute (ILRI) | Application to carry out genetic transformation of cassava for stress tolerance under laboratory and greenhouse conditions in Kenya | ILRI facility-Nairobi | Stress tolerance | 11th March 2011 | Approval was given after a thorough risk assessment and the risk management measures put in place were found acceptable. |
| 4 | International Livestock Research Institute (ILRI) | Application to carry out genetic modification of Yam (Dioscorea spp) for nematode resistance in laboratory and greenhouse | ILRI facility-Nairobi | Nematode resistance | 11th March 2011 | Approval was given after a thorough risk assessment and the risk management measures put in place were found |

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| | | conditions in Kenya | | | | acceptable. |
| 5 | International Livestock Research Institute (ILRI) | Application to carry out genetic modification work of cassava for resistance to cassava brown streak disease under Laboratory and greenhouse conditions in Kenya | ILRI facility-Nairobi | Virus resistance | 11th August 2011 | Approval was given after a thorough risk assessment and the risk management measures put in place were found acceptable. |
| 6 | International Livestock Research Institute (ILRI) | Application for contained use of Knockout Mice of C57BL/6 mouse strain and A/J mouse strain from Korea, for laboratory studies of gene function. | ILRI facility-Nairobi | Trypanosome resistance model studies on mice | 1st December 2011 | Approval was given after a thorough risk assessment and the risk management measures put in place were found acceptable. |
| 7 | International Livestock Research Institute (ILRI) | Application for Proof of Concept: Test of transgene in cattle (Bos Taurus) under containment to study basic mechanisms underlying trypanosome resistance. | ILRI facility-Nairobi | Trypanosome resistance in cow | 1st December 2011 | Approval was given after a thorough risk assessment and the risk management measures put in place were found acceptable. |
| 8 | International Livestock Research Institute (ILRI) | Application to carry out genetic modification of banana for development of doubled haploid plants under laboratory and greenhouse | ILRI facility-Nairobi | Double haploidy to speed up the breeding process | 11th May 2012 | Approval was given after a thorough risk assessment and the risk management measures put in place were found acceptable. |

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| | | conditions in Kenya. | | | | |
| 9 | International Livestock Research Institute (ILRI) | Application for accelerating the development of improved vaccines against livestock infections caused by members of the Mycoplasma mycoides cluster through the application of targeted mutagenesis | ILRI facility-Nairobi | Vaccine development | 11th May 2012 | Approval was given after a thorough risk assessment and the risk management measures put in place were found acceptable. |
| 10 | International Livestock Research Institute (ILRI) in collaboration with Kenyatta University | Application to introduce Genetically modified sweet potato with weevil resistance for contained use in laboratory and greenhouse trials in Kenya | ILRI facility and Kenyatta University-Nairobi County | Insect resistance | 6th April 2010 | The approval was given by the National Biosafety Committee after a thorough risk assessment and the risk management measures put in place were found acceptable. |
| 11 | International Livestock Research Institute (ILRI) in Collaboration with International Potato Centre (CIP) | Application to conduct research on late blight resistant potato containing resistance genes under laboratory and green house conditions in Kenya. | ILRI Facility-Nairobi | Disease resistance | 5th November 2012 | Approval was given by the National Biosafety Authority after a thorough risk assessment and the risk management measures put in place were found acceptable. |
| 12 | International Livestock Research | Application for contained use activities | ILRI Biosafety Level 2 | Animal vaccines rationally | 6th March 2014 | Approval was given after a thorough risk |

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| | Institute (ILRI) | involving recombinant antigen delivery systems containing defined antigens of the African swine fever virus (ASFV) and rationally attenuated or mutated ASFV viruses. | Facility, Nairobi County | designed for the specific control and eradicatio n of diseases | | assessment and the risk management measures put in place were found acceptable. |
| 13 | International Livestock Research Institute (ILRI) | Application for contained use activities involving development of improved vaccines for the control of East Coast Fever Disease in cattle in Africa. | ILRI Biosafety Level 2 Facility, Nairobi County | Animal vaccines rationally designed for the specific control and eradicatio n of diseases | 14th April 2014 | Approval was given after a thorough risk assessment and the risk management measures put in place were found acceptable. |
| 14 | International Livestock Research Institute (ILRI) | Application for contained use activities involving the development of effective Rift Valley Fever Vaccines for use in sheep. | ILRI Biosafety Level 2 Facility, Nairobi County | Animal vaccines rationally designed for the specific control and eradicatio n of diseases | 14th April 2014 | Approval was given after a thorough risk assessment and the risk management measures put in place were found acceptable. |
| 15 | International Livestock Research Institute (ILRI) | Application for contained use activities involving development of an agrobacterium-mediated transformation and | ILRI Biosafety Level 2 Facility, Nairobi County | Drought tolerance | 14th April 2014 | Approval was given after a thorough risk assessment and the risk management measures put in place were found |

