GUIDELINES FOR INSPECTION AND MONITORING GMOS IN KENYA

Introduction

Inspection, Monitoring and Evaluation is a fairly new discipline all over the world. Monitoring is a regular, systematic and consistent assessment of the progress achieved in the implementation of an activity that is aimed at meeting set objectives, to ensure accountability, cost effectiveness, timeliness and quality and must include taking corrective measures. Inspection is the official examination of a regulated article to determine if genetically modified organisms are present and or to determine compliance with the laws and regulations.

The basic assumption in monitoring and evaluation is that, effective implementation of a project will have a positive impact on the economy, welfare of people, etc.

The main objective of monitoring and inspection is to ensure that the development, transport, use, transfer and release of any LMO are undertaken in a manner that prevents or reduces the risks to biological diversity taking also into account risks to human health.

Inspection and monitoring are an integral part of the biosafety framework to be implemented in Kenya due to:

- The rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity taking also into account risks to human health.
- The limited capabilities of many developing countries including Kenya to cope with the nature and scale of known and potential risks associated with living modified organisms.

Genetically Modified Organisms (GMOS) also called Living Modified Organisms (GMO's) are living organisms that possess a novel combination of genetic material obtained through the use of modern biotechnology. According to the Cartagena protocol on Biosafety, a living organism means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses or viroids.

- Modern biotechnology refers to
    a) *In vitro* nucleic acid techniques, including recombinant DNA (rDNA) and direct injection of nucleic acid into the cells or organelles or
    b) Fusion of the cells beyond the taxonomic family e.g. plant protoplasts that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional bleeding and selection.

The guidelines on biosafety in Kenya focuses on trans boundary movement of GMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account also risks to human health.

Modern biotechnology has great potential for human well being if developed and used with adequate safety measures for the environment and health.

2. Necessity to undertake monitoring and inspection

Inspection

Inspectors verify that the facility is appropriate for working with GMO/reagents while ensuring the safety of workers, facility and unintended or undesirable effects on human health and environment. Inspection will cover laboratory, growth chamber, and greenhouse and trial field and areas of focus will include the following aspects facilities:

- personnel,
- security,
- operational procedures

The inspector will determine if guidelines for good laboratory, growth chamber, greenhouse and field practices are adhered to. There are several reasons why monitoring and inspection of GMO is to be done in Kenya among these are:

- To keep track of the GMOS country
- To ensure that the conditions specified in the permit are followed
- To ensure labs are not handling GMOs which are in levels beyond what is approved
- To ensure that physical containment qualified persons handle facilities.
- To oversee that the field releases are done as per the requirements of NBC or the Board.
- To ensure that the plans and methods for monitoring and plans for emergency measures in case of accidents are in place
- To ensure that the commercial marketing of GMOs is properly authorised
- To collect information which may help to determine the impacts of the GMO to the environment
- To ensure compliance

3. Scope

These guidelines shall apply to trans boundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account also risks to human health.

4. Stages for inspection and monitoring

- Point of entry to address importation
- Storage and Handling
- Transportation
- Research laboratories
- Greenhouses
- Field confinement or testing in open quarantine and restricted sites
- Field releases to the general environment
- Pre-harvest
- Post-release- market

5. Introduction and commercialisation

Before the introduction of a GMO into the environment or into the market, permit must be obtained from the relevant Government agency. The regulatory body will control the introduction and commercialization of GMO's in Kenya. To introduce means to import, move interstate, or release into the environment (Annex 1) .

A submission fee will be prescribed which will be included together with the application. Officers from Custom and Excise Department of Kenya Revenue Authority (KRA) and the regulatory body shall monitor and inspect entry of GMO's for use in agriculture while Public Health Officers from the Ministry of Health will certify that GMO's intended for food or feed are safe.
Institutions like Universities and Agricultural Research Institutes and appropriate persons from these institutions will undertake research and develop GMO which are suitable for release in Kenya.
The recommendation for release and marketing of GMO's will take into account the socio – economic considerations arising from the impact of GMO's on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities. The possibility of gene flow between GMO's and landraces as well as wild relatives should also be taken into account.
The regulatory body will liaise with the Biosafety Authority on all matters regarding the importation, release and commercialization of GMO's.

6. Researching and developing stage

During the research and development of the GMO, there is a need to promote dialogue among the various stakeholders and reduce uncertainty about GMOS, and help design the transgene. There is also the importance of assessing GMO to evaluate the benefits vis a vis the risks e.g. its effect and impact on non-targets and other biodiversity. It will also be assessed to determine the gene flow to landraces and wild relatives and its consequences.

7. Risk assessment and risk management:

Risk assessment:
The purpose of risk assessment is to identify and evaluate the potential adverse effects of GMOs on the conservation and sustainable use of biological diversity in the likely potential receiving environment taking also into account the risks to human health. The risks to be assessed include: the expression of toxic or allergenic compounds, increased persistence in the environment and increase in weediness, transfer of genetic material, instability of the genetic modification, unintended effects. The risk assessment will be done by the Authority but then the inspection and monitoring will be done in the field and in the laboratories in order to verify the compliance with the permit conditions.

Methodology:

- Identification of any novel genotypic and phenotypic trait associated with the GMO that may have adverse effects on biological diversity in the likely potential receiving environment taking also into account risks to human health.

- An evaluation of the likelihood of these adverse effects being realized taking into account the kind of exposure of the potential receiving environment to the GMO.
- An evaluation of the consequences should the adverse effects be realized.

Risk Management:

The purpose of risk management is to establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions regarding the use, handling and transboundary movement of GMOs. Risk management allows appropriate period of observation of GMOs on a case-by-case basis, commensurate with its life cycle/generation time before its intended use. It will also help identify and evaluate GMOs or their traits that may have adverse effects on human health and environment.

