NO. 2 OF 2009

THE BIOSAFETY ACT

SUBSIDIARY LEGISLATION

List of Subsidiary Legislation

Page

1. The Biosafety (Contained Use) Regulations.....3
2. The Biosafety (Environmental Release) Regulations..... 63
3. The Biosafety (Import, Export and Transit) Regulations.....75
4. The Biosafety (Labelling) Regulations..... 85

THE BIOSAFETY (CONTAINED USE) REGULATIONS

ARRANGEMENT OF REGULATIONS

PART I – PRELIMINARY

Regulation

1. Citation
2. Interpretation
3. Objective
4. Exceptions

PART II – CONTAINMENT MEASURES

5. Classification of containment levels
6. Institutional Biosafety Committee
7. Application for contained use
8. Consideration of application
9. Approval
10. Validity of the approved activity
11. Suspension or revocation of approval
12. Handling of new information
13. Contingency plans
14. Contents of contingency plans
15. Emergency measures

PART III – MISCELLANEOUS

16. Information sharing and records
17. Registration of decisions in the National Biosafety Clearing House
18. Confidential information
19. Good containment measures
20. Handling of modified plasmids and vectors
21. Penalties

SCHEDULES

TECHNIQUES WHICH DO NOT LEAD TO GENETICALLY MODIFIED ORGANISMS

CONTAINMENT MEASURES

APPLICATION FORMS FOR CONTAINED USE ACTIVITIES

FORM FOR APPROVAL TO CONDUCT CONTAINED USE ACTIVITY USING GENETICALLY MODIFIED ORGANISM

CONTINGENCY PLAN

THE BIOSAFETY (CONTAINED USE) REGULATIONS

[Legal Notice 96 of 2011]

PART I – PRELIMINARY

1. Citation

These Regulations may be cited as the Biosafety (Contained Use) Regulations.

2. Interpretation

In these Regulations unless the context otherwise requires—

"accident" means any incident involving a significant and unintended release of genetically modified organisms in the course of their contained use which could present an immediate or delayed hazard to human health and the environment;

"applicant" means a person making an application under these Regulations;

"Authority" means the National Biosafety Authority established under section 5 of the Act;

"Biosafety Clearing-House" means a mechanism for exchange of scientific, technical, environmental, socio-economic and legal information and experience with genetically modified organism;

"confined field trial" means any activity undertaken within a field and which involves genetically modified organisms which are controlled by specific measures to ensure safety for humans and for the environment;

"contained use" means any activity undertaken within a facility, installation or other physical structure, which involves genetically modified organisms which are controlled by specific measures;

"contained use premises" includes a facility, field, installation or other physical structure in which contained use is undertaken;

"Institutional Biosafety Committee" means a committee established under regulation 6 of these Regulations;

"genetically modified organism" means an organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology techniques;

"modern Biotechnology" includes the application of—

(a) in-vitro nucleic acid techniques including the use of recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or

(b) fusion of cells beyond the taxonomic family, that overcome natural physiological, reproductive and recombinant barriers and which are not techniques used in traditional breeding and selection;

"regulatory agency" means a regulatory agency as set out in the First Schedule to the Act, or such other agency as the Cabinet Secretary may, by Order in the *Gazette*, determine.

"research institution" includes a university, or any other research institution registered in Kenya or established under a written law, carrying out research involving genetically modified organisms;

"screening for completeness" means the evaluation of an application to ensure that all the administrative as well as technical requirements are met.

3. Objective

The objective of these Regulations is to ensure that potential adverse effects of genetically modified organisms are addressed to protect human health and the environment when conducting contained use.

4. Exceptions

These Regulations shall not apply—

(a) to genetically modified organisms which are pharmaceuticals for human use;

(b) where genetic modification is obtained through the use of the techniques or methods listed in the First Schedule;

(c) to the storage, culture, transport, destruction, disposal or use of genetically modified organisms which have been released into the environment in accordance with the Biosafety (Environmental Release) Regulations (sub. leg).

PART II – CONTAINMENT MEASURES

5. Classification of containment levels

(1) The Authority shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment, which might arise from the contained use of a genetically modified organism.

(2) The Authority in consultation with the relevant regulatory agency shall assess the suitability of a contained use premises to conduct contained use activity involving genetically modified organism.

(3) Upon carrying out the assessment, the Authority in consultation with the relevant regulatory agency shall determine the containment level of the contained use premises in accordance with the provisions of the Second Schedule.