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| | | regeneration protocol for cowpea with drought tolerance trait. | | | | acceptable. |
| 16 | International Livestock Research Institute (ILRI) | Application for contained use activities involving genetic modification for cassava expressing resistance to Cassava Bacterial Blight Disease (CBB). | ILRI Biosafety Level 2 Facility, Nairobi County | Disease resistance – Cassava Bacterial Blight | 14th April 2014 | Approval was given after a thorough risk assessment and the risk management measures put in place were found acceptable. |

**Annex III: Approved Confined Field Trials (CFTs) Activities of Genetically Modified Organisms**

| NO | NAME OF APPLICANT | TITLE OF APPLICATION | LOCATION/SITE OF TRIAL | INTRODUCED / MODIFIED TRAIT(S) | DATE APPROVED | REMARKS |
|---|---|---|---|---|---|---|
| 1 | Kenya Agricultural Research Institute (KARI) | Application to introduce Transgenic maize with water efficiency event MON 87460 to carry out confined field trials under moisture stress at Kiboko in Kenya | KARI, Kiboko sub-station, Makueni County | Water efficiency/ Drought tolerance | 16th August 2010 | Approval was given after a thorough risk assessment and the risk management measures put in place were found acceptable. |
| 2 | Kenya Agricultural Research Institute (KARI) | Application to conduct confined field trial of transgenic Cassava expressing siRNA and G5 protein for resistance to cassava Mosaic Disease in Kenya | KARI Alupe Sub-centre, Busia County | Virus resistance | 18th January 2011 | Approval was given after a thorough risk assessment and the risk management measures put in place were found acceptable. |
| 3 | Kenya Agricultural Research Institute (KARI) | Application to introduce transgenic cassava containing Pro-vitamin A (DXS+PSY) genes for confined field trials in Kenya | KARI Alupe Sub-centre, Busia County | Nutritional change; Vitamin A enhanced cassava | 18th January 2011 | Approval was given after a thorough risk assessment and the risk management measures put in place were found acceptable. |
| 4 | Kenya Agricultural Research Institute (KARI) | Application to conduct a CFT of transgenic sorghum containing pro-vitamin A, improved | KARI, Kiboko sub-station, Makueni | Nutritional change; Bio-fortified sorghum | 11th August 2011 | Approval was given after a thorough risk assessment and the risk |

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| | | sorghum protein quality, digestibility, enhanced iron and Zinc availability | County | | | management measures put in place were found acceptable. |
| 5 | Kenya Agricultural Research Institute (KARI) | Application by KARI to conduct confined field trial of transgenic cassava expressing siRNA for resistance to cassava brown streak disease in Kenya | KARI Mtwapa Centre, (Kilifi County) | Virus resistance | 27th April 2012 | Approval was given after a thorough risk assessment and the risk management measures put in place were found acceptable. |
| 6 | Kenya Agricultural Research Institute (KARI) | Application to conduct Confined Field Trial of transgenic maize with Bt event MON810 containing Cry1ab gene to evaluate the efficacy of Bt delta (δ) endotoxin against maize stem borers in Kenya. | KARI, Kiboko sub-station, Makueni County | Insect resistance | 30th Octobe r 2012 | The approval was given by the National Biosafety Authority after a thorough risk assessment and the risk management measures put in place were found acceptable. |
| 7 | Kenya Agricultural Research Institute (KARI) | Application to introduce cassava containing Cassava Brown Streak Disease (CBSD) genes for confined field trials in Kenya. | Two sites namely; KARI Alupe Research Sub-Centre (Busia County) and KARI Mtwapa Research Centre | Virus resistance | 26th Septem ber 2013 | The approval was given by the National Biosafety Authority after a thorough risk assessment and the risk management measures put in place were found |

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| | | | (Kilifi County | | | acceptable. |
| 8 | Kenya Agricultural Research Institute (KARI) | Application for the evaluation of transgenic Gypsophila paniculata (Baby's breath) containing PAP-1 Gene for pink flower colour stability at a CFT Facility at Beauty Line Farm, Naivasha, Kenya. | Beauty Line Flower Company-Naivasha, Nakuru County | Pink colour flower stability | 9th December 2013 | The approval was given by the National Biosafety Authority after a thorough risk assessment and the risk management measures put in place were found acceptable. |
| 9 | Masinde Muliro University of Science and Technology (MMUST) | Application for confined field trial (CFT) on the evaluation of transgenic cassava expressing African cassava mosaic virus (ACMV) and cassava brown streak virus (CBSV) resistance in Kenya | KARI–Alupe Sub Centre, Busia County | Virus resistance | 6th March 2014 | The approval was given by the National Biosafety Authority after a thorough risk assessment and the risk management measures put in place were found acceptable. |