A summary of the risk assessment of the effects of the GMO on the conservation and sustainable use of biological diversity, taking into account risks to human health will be given by the notifier / exporter.

The exporter will carry out the risk assessment and meet the cost of the assessment.

Risk management personnel will establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment associated with the use, handling and transboundary movement of GMOS. They shall impose necessary measures to prevent adverse effects of GMOS on conservation and sustainable use of biological diversity, taking into account risks to human health.

A risk assessment shall be carried out prior to the first release of a living modified organism.

8. Good Laboratory and Research Procedures

The Good Laboratory Practice has been in use in various laboratories. It is necessary that the laboratories undertaking GMO work are inspected to ensure that at least the minimum conditions for good laboratory practice are in place (Annex 2)

Appropriate laboratories should be identified in Research Institutions and Universities where good laboratory practices are upheld. They should have appropriate equipment to conduct biotechnological research and should have protective clothing, disposal facilities, cabinets etc. The inspectors will be monitoring exposure at workplace.

9. Containment facilities

To enable researchers to evaluate and develop GMOs under conditions which minimize the impact on the environment. It is important that the containment facilities are specified and should conform to the level of hazard (Table 3) that may be caused by the GMO (Annex 3). Both Physical and Biological Containment facilities will be inspected prior to the introduction of GMO and also during the project or programs implementation. The different levels of biosafety containment facilities are indicated in the Table 4.

10. Limited field releases

The confined field trials are necessary before first release. Confined field trials will be used for research of GMOs with novel traits to provide developers with an opportunity to:

a) Evaluate the performance of the GMOs

b) Study the environmental safety of the GMOs

c) Address the criteria and information required for risk assessment

d) Generate data for registration of variety

The exporter/ importer must apply for permit to conduct field trials
A map of confined field trial must be submitted before authorization

(i) To show general location
(ii) Exact trial dimensions and an indication of surrounding crops, particularly those that may lie within isolation distance.

The trial stations for GMOs will be restricted in terms of size and number e.g. no more than one hectare per trial site location and no more than 5 trial sites per province.

Inspectors will have authority to enter and inspect the trials either having given prior notice or even without a notice (Annex 4). In other words there will be non-notification inspection for surveillance or for routine purposes. There may also be prior notification for inspection. In case of prior notification, the information could be sought from the person concerned with the activity and this may assist the inspectors to determine whether to go on with the inspection or whether to rely on the information provided and consequently cancel the scheduled inspection.

11. Release to the market for food or feed (Annex 5).

Public awareness is necessary for the marketing of the GMO.
Biosafety Clearing House information will be needed if the GMO which is a transgene

(a) Is for food of feed.
(b) Has not known adverse effects on human health or environment

12. Accidental releases and mitigation

The inspectors will inform the Authority of the need to notify affected states or organizations for emergency measures to be put in place in case of accidental release.
All mitigation measures will be employed in the event that physical or biological containment inadvertently breaks down.

13. Monitoring during pre-release and post release experimentation.

The following principles are important and practice-oriented elements of *on field monitoring*:

a). Case-by-case observation of genetically modified organisms (GMO).
b). Utilization of existing infrastructures in the fields of agriculture, plant breeding

and, seed production to ensure the practicability of the observations.
c). Expert evaluation and communication of the obtained results.

Monitoring during pre-release:
The primary purpose is to assess the practical efficacy of adopted safeguards
Safeguards should be employed to reduce risks to acceptable level
If an adverse effect is detected its significance should be assessed and if found to have a high potential of significantly affecting environment emergency control measures should be taken including termination of release (Annex 4).

Post-release monitoring:
This will involve GMOs already released into the market. The main concern will be the possibility of continued novel trait in the environment during post harvest release if the trait has the potential to cause harm (Annex 7). Measures should be taken to ensure the released organism is absent after the trial is concluded. Any dispersal of the organism or gene should be monitored and control measures undertaken to control it.

Both pre- release and post release monitoring are necessary in order to determine whether the transgene genotype and phenotype

(a) is stable
(b) can be inherited
(c) has no epistatic effects
(d) is expressed as intended in different ecological zones.

It is important that tracking and surveillance are undertaken in order to determine effect of transgene GMO on non target and biodiversity impacts including risk to human health and also to prevent unintentional transboundary movement.

Monitoring and handling of new information
Following the placing on the market of a GMO as or in the product, the notifier shall ensure that that monitoring and reporting on it are carried out according to the conditions specified in the consent.

If new information has become available, from the users or other sources, with regard to the risks of the GMO to human health or the environment after the written consent has been given, the notifier shall immediately take measures necessary to protect human health and the environment, and inform the NBC accordingly. This will help determine whether there is need for amending the risk management strategy, especially if the initial risk given in the risk assessment report has changed.

The objective of monitoring is to:

- Confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in receiving environment are correct.
- Identify the occurrence of adverse effects of the GMO or its effects on human health
- Occurrence of the GMO in the environment in which it was not intended.

The interpretation of data collected by monitoring should be considered in the light of other existing conditions and activities. Where changes in the environment are observed, further assessment should be considered to establish they are a consequence of the GMO or its use, as such changes may be the result of environmental factors other than placing of the GMO on the market.

Adverse effects may occur directly or indirectly through mechanisms which may include:

- the spread of the GMO in the environment
- the transfer of the inserted genetic material to other organisms, or the same organism whether genetically modified or not
- phenotypic or genetic instability
- interactions with other organisms
- changes in management, including where applicable, in agricultural practices.

14. Tracking the residual GMOs

Records of all confined GMO field trials, including current season and post-harvest site monitoring, disposition of plant material, activities related to trial site compliance, and experimental data, must be maintained by the applicant and must be made available to the regulatory body or its agent on request. No harvested material or by-product from a confined field trial may be used as human food or livestock feed without approval of the regulatory body.
Progeny from any GMO trial cannot be retained for future planting without prior authorization by the regulatory body.
Applicants must notify the regulatory body in writing of crop Species planted on trial sites for each year the sites are subject to post -harvest restriction.