(4) The containment levels under this Regulation apply to laboratory, greenhouse or screen house activities.

(5) Appropriate measures for confined field trials shall be determined through procedures developed by the Authority in consultation with the relevant Regulatory Agency.

6. Institutional Biosafety Committee

(1) A research institution undertaking contained use activities shall establish an Institutional Biosafety Committee.

(2) An Institutional Biosafety Committee shall consist of—

(a) biosafety officer(s);

(b) scientist(s) in the relevant field;

(c) representative(s) of technical staff;

(d) representative(s) of laboratory management;

(e) representative(s) of the community where the premises are situated; and

(f) representative(s) of the relevant regulatory agency.

(3) The functions of an Institutional Biosafety Committee shall be—

(a) to prepare applications for contained use activities and refer the applications to the Authority for approval;

(b) to advise the research institution on matters relating to biosafety;

(c) to assist the institution in the establishment of the appropriate monitoring mechanisms for risk assessments and risk management;

(d) to ensure compliance with the conditions set out in the approval;

(e) to review and ascertain the suitability of both physical and biological containment and control procedures appropriate to the level of assessed risk involved in research, development and application activities;

(f) to advice the institution and principal investigators on mitigation measures to be undertaken in case of an accident.

(4) A person shall not carry out contained use activity under these Regulations unless such activity is carried out within, or in collaboration with, a research institution.

(5) A person who contravenes sub regulation (4) commits an offence.

7. Application for contained use

(1) A person shall not undertake contained use without the written approval of the Authority.

(2) An application for contained use shall be made to the Authority through an Institutional Biosafety Committee.

(3) An application for contained use shall be in the form set out in the Third Schedule to these Regulations and shall be accompanied by an application fee of one hundred and seventy thousand shillings.

(4) A person who contravenes subregulation (1) commits an offence.

8. Consideration of application

(1) Upon receipt of an application under regulation 7, the Authority shall screen for completeness and circulate the application to the relevant regulatory agencies for further information, comments or reasoned objections.

(2) The Authority shall examine the application to confirm—

(a) that the application conforms with the requirements of these Regulations;

(b) the accuracy and completeness of the information given;

(c) the risk assessment submitted by the applicant;

(d) the level of contained uses; and

(e) where appropriate, the suitability of the containment and other protective measures, the waste management, and contingency measures.

(3) The Authority may—

(a) require the applicant to provide further information; or

(b) require the applicant to modify the conditions of the proposed contained use, or to amend the level assigned to the contained use; or

(c) limit the time for which the contained use should be permitted or subject it to certain specific conditions.

(4) The Authority shall communicate its final decision within one hundred and fifty days of receipt of the application but not earlier than ninety days of such receipt.

(5) For the purpose of calculating time, any period of time during which the Authority is awaiting any further information that it may have requested from the applicant shall not be taken into account.

9. Approval

(1) An approval for contained use shall be in the form set out in the Fourth Schedule.

(2) An approval granted under these Regulations shall be valid for the period of the activity in respect of which it is granted.

(3) An approval for contained use is not transferable.

10. Validity of the approved activity

(1) An approval under these Regulations shall be for the period of the activity.

(2) A grantee under these Regulations shall submit quarterly reports on the progress of the activity during the period of the approved activity.

11. Suspension or revocation of approval

(1) The Authority may suspend or revoke an approval granted under these Regulations, where the grantee is in contravention of the provisions of these Regulations.

(2) The Authority shall, before suspending or revoking an approval, give a written notice to the grantee to put in place such appropriate containment measures or other protective measures.

12. Handling of new information

(1) A grantee who subsequently becomes aware of information which could have significant consequences for the risks posed by it, shall inform the Authority of such information as soon as possible.

(2) A person who withholds any information that becomes available before and after the approval of the application, and which could reasonably be expected to change the evaluation of the risk posed by the activity, commits an offence and is liable on conviction to a fine not exceeding two million shillings or imprisonment for a term not exceeding ten years, or both.

(3) Where information which could have significant consequences for the risks posed by the contained use, subsequently becomes available, the Authority may require the grantee to modify the conditions of, or suspend or terminate, the contained use.

(4) A grantee, who wishes to request for an extension or to modify the contained use, may make a written request to the Authority and the Authority shall within thirty days acknowledge receipt of the request.