## Annex IV: Some Ministry of Agriculture, Livestock and Fisheries, Food Security Projects and Programmes

| MEDIUM TERM FOOD SECURITY INTERVENTIONS | | | | | |
|---|---|---|---|---|---|
| *Project* | *Broad objective* | *Coverage* | *Funding to date* | *Partners* | *Major Achievements* |
| **National Accelerated Agriculture Inputs Access Programme (NAAIAP)** | Provision of subsidized inputs (seeds and fertilizer-Kilimo Plus pack for 1 acre) to small scale producers to increase agricultural productivity; credit support to progressive farmers- Kilimo Biashara | 35 Counties | Ksh 4.2 Billion | GoK<br>IDA<br>FAO<br>Egyptian Aid<br>Japan 2KR<br>Equity Bank | i) 638,460 small scale farmers supported<br>ii) Support to 19,000 returning victims of 2007/08 PEV<br>iii) 4,700 agro inputs suppliers trained and supported.<br>iv) 45,000 farmers given loan worth Ksh 1.42 Billion from commercial banks repayable at low interest rate of 12% |
| **Traditional High Value Crops Project**<br>**(Orphan crops)** | To promote cultivation and utilization of high value traditional crops (orphaned crops); to improve food diversification and drought tolerance | 101 ASAL districts | Ksh 1.05 Billion | GoK<br>EU/WB<br>GIZ<br>FAO | i) 4,750 MT of assorted seeds of high value traditional crops given to over 350,000 poor farmers.<br>ii) Over 7 Million cassava cuttings and potato vines distributed to poor farmers for planting. |
| **Njaa Marufuku Kenya (NMK)** | Provide cash grants to Community Groups, and private sector organizations to promote innovative food security initiatives; support school meals programmes. | Entire Country | Ksh 797 million | GoK<br>FAO | i) 4282 groups with grants of Ksh 536 million.<br>ii) 68 primary schools with grants of Ksh 149 million<br>iii) 98 private sector organizations and NGOs with grants of Ksh 112 Million. |

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| **Management of Post Harvest Crop Losses** | To manage post harvest crops losses | 40 Districts | Ksh 760 million | GoK | i) Procurement and distribution of 36 mobile driers of each capacity 5 tons per hour worth Ksh 750 million<br>ii) Development of Detailed Designs, Drawings and Bills of Quantities for 40 community stores to be constructed soon<br>iii) Construction of 8 cold stores and purchase of 44 refrigerated trucks for horticulture crops through HCDA<br>iv) Training of over 1.5 million farmers on post harvest and aflatoxin management |
| **Japan KR Food Aid Project** | Importation of food (maize) during periods of shortage; sale of imported maize to generate funds for food security support | Nationwide | 2.2 Billion | GoK<br>JICA | i) 70,199 MT of maize imported.<br>ii) 62,000 vulnerable households supported<br>iii) Ksh 1.5 Billion generated to support food security projects |
| **LONG TERM FOOD SECURITY INTERVENTIONS** | | | | | |
| **Rice Development Programme** | Promote rice as a strategic crop for food security | Country wide; major irrigation schemes | 1.7 Billion | GoK<br>JICA | i) Procurement and supply of 35 Rice mills to 35 farmers groups<br>ii) Purchase of 5 walking tractors<br>iii) Expansion of KARI seed supply unit<br>iv) Rehabilitation and modernization of Mwea and Ahero irrigation schemes (on-going)<br>v) Promotion of NERICA rice variety for non-irrigated rice |
| **Smallholder Horticulture Empowerment Promotion Unit** | To establish effective support system for horticulture smallholders nationwide. | Nyanza & Western provinces (22 counties) | 128 million | GoK<br>JICA | i) 12,000 farmers trained<br>ii) 282 groups supported |