15. Notification requirements and procedures

A written consent should be given to the exporter by the regulatory body within 150-210 days where approved with a copy to Biosafety Authority.
Where an application is rejected additional information may be sought.

16. Packaging / handling / storage / transportation

In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, GMOS should handled, packaged and transported under conditions of safety, as per relevant international rules and standards.
GMOS intended for direct use as food or feed should be clearly labeled e.g.
"use as food, do not introduce into environment." etc.
GMOS destined for contained use should specify the requirements for safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the GMOS are consigned (Annex 1)

17. Labeling, traceability and identification

To ensure good laboratory practice, supervisors should ensure that all-incoming containers of hazardous materials bear a label specifying:

- the name of the hazardous chemical.
- the appropriate hazard warning.
- the name and address of the manufacturer or other responsible party.

They should also ensure that workers do not remove or deface labels on containers of hazardous chemicals. When chemicals are transferred from the manufacturer's original container to a secondary container, that new container should be appropriately labeled as to chemical identity and hazard warning (Annex 2)

The inspectors will ensure that all the necessary measures regarding the placing on the market, the labeling and packaging of GMOs or their products comply with the relevant requirements applicable in Kenya as specified by a competent authority as given below (Annex 6):

GMOS for intended introduction into the environment should be clearly identified stating:

(a) the relevant traits and / or characteristics
(b) any requirements for safe handling, storage, transport and use
(c) the contact point for further information
(d) the name and address of importer and exporter
(e) a declaration that the movement is in conformity with the Biosafety guidelines applicable in Kenya.

18. Expertise and capacity needed for inspectors and handlers.

Inspectors and handlers should be trained graduates with a good background in

(a) Molecular biology
(b) Genetic transformation of plants
(c) Plant pathology
(d) Microbiology
(e) Entomology
(f) Others are engineers, architects, lawyers etc.

In-service courses and short courses will be undertaken by all the inspectors so as to induct them on the role of inspectors in as far as genetic modifications is concerned.

19. International agreements

The inspectors and handlers are expected to keep abreast with the requirements of international agreements and protocols such as Cartagena Protocol on Biosafety, Voluntary Code of Conduct under UNIDO, Codex alimentarius IPPC, CBD, and FAO

20. Regional arrangements and transboundary role of the inspectors

The inspection and monitoring should forge linkages with the neighbouring countries so as to encourage collaboration on matters of inspection. This linkage calls for appropriate domestic measures to be put in place to prevent illegal transboundary movement.

21.Compliance

The exporter and importer should comply with international rules regarding transboundary movement of GMOS and take responsibility for any damage or adverse effects that may arise as a result of the use of the GMOS especially with regard to biological diversity and risks to human health. The work of inspection and monitoring will entail assisting the Authority to enforce compliance with the Biosafety law by providing the necessary information. The framework of inspection and monitoring

will have a schedule of data and information collection system and in this respect the inspectors will determine frequency of data collection and determine who will collect the data.

The inspectors will also ensure that the information collected from the field is availed to all players through the Authority facilitate fast corrective measures.

Financial arrangements

The cost of risk assessment is to be met by notifier / exporter. Similarly, it will be necessary that the cost of inspection and monitoring is considered up-front to facilitate effective and timely inspection and monitoring.

A GUIDE TO INSPECTION AND MONITORING OF GENETICALLY ENGINEERED ORGANISMS

Annex I Shipment Information

Table 1A. Handling Transport, Packaging and Identification of GMO for Contained Use

Kenya Revenue Authority Import Declaration Form

Invoice

Date

	Exporter	Importer/Consignee	Contact Point Exporter Importer/Consignee Other
Company Or Institution			
Contact Person			
Street			
City, Postal Code			
Country			
Phone, Fax			
Email			

	Shipper reference number	Shipper contact details

Item	Amount	Weight/Volume	Description	Value

			Living modified organisms:	

ANY EQUIREMENTS FOR SAFE HANDLING, TRNSPORT AND USE	• As provided under application existing international requirements, • As provided under domestic regulatory framework, if any, • Any other requirements agreed to by the importer and exporter, or • In the event there is no requirement, indicate that there is no specific requirement

Table 1B. Handling Transport, Packaging and Identification of GMO for Contained Use
of Dangerous Goods

Shipper: Name Company or Institution Address Phone number	Air Waybill No Shipper's reference Number (optional)
Consignee: Company or Institution Contact Person Street, City Postal Code, Country Phone, Fax Email	Contact point Shipper Consignee Other Company or Institution Contact Person Street, city Postal Code, Country Phone, Fax
Two completed and signed copies of this Declarations must be handed to the operator	**WARNING**
TRANSPORT DETAILS Airport of Departure This shipment is within the Limitations prescribed for: Delete non-applicable) PASSENGER AND CARGO AIRCRAFT Airport of destination:	Failure to comply in all respects with the applicable Dangerous goods regulations may be in breach of the application law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent. Shipment Type: (delete non-applicable) NON-RADIOACTIVE

NATURE AND QUALITY OF DANGEROUS GOODS							
Dangerous Goods Identification							
Proper-shipping Name	Class or Division	UN or ID No	Packing Group	Subsidiary Risk	Quality and Type of Packing	Packing Instruction	Authorization
Infectious Substances Affecting Humans HIV gene bank in E.coli K12 Living modified organisms Dry Ice							
Additional requirements for the safe Handling, Storage, Transport and Use Prior Arrangements As Required By The IATA Dangerous Goods Regulations 1.3.3.1 Have Been Made. IATA/ICAO USED This material is for contained use only in a certified Safety Level 2 Facility 24hr. Emergency Contact Telephone No.							
I hereby declare that the contents of this consignment are fully and accurately Name/Title of signatory Described above by the proper shipping name and are classified, packaged, Name/Title of Signatory Marked and labeled/placarded, and are in all respects in proper condition for Place and Date Transport according to applicable international and national governmental regulations City, state, Country Date Signature (see warning above)							