(5) The Authority shall review the request and where it considers that the proposed extension or modification—

(a) does not require risk assessment, the Authority shall communicate its decision within thirty days from the date of the receipt of the request; or

(b) may have material effect on the outcome of the risk assessment upon which the decision was based, the Authority shall, if is satisfied that a change is warranted, make a decision within one hundred days from the date of the receipt of the request.

13. Contingency plans

The Authority shall ensure that before contained use commences—

(a) the applicant draws up a contingency plan for contained use to mitigate against risk, whether immediate or delayed, to humans outside the premises or to the environment as a result of failure of the contained use measures;

(b) Information on such contingency plans, including the relevant safety measures to be applied, is supplied, to the relevant regulatory agency for purposes of monitoring for compliance.

14. Contents of contingency plans

Every contingency plan shall be in the form set out in the Fifth Schedule.

15. Emergency measures

(1) In the event of an accident, a grantee shall inform the Authority immediately and shall provide the following information—

(a) the circumstances and location of the accident;

(b) the identity and quantities of the genetically modified organisms;

(c) any information necessary to assess the effects of the accident on human beings, and the environment; and

(d) the measures taken to mitigate against risk.

(2) Where information is given pursuant to subregulation (1), the Authority shall—

(a) ensure that necessary measures are taken to control the effects of the accident;

(b) where possible, collect, information necessary for a full analysis of the accident; and

(c) where appropriate, make recommendations on how to avoid a similar accident in the future and to limit the effects thereof.

(3) A person who contravenes subregulation (1) commits an offence.

PART III – MISCELLANEOUS

16. Information sharing and records

(1) The Authority shall maintain a register which shall contain—

(a) a copy of the—

(i) application;

(ii) risk assessment document;

(iii) decision document;

(iv) approval document; and

(v) contingency plan;

(b) a list of institutional biosafety committees; and

(c) any other information that the Authority may deem necessary.

(2) The register shall be open for inspection by any interested person upon payment of an inspection fee of five hundred shillings.

(3) The Authority shall establish a procedure for the exchange of information and experiences gained.

17. Registration of decisions in the National Biosafety Clearing House

The Authority shall register all decisions made under these Regulations in the National Biosafety Clearing House within thirty days of making the decision.

18. Confidential information

(1) An applicant may request that certain information in his application be treated as confidential and shall give reasons for the request.

(2) The Authority shall determine if the information should be kept confidential and shall communicate its decision to the applicant in writing.

(3) The following information shall not be considered confidential—

(a) name and address of the applicant;

(b) the general characteristics of the genetically modified organism;

(c) class of contained use and measures of containment; and

(d) the evaluation of foreseeable effects, in particular any harmful effects on human health and the environment.

(4) The authority shall protect the intellectual property rights of the applicant.

(5) Where an applicant withdraws an application, the Authority shall maintain confidentiality on the information supplied.

19. Good containment measures

An applicant shall apply the general principles and the appropriate containment and other protective measures set out in Part II of the Second Schedule to these Regulations corresponding to the class of the contained use.

20. Handling of modified plasmids and vectors

Modified plasmids or vectors used as tools for modern biotechnology shall be approved by the relevant regulatory agency.

21. Penalties

A person who contravenes any of the provisions of these Regulations commits an offence and is liable on conviction to a fine not exceeding twenty million shillings or to imprisonment for a term not exceeding ten years, or both.

FIRST SCHEDULE

[r. 4]

TECHNIQUES WHICH DO NOT LEAD TO GENETICALLY MODIFIED ORGANISMS

The following technical procedures shall not be considered to amount to formation of genetically modified organisms without concurrent use of recombinant heritable genetic material—

(a) in vitro fertilization;

(b) bacterial conjugation, transformation, transduction and similar natural processes;

(c) polyploidy and haploidy induction;

(d) Mutagenesis.

SECOND SCHEDULE

[r. 5(3)]

CONTAINMENT MEASURES

PART I

CLASSIFICATION OF CONTAINMENT LEVEL

Level 1 Activities with no or negligible risk of adverse effect on human health, the environment and biological diversity.

Level 2 Activities with low risk of adverse effect on human health, the environment and biological diversity that can easily be eliminated using generally known procedures for which the level of containment and protective measures are laid down.

Level 3 Activities with a moderate risk of such adverse effect on human health, the environment and biological diversity that can only be eliminated by especially demanding interventions for which the level of containment and protective measures are laid down.