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| **Project (SHEP UP)** | | | | | iii) 600 extension officers trained<br><br>iv) 7 km rural access road repaired |
| **Kenya Agricultural Productivity And Agribusiness Project (KAPAP)** | increase agricultural productivity and incomes of participating smallholder farmers | In selected districts in all provinces except Nairobi. | 4.79 Billion | GoK<br><br>WB | i) National Agricultural Sector Extension Policy (NASEP) and its Implementation Framework (NASEP-IF) developed and approved by cabinet;<br><br>ii) Inventory of Agricultural Extension Service Providers in Kenya undertaken;<br><br>iii) Inventory of developed Kenya Agricultural Research Institute (KARI) technologies undertaken;<br><br>iv) Draft National Agricultural Research System (NARS) Policy developed;<br><br>v) Uptake of new technologies and practices in 20 pilot districts;<br><br>viii) Support to Assessment of the Alignment of Existing sector Programmes/Projects to ASDS and MTP; and<br><br>Undertake ICT Needs Assessment for KARI, AIRC and KAPP Secretariat |
| **Eastern Africa Agricultural Productivity Project (EAAPP)** | To improve livelihood, agricultural production, reduce poverty, enhance food security and reduce unemployment | Regional – Kenya, Uganda, Tanzania and Ethiopia.- Kenya | Ksh 900 Million | GoK<br><br>IDA | i) Construction of Centre of Excellence (on-going)<br><br>ii) Support to 17 research projects ongoing.<br><br>iii) Bulking of rice, cassava, wheat and pasture seeds/planting materials at KARI centres and supply to farmers<br><br>iv) 9 micro enterprises supported for produce processing and value addition<br><br>v) Breeder seed production for wheat, rice and cassava<br><br>vi) Training of 1,200 farmers<br><br>vii) Training of 125 staff |

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| **NALEP-SIDA** | Promote pluralistic, efficient, effective and demand-driven extension services. | Entire Country | Ksh | SIDA | i) 900,900 Farmers reached through Extension/Training<br>ii) 5,751 Staff Trained<br>iii) 21,031 farm business plans developed with farmers<br>iv) 315 Farmers' stakeholder Fora<br>v) Credit access to 27,791 farmer groups<br>vi) 820,000 Women Youth Benefit from CC training<br>(NB: This project ended December 2011. Another project ASDS has been formulated to carry on) |
| **Promotion of Private Sector Development in Agriculture (PSDA)** | To support private investment in agriculture by supporting small and medium agricultural production and processing enterprises | 30 counties spread in Central, Eastern, Rift Valley, Western and Nyanza provinces. | 1.8 Billion | GoK<br>GIZ | i) 8 value chain studies for 8 commodities completed<br>ii) 330 biogas stations and 850,000 energy saving stoves installed<br>iii) 11 micro enterprises supported for produce processing, value addition and exporting<br>iv) Establishment and support of the Agribusiness Training Centre (ATC) at Cooperative College, Nairobi |
| **Small-scale Horticulture Development Project (SHDP)** | To increase household incomes of small scale horticultural production through increased production of horticultural products and enhanced marketing. | Kajiado, Narok, Nakuru, Elgeyo marakwet, Tharaka Nithi, Embu and Machakos | Ksh 2.1 Billion | GoK<br>ADB | i) Kabaa and Kathiga Gacheru irrigation schemes completed; Kabaa commissioned in November 2011.<br>ii) 3 other schemes above 70% completion.<br>iii) 18 KM access roads completed; 50 KM between 30-80% complete<br>iv) over 3,000 farmers trained. |

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| | | Counties. | | | |
| **Smallholder Horticultural Marketing Project (SHOMAP)** | To support value chain development of major horticulture crops and improve their marketing infrastructure | Nyanza<br>Western<br>Rift Valley<br>Central<br>Eastern | 1.9 Billion | GoK<br>IFAD | i) 14 Horticulture crops value chain analysis studies concluded.<br>ii) 161 marketing groups formed (134 trained).<br>iii) 46,400 borrowers benefitted – credit value of 2.1 Billion.<br>iv) 7 Roads spot repairs completed.<br>v) 10 bridges and drifts<br>vi) 25 markets structure designs completed; constructions to start soon |
| **Enhancement of Food Security through water harvesting** | Harvesting and conservation of rain water for agriculture production ; implementation of Constituency Based Water Harvesting Initiative. | Nationwide | Ksh.162 Million | GoK | i) 278 Water pans/dams constructed; 3011 pans/dams to be done this year.<br>ii) 82,500 farmers directly use harvested water for crop production |
| **Support to Irrigation** | Revive and renovate old irrigation schemes, expand new scheme, increase crop area under irrigation | Countrywide | 2.2 Billion | GoK<br>ADB<br>JICA | i) Infrastructure developed in 10 irrigation schemes<br>ii) 40,936 Ha put under rice and maize production; total area under irrigation increased from 119,000 Ha in 2010 to 159,936 Ha. (For details on irrigation potential earmarked for future development, please see annex 2). |