Table 2. Handling Transport, Packaging and Identification of GMO for intentional introduction into the environment

Kenya Revenue Authority Import Declaration Form

Invoice

	Exporter	Importer	Contact Point Exporter Importer Other
Company Or Institution			
Constant Person			
Street			
City,Postal Code			
Country			
Phone; Fax			
EMAIL			

Shipping details	Shipper reference number	Shipper contact details

Item	**Amount**	**Weight/Volume**	**Description**	Value

Any Requirements For The Safe Handling, Storage, Transport And Use	• **See permit RICE3434-02**

I declare that transboundary movement/shipment is in conformity with the requirements of the Cartagena Protocol applicable to the exporter.

Signature of exporter_____ Date _____

Table2B. Handling Transport, Packaging and Identification of GMO for intentional introduction into the environment (Example of Completed form)

Kenya Revenue Authority Import Declaration Form
Invoice

	Exporter	Importer	Contact Point **Exporter** **Importer** **Other**
Company Or Institution			
Contact Person			
Street			
City, Postal Code			
Country			
Phone; Fax			

Email			

Shipping details	Shipper reference number	Shipper contact details

Item	Amount	Weight/Volume	Description	Value
Any Requirements For Safe Handling, Storage, Transport And Use		**No Specific Requirement**		

I declare that this transboundary movement/shipment is in conformity with the requirements of the Cartagena Protocol applicable to the exporter.

Signature of exporter_____
Date_____

Annex 2. Good Laboratory Practices

1. Awareness
Are laboratory workers familiar with unsafe conditions and actions, and appropriate corrective measures? .

Are all the working area/storage/containers clearly demarcated?
Are chemicals properly labeled and stored appropriately and bearing the following information:

- Type of container
- Note expiration dates of chemicals
- Use
- Storage condition

Biohazards & Infectious Waste

1. What chemicals/reagents /gmo are used in the lab?
2. What is the certified biosafety level of the lab?
3. Who certified the lab?

Biohazards

Is the concept of "universal precautions" being observed when infectious materials or by-products are present? Yes _____ No _____.

Are international biohazard symbols posted on all entrances to biohazard work areas along with pertinent emergency information? Yes ___ No _____

The laboratory supervisor is responsible for the safety of laboratory workers in their area. In handling biohazardous materials, the supervisor should consider:

- The biosafety level established for the lab by NBC.
- Laboratory supervisor s 'qualification/experience
- Qualifications of the other persons working in the lab

Access to the Labs

Is access restricted to authorized personnel only Yes ___ No _____.

Waste Disposal

Are waste disposal containers/bins/bags provided? Yes ____ No____
Are waste disposal areas clearly designated?

Biological Wastes? Yes ____ No _____

Animal wastes? Yes ____ No _____
.
Sharps? Yes ____ No _____

Spillage wastes? Yes ____ No _____

Isolation wastes? Yes ____ No _____

Are all biological materials, including recombinant DNA, being autoclaved prior to discarding? Yes ____ No _____.

Decontamination of Material

Autoclave (Wet Heat-Steam)
Is "Autoclave Usage For Safety and Quality Control" sign posted? Yes ____ No ____

Disinfectants
Is any of the following disinfectants in use?

- Alcohols? Yes ____ No ____
- Quaternary Ammonium Compounds? Yes ____ No ____
- Chlorine/Iodine? Yes ____ No ____
- Ethylene Oxide Gas? Yes ____ No ____

Personal Hygiene

Are instructions on personal hygiene provided?

- Hand washing before leaving laboratory. Yes ____ No _____
- Laundering clothing worn in laboratory separately from other clothing Yes ____ No _____
- Mouth pipette anything in the lab? Yes ____ No _____.
- Eating, drink or apply cosmetics in a laboratory or areas where chemicals/hazardous agents are stored? Yes ____ No _____
- Smoking in prohibited areas of the Biotechnology laboratories? Yes ____ No _____
- Food storage in a refrigerator where hazardous materials are stored ? Yes ____ No _____
- Eating or drinking from laboratory glassware ?Yes ____ No _____
- Wearing contact lenses in the laboratory ?Yes ____ No _____
- Wearing g long hair, loose sleeves/cuffs, rings, bracelets, etc. in close proximity to open flames or operating machinery ?Yes ____ No _____
- Keeping exposed skin covered eg wearing of shorts, sleeveless or short sleeve shirts, skirts or open-toed shoes in the laboratory? Yes ____ No ___.

Fire prevention

- Are workers aware of potential ignition sources in lab? Yes ____ No _____
- Is appropriate storage provided for flammable liquids ?Yes ____ No _____
- Are all electrical equipment cords inspected regularly? Yes ____ No _____.
- Are fire extinguishers clearly marked and in good conditions? Yes ____ No _____

Housekeeping

- Is laboratory work areas maintained n a good state of order ? Yes ____ No _____.
- Are there at least two clear passages to laboratory exits ? Yes ____ No _____..
- Is all equipment inspected before use? Yes ____ No _____.e.

Emergency Procedures

Safety and Biosafety Personnel.

Name _____

Phone Number_____

Are the contacts posted in the facility or outside the door? Yes ___ No_____

Are following safety devices provided and clearly marked?:

- Safety shower Yes ____ No _____
- Eye wash station Yes ____ No _____
- Protective respiratory gear Yes ____ No _____
- Fume hood Yes ____ No _____
- Spill cleanup materials Yes ____ No _____
- First aid kit Yes ____ No _____
- Fire alarm Yes ____ No _____
- Fire extinguisher Yes ____ No _____

- Smoke detectors Yes ____ No _____
- Emergency exits Yes ____ No _____

Miscellaneous

- Are children and pets restricted into the laboratory? Yes ___ No___
- Is working after hours allowed? Yes ___ No _____
- Are other laboratory personnel informed of the presence of others? Yes __ No ____

Personal Protective Equipment

Eye Protection

- Are appropriate eyewear provided and used at all times? Yes____ No_____.

Protective Clothing

- Are appropriate protective clothing worn in the facility? Yes____ No_____.
- Are the protective clothing of the appropriate material? Yes____ No_____

Hand Protection

1.Are personnel into the habit of wearing protective gloves? Yes____ No_____.
2.Are the gloves of the appropriate make as specified below and free from holes, punctures, and tears? Yes____ No_____. .

A. PVC protects against mild corrosives and irritants.
B. Latex provides light protection against irritants and limited protection against infectious agents.
C. Natural Rubber protects against mild corrosive material and electric shock.
D. Neoprene for working with solvents, oils, or mild corrosive material.
E. Cotton absorbs perspiration, keeps objects clean, and provides some limited fire retardant properties.
3.Are hands washed soon after removing protective gloves? Yes____ No_____

Foot Protection

- Is appropriate footwear eg closed shoes) being worn in the facility? Yes____ No____

Head Protection

- Are personnel encouraged to restrain long hair and use caps, elastic bands or hairnets ? Yes ____ No _____.

Respiratory Protection

- Is a respiratory protection program against noxious fumes and contaminants, in place? Yes____ No____

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Laboratory Safety Equipment

1.Are the following Equipment provided in the laboratory?

- Laboratory Chemical Fume Hood? Yes ___ No

- Lamina flow cabinets? Yes____ No____
- Chemical Storage Cabinets? Yes____ No____
- Refrigerators? Yes____ No____
- Eyewash Stations? Yes____ No____
- *S*afety Showers? Yes____ No____
- Fire Safety Equipment? Yes____ No____
- Are all workers instructed on the use and handling equipment? Yes __ No _____

2.Is the equipment in working and serviceable condition? Yes __ No _____

First Aid and Emergency Procedures

- Are first aid/ equipment installed in the every laboratory? Yes ___ Yes___
- Are emergency procedures and equipment provided? Yes ___ Yes___
- Are workers familiar with first aid and emergency procedure? Yes ___ Yes___

Labeling

1.Are labels clearly posted in the facility and containers? Yes ___No____.
2.Are the following warning /hazard signs appropriately posted?

- Danger? Yes ____ No _____.
- Contains Inorganic Arsenic? Yes ____ No _____.
- Cancer Hazard? Yes ____ No _____.
- Harmful If Inhaled Or Swallowed? Yes ____ No _____.
- Use Only With Adequate Ventilation? Yes ____ No _____.

Hazard Information

- Are hazard warnings displayed on hazardous chemical containers? Yes __ No _____
- Are picture and symbol of hazard warnings accompany hazardous compounds? Yes ____ No _____.
- Are the following hazardous compounds stored in the facility explosives _____, poisons _____, oxidizers_____, compressed gases_____, flammables _____, radiation_____, corrosives_____, biohazards _____ (please indicate Yes or No)

Label Use

Are all incoming containers of hazardous materials bear a label specifying:

- the name of the hazardous chemical? Yes ___ No _____.
- the appropriate hazard warning? Yes ___ No _____.
- the name and address of the manufacturer or other responsible party? Yes ___ No _____.

Employee Orientation

1.Are worker's trained at initial arrival to the facility and prior to new exposure situations? Yes ___ No _____
2.Employee Information

A. Are workers familiar with all procedures in the work area? Yes ___ No _____

B. Location and availability of known reference material on the hazard? Yes ___ No _____

C. Safe handling, storage and disposal of hazardous chemicals? Yes ___ No _____

D. Signs and symptoms associated with exposures to hazardous chemicals ? Yes ___ No _____

Employee Training

- Are workers appropriately trained how to handle equipment? Yes ___ No _____ .

Record-keeping

- Are records kept of staff attendance Yes ___ No _____.
- Are there signed statement from employees indicating that they have received the appropriate training ? Yes ___ No _____..

Annex III Containment Facilities

Address of Facility	Responsible Person
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
Telephone Number _____	Telephone Number _____

Location Of All Facilities Covered By This Inspection

Building Name_____
Room/Laboratory_____
Growth Chamber Identification_____
Greenhouse Number or other Identification_____

1. Is there a written policy regarding handling of GMO/ rDNA in this facility? Yes___ No____

2. Provide name and title of the chairperson of the Institutional Biosafety Committee (IBC)
   _____

3. Provide name and title of the scientist who will conduct the research?
   _____

4. Is the scientist who is conducting the research the applicant? Yes_____ No_____

5. What other scientists and technicians will be working on the research?

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6. Do researchers and laboratory technicians practice and adhere to the guidelines governing work with GMOs? Yes___ No_____

Physical Design And Security

7. Provide a short description of how the GMO is physical marked and identified in the laboratory, growth chamber, and greenhouse. Provide floor plan and/or map of facilities if possible

8. Is the general area secure from public access? Yes___ No___
If not, please elaborate.

9. Is the general area secure from unauthorized personnel? Yes___ No____
If not, please elaborate.
10. Can individual laboratories be locked? Yes____ No____
11. Is a sign posted on the facility door stating presence of GMOs Yes__ No_____

If not, when will a sign be installed? Date_____

12. Who else is allowed in the research areas?
Cleaning Personnel Yes____ No__, Other Yes___ No____

13. How distant from each other are the germination laboratories, growth chambers, and greenhouses? Be specific.

12. What kind of records, logs, or inventory are maintained regarding receipt, increase, and destruction of GMOs ?

i. Handling of GMO - Germination

13. Is there a cabinet to store seeds, plant material, tissue cultures, e.t.c?
Yes___No____
If yes, does it have a lock? Yes_____ No_____

14. Is the storage container identified with a sign stating it contains a GMO Yes_____ No_____
If not, when will a sign be installed? Date_____

15. Where will seeds, tissue cultures, plant material, etc. be grown or germinated?

16. What medium will be used for seed germination? (e.g., germination paper, perlite, sand)

17. Is there any danger of seeds, tissue cultures, plants material, etc. being lost during this germination process, or of ungerminated seed being transferred into subsequent research stage? Ye ___ No____

18. Are there any cracks or irregular surfaces in the germination laboratory/chamber that could trap seeds? Yes_____ No____ If yes, describe size and location of cracks.

19. Are there water drains in the laboratory? Yes___No____

20. Are the drains screened? Yes____No____ If so, what is the size of the screen?

21. Does the drain system enter into a special waste trap? Yes___No____

22. How will the germinated seed be moved to the growth chamber?

23. How will petri dishes, tissue culture, spores, plant materials, etc. be moved from the laminar flow hood, to the incubator, to the growth chamber?

24. How will the GMOs be kept separate from other organisms?

ii. Handling of GMO - Growth Chamber__

25. Does growth chamber have access by authorized personnel only? Yes____ No_____

26. Describe the growth chamber. Lab top__ walk in____ built on site_____ other____.

27. Will the material be grown with any other plant materials in the same chamber? Yes__ No____
If yes, name the types of plants.

28. How will genetically engineered plants and/or containers be physically marked?

29. Does the growth chamber have water drains? Yes_____No_____
If so, can they be screened? Yes_____ No_____

30.Does the drain system enter into a special was trap? Yes____No_____

31. Where is the autoclave or incinerator in relation to the growth chamber?

32. Can the growth chamber be locked and separated from other growth chamber(s)? Yes__No__

33. How will the material be transferred to the greenhouse?

34. How will the regulated article be kept separate from other organisms?

iii. Handling of GMO - Greenhouse__

35. What is the name of the greenhouse manager?_____

36. Is the greenhouse accessed by authorized personnel only? Yes___No____

37. A. Has the greenhouse a double door entry system? Yes___No____
B. Is the greenhouse entry through a "headhouse"? Yes_____No_____

38. A. Do the greenhouse doors have locks? Yes____No_____
B. Is there a rear exit door? Yes____No_____

39. What type of greenhouse? Glass____ Lexan____Plastic Poly____Screen____Other_____
If screen, what size mesh? _____ If Poly, what thickness?_____

40. What are the approximate outside dimensions of the Greenhouse(s)?

41. A. Do the roof vents open? Yes_____ No_____
B. If the roof vent opens, is it screened? Yes___ No___What size is the screen mesh?_____
42. What kind of floor does the greenhouse have?
Concrete_____ Gravel____ Packed Dirt_____ other (Explain)_____

43. Does the greenhouse has water drains? Yes_____ No_____
Do they enter into a special waste trap? Yes_____ No_____
44. A. Does the greenhouse have black light traps for vectors? Yes_____ No____
B. Does the greenhouse have "Sticky Board" traps for vectors? Yes___No___
C. Does the greenhouse have other kinds of vector traps? Describe.

45. How will the plants be grown in the greenhouse? On Benches____ In Flats___In Pots___ Other (describe)_____

46. Will there be physical markers on each plant or container indicating that the plants will be grown?

47. Where is the autoclave or incinerator in relation to where the plants will be grown?

48. Are there any openings in the greenhouse through which animals and pollinating insects could enter? Yes____ No____

49. How will the GMO be kept separate from other organisms?

iv. General Considerations

What kind of "spill response" action plan/equipment is available for items spilled in transit between labs, chambers, and greenhouses?

What containers are used for carrying items to avoid spillage?

Are any similar plants growing in the area, either on the facility grounds or outside of the facility grounds?

What other factors are present which may influence the handling of seed or plants and may have an effect on containment or risk?

Inspect for other specific conditions as stipulated on the permit.

_____
_____

Name of state Plant Pest regulatory Official Performing Inspection

Printed Name of PPQ Officer Performing Inspection

_____

Signature

Instructions to the inspector: Complete this form and return to The Competent Authority eg NBC

v. Reinspection of Containment for Genetically Engineered Organisms

Address of Facility
_____
_____
_____

Applicant (Responsible Person)
Name_____
_____
Address_____

Telephone Number

Telephone Number

Location of all facilities covered by this Inspection
Building Name_____
Room/Laboratory_____
Growth Chamber Identification_____
Greenhouse Number or other Identification _____

Research Qualifications_____

1. Who is the scientist responsible for conducting the research?

_____

2. Who was the responsible scientist at the time of the initial facility inspection?

_____

3. Do researchers and laboratory technicians regularly review, practice, and adhere to the permit protocol and the conditions described in the permit? Yes____ No _____

4. Conditions were reviewed by applicant and/or technicians on _____ (date).

5. Have any major changes occurred or new operational procedures been instituted since the initial inspection? Yes____ No____ If YES, initiate and complete a new facility inspection checklist.

6. Are the permit articles or any other regulated organisms derived from these articles still in use? Yes ____No_____ or in storage? Yes ____No____

7. Have all of the GMOs been properly destroyed? Yes ____ No____
Date_____. If yes, no further action is required.

General Considerations_____

Remarks and/or observations.

Other factors which may influence the handling of seed or plants and may have an effect on continued containment or unwanted release.

Inspect or spot check for other specific conditions as stipulated in the permit.

_____ _____

Name of State Plant Pest Regulatory Official Performing Inspection

Printed Name of PPQ Officer Performing Inspection

_____

Signature

Table 3. Criteria for assigning crops/GMO to biosafety levels

Criteria	**Transgenic Plants**	**Transgenic Microbes** **Exotic**	**Non-Exotic**	Transgenic **Insects/Animals/Assoc. Microbes**
Not a noxious weed or cannot outcross with one	BL1-P			
Not easily disseminated				
No detriment to environment		BL2-P or BL1-P +	BL1-P	BL2-P or BL1-P +
Noxious weed or can interbreed with weeds	BL2-P or BL1-P +			
Contains complete genome of non-EIA*	BL2-P or BL1-P +			
Contains genome of EIA	BL3-P or BL2-P +			
Treated with an EIA	BL3-P or BL2-P +			
Detriment to environment		BL3-P-4**	BL2-P or BL1-P +	Bl3-P or Bl2-P +
Involves EIA with detriment to environment	BL3-P or Bl2-P +			
May reconstitute genome of infectious agent in planta	BL3-P or Bl2-P +			
Contains Vertebrate Toxin	BL3-P	BL3-P	Bl3-P	
*EIA-Exotic infectious Agent				
**BL4-P containment is recommended only for experiments with readily transmissible exotic infectious agents whether transgenic or not, such as air-borne fungi or viruses in the presence of their arthropod vectors that have the potential of being serious pathogens of major Kenya crops.				

Table 4 Standard Practices for containment of plants in the greenhouse

	Biosafety Level			
Practices	BL 1-P	BL 2-P	BL 3-P	BL 4-P
Access	Discretionary access	Access limited to individuals directly involved with experiment	Access restricted o required personnel only	Access restricted: secure locked doors; record kept of all entry/exit; clothing change/shower room through air lock is only means of entry/exit.
Instructions	Personnel must read and follow instructions	Personnel must read and follow instructions	Personnel must read and follow instructions	All who enter advised of hazards and safeguards
Procedures	Procedures followed appropriate for organisms	Greenhouse manual to advise of consequences: give contingency plans	Greenhouse manual to advise of consequences: give contingency plans	Greenhouse manual prepared and adopted; personnel required to follow contingency plans
Records	Records kept of experiments in facility	Records kept of experiments and movement in/out of greenhouse	Records kept of experiments and movement in/out of facility	Records kept of experimental material moving in/out of greenhouse
Transfer of materials		Containment required for movement in/out of greenhouse	Containment required for movement in/out: external decontamination	Special packaging containment for movement in/out of greenhouse: airlock or decontamination for removal

Delivery				Entry of supplies/materials through special chamber
Disposal	Biologically inactive experimental organisms at end of experiment	Biologically inactive experimental organisms at end of experiment: decontaminate gravel periodically	Biologically inactive experimental organisms at end of experiment (including water runoff); decontaminate equipment & supplies	Decontaminate experimental materials prior to removal from area by autoclaving/other means; all runoff water collected and decontaminated
Pest Control	Pest control program	Pest control program	Pest control program	Chemical control programmes for pests and pathogens
Precautionary Measures	Appropriate caging and precautions for escape of motile organisms	Appropriate caging and precautions for escape of motile organisms	Appropriate caging and precautions for escape of motile organisms	Appropriate caging and precautions for escape of motile organisms
Labeling		Sign for restricted experiment in progress with plant names, person responsible, special requirements	Sign for restricted experiment in progress; person responsible, special requirements; biohazard symbol if a risk to humans	Sign for restricted experiment in progress; person responsible, special requirements; biohazard symbol if a risk to humans
Disinfection/Fumigation			Minimize aerosol creation to reduce contamination	Standard microbiological procedures to decontaminate equipment and containers

Hygiene		Protective clothing worn to minimize dissemination; hanc washed before leav facility
Accidents/ accidental release		This should be Notified to the Competent authorit

Table 5. Mesh Sizes for Insect/Pollen Containment

	Screen Hole Size		
Adult Insect	**Mesh**	*Microns*	*Inches*
Leaf minors	40	640	0.025
Silverleaf whiteflies	52	460	0.018
Aphids	78	340	.0013
Thrips	132	190	0.0075
Pollen	50	512	

Annex IV: Limited Field Release Monitoring of GMOs

Name of the GMO_____
Type of genetic modification_____
Address of research facility _____
Applicants (Responsible person) Name _____
_____ Address_____

General location of the area _____
_____

1) Is the transgene genotype stable? Yes___ No___
   If no, explain.
2) Is the transgene phenotype stable? Yes____No____
   If no, explain.
3) Is the transgene stably inherited? Yes____ No____
   If no, explain.
4) Are there any epistatic effects in the GMO i.e. are there any genes that are silenced? Yes___ No____
   If yes, explain
5) If there is no gene silencing, is the transgene phenotype expressed as intended in different ecological zones? Yes__ No___

6) Does the GMO release have any undesirable effect on non target organisms in the environment such as competitors, preys, hosts, symbionts, predators, parasites and pathogens? Yes___ No___
   If yes, explain.
7) Does the GMO have any undesirable effect on the environment/ biodiversity in general? Yes___ No___
   If yes, explain.
8) Does the GMO pose any risk to human health, such as disease to humans including allergenic or toxic effects? Yes___ No___
   If yes, explain.
9) Does the GMO pose any risk to animals and plants, including allergenic or toxic effects? Yes___ No___

10) Is there any evidence the GMO may affect the dynamics of populations of species in the receiving environment and the genetic diversity of these species? Yes___ No____
    If yes, explain.

11) Is there any evidence the release of the GMO has altered the susceptibility to pathogens facilitating the dissemination of infectious diseases and/ or creating new reservoirs or vectors? Yes___ No___

12) Is there any evidence the GMO release has compromised prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of of genes conferring resistance to antibiotics in human or veterinary medicine? Yes___ No___.

13) Are there any studies being undertaken to indicate whether the GMO release has any effect on biogeochemical cycles such as changes in soil decomposition of organic material? Yes___ No___

14) What measures are being taken to prevent unintentional transboundary movement?
    _____
    _____
    _____

15. Has the GMO material been field tested undergone satisfactory evaluation under confinement facilities? Yes_____ No____
16. Has the researcher submitted an application to the NBC? Yes___ No___
    If yes, has the NBC approved the application? Yes___ No___
    Does the researcher have a release permit issued by the relevant regulatory authority? Yes___ No___
17. Is the researcher complying with the conditions given in the research permit? Yes___ No___
18. Does the researcher have a proper record of the results of his experiments? Yes____ No____
    if yes, has he/she submitted a copy of the results to the NBC?

19.Is the researcher conducting field experiments using exotic plant pests, pathogens or micro-organisms? Yes___ No___

20.Are the GMO plants under field evaluation being grown in plots located in restricted entry plots? Yes___ No___

21.What measures are being undertaken to prevent pollen from spreading? e.g bagging or deflowering etc.

---

22. Is their suitable plot isolation to prevent pollen transmission to other plants?
Yes_____ No_____
If yes, give details
_____
_____
_____

23.Is the harvested GMO material properly labelled and stored? Yes_____ No_____

24.Are there any known planned developments or changes in land use in the region which could influence the environmental impact of the GMO release? Yes___ No___.
If yes, specify.

Table 6. Isolation Distance (in ft) from contamination sources for selected groups

Crop	Foundation	Registered	Certified
Alfalfa	600	300	165
Maize (inbred)	660	-	-
Maize (Hybrid)			660
Cotton (Hybrid)	0	0	0
Grasses	900	300	165
Beans	0	0	0
Onion	5280	2640	1320
Peanuts	0	0	0
Pepper	200	100	30
Rape (self pollinated)	660	-	330
Rape (cross pollinated)	1320	-	330
Rice	10	10	10
Soybeans	0	0	0
Sunflower	2640	2640	2640
Sunflower hybrid	2640	-	2640
Tomato	200	100	30
Watermelon	2640	2640	1320

Annex V. Release To The Market For Food Or Animal Feed

Has the GMO material being considered for release into the Kenyan market been thoroughly tested for :

1. Agronomic values? Yes___ No____

2. True to type character (Phenotype)? Yes____ No____
3. Expression of particular genetic component? E.g. disease resistance, etc. Yes____ No____
4. Risk to human health and environment? Yes____ No____
5. If transgenic material is for the export, has Kenya will assessed the Biosafety practices in place at the proposed destination to ensure a negative impact on the local environment is avoided? Yes_____ No_____
6. If the transgenic material is for export, is there explicit approval in writing from the recipient country? Yes____ No_____

Conditions necessary for GMO release to market for food

1. Is the GMO contained in the commercial product specified by name or code? Yes____ No_____
2. Is the name and full contact of the person responsible for placing it on the market given? Yes_____ No____
3. Is the name and full address of the supplier of the control samples given? Yes___ No___
4. Is there a description of how the product and the GMO contained therein should be used? Yes___ No___
5. (a) Is there any difference in use or management of the GMO compared to similar non-GMO product? Yes___ No___
6. (b) If yes, is the difference in use highlighted? Yes___ No___
7. Is there a description of geographical areas and type of environment where the product is intended to be within the country? Yes___ No___
8. Are the intended categories of users of the product given on the label? eg. Industry, agriculture, skilled traders etc. Yes____ No_____
9. Is the information on the genetic modification sufficient for the purpose of registration, detection and identification of particular GMO contained in the product to facilitate post marketing control and inspection? Yes____ No___
10. Does the GMO product indicate either by leaflet or labeling measures to take in case of unintended release or misuse? Yes____ No____

Annex VI. GMO Product Identification and Labeling

- Does the label or accompanying document show
  1. The commercial name of the product? Yes___ No___
  2. The name of the GMO? Yes____ No____
  3. Name and address of importer and exporter? Yes____ No___
  4. Name of the dealer i.e. contact person who is established in the country? Yes ____ No____
  5. The contact point for further information? Yes___ No____

6. Precautionary measures regarding use and measures to take in case of unintended release or misuse? Yes____ No_____
7. Specific instructions or recommendations for safe storage and handling, and transport? Yes____ No___
8. Directions and proposed restrictions in the approved use of the GMO eg. For use as human food / or animal feed only. Yes____ No____
9. Is additional labeling with the words " **This product contains genetically modified organisms**" appearing on the label or accompanying document? Yes___ No___

- For products where in adventitious or technically unavoidable traces of authorized GMOs cannot be excluded, a minimum threshold may be established below which these products shall not have to be labeled as GMOs.

Annex VII: Post-Release Monitoring

1. Is their a record of all confined field trials, including current season and post harvest site monitoring? Yes___ No_____
2. How is the plant material disposed of?
3. Is the progeny from the first trial retained for future use? Yes___ No___
4. If yes, is there approval from the NBC? Yes___ No____
5. Is there a record of other crop species planted on the trial site? Yes___ No___
6. If yes, is the record sent to the NBC? Yes___ No___

To be filled by Inspectors

Is the monitoring plan submitted to the regulatory body sufficient in terms of:

1) Monitoring techniques: such as the methods for tracing the GMOs; specificity, sensitivity and reliability of the techniques; methods for detecting transgene transfer; duration and frequency of monitoring.

_____
_____
_____
_____
_____

2) Control of the release

_____
_____
_____
_____

3) Waste treatment (where applicable)

_____
_____

_____
_____

4) Emergency response plans

_____
_____
_____
_____

Full names of Inspector _____
Signature _____Date_____