Level 4 Activities with high risk of adverse effect on human health, the environment and biological diversity for which the level of containment and protective measures are laid down.

PART II

[r. 19]

GENERAL REQUIREMENTS FOR GOOD CONTAINMENT MEASURES

A: CHECKLIST FOR INSPECTION — ANIMAL UNITS

		Containment level			
Specification		1	2	3	4
1	Isolation of animal unit	optional	yes	yes	yes

2	Animal facilities separated by lockable doors	optional	yes	yes	yes
3	Animal facilities designed to facilitate decontamination (waterproof and easily washable material, cages etc.)	optional	optional	yes	yes
4	Floor and/or walls easily washable	optional	floor	floor and walls	floor and walls
5	Floor to wall, wall to ceiling and wall to wall junctions should be rounded for easy cleaning	yes	yes	yes	yes
6	All joints between door frames and wall should be sealed	yes	yes	yes	yes
7	Animal facilities have to be cleaned regularly. Sinks have to be disinfected regularly.	no	yes	yes	yes
8	Surfaces have to be disinfected after work	no	yes	yes	yes
9	Used cages have to be decontaminated	yes	yes	yes	yes
10	Material to be sterilised or incinerated as well as used cages	yes	yes	yes	yes

	have to be transported so that the environment is not contaminated				
11	Hands have to be decontaminated and washed if there is the possibility of contamination and after handling animals and waste	yes	yes	yes	yes
12	Access to animal facilities is restricted	yes	yes	yes	yes
13	An animal unit shall have installed devices to detect fires, ventilation and heating failures and the intrusion of unauthorised personnel	yes	yes	yes	yes
14	Where appropriate, an inspection window should be fitted in the door	yes	yes	yes	yes
15	Animal facilities have to be aerated appropriately	yes	yes	yes	yes
16	Wild forms of the animals inside the facility should not be able to enter	yes	yes	yes	yes

	the facility. Separate male and female of the species to avoid reproductive transmission, unless reproductive studies are part of the experiment				
17	Measures to control undesired species such as insects and rodent	yes	yes	yes	yes
18	Drains and any other services that enter through the walls or floor should prevent the ingress of rodents and insects	yes	yes	yes	yes
19	Accidents, bites and scratches caused by animals have to be reported to the project leader who makes a written report	yes	yes	yes	yes
20	Personnel has to be trained in the handling of the animals	yes	yes	yes	yes
21	There have to be written records about the transfer of foreign	yes	yes	yes	yes

	genes, about the breeding experiments and the disposal of animals				
22	Transgenic animals have to be identified easily. The insert can serve as an additional marker	yes	yes	yes	yes
23	Food and tobacco has to be stored so that it cannot come in contact with transgenic animals	yes	yes	yes	yes
24	Protective clothing and shoes have to be worn. They have to be changed or cleaned when the facility is left.	yes	yes	yes	yes
25	Protective clothing has to be stored separated	no	yes	yes	yes
26	Rodent barrier in front of doors should be installed, alternative doors should be self-closing, to rooms where animals are housed and handled to prevent the	yes	yes	yes	yes

	escape of animals				
27	Animal species shall be housed in appropriate cages, runs, pens suitable for their requirements	yes	yes	yes	yes
28	No animals should be admitted other than for experimental purposes	yes	yes	yes	yes
29	Biohazard sign	no	yes	yes	yes
30	Doors have to be closed if infected animals are held. There must be a sign indicating the kind of work	no	yes	yes	yes
31	The laboratory should contain a washbasin with taps that should be of a type that can be operated without being touched by hand, facilities for hand disinfecting shall be provided	no	yes	yes	yes
32	Use of safety cabinets where aerosols are released	no	yes	yes	yes

33	An autoclave should be available when genetically modified micro-organisms are used in experiments	yes	yes	yes	yes
34	In experiments where genetically modified micro-organisms are used contaminated material and waste should be inactivated	yes	yes	yes	yes
35	If genetically modified organisms can be transmitted, working tools and equipment have to be sterilised	no	yes	yes	yes
36	Waste contaminated with genetically modified organisms must only be transported in suitable containers	no	yes	yes	yes
37	Genetically modified organisms must only be transported in breakproofed	no	yes	yes	yes

	and closed containers				
38	Where risk assessment indicates the animal room and contents will need to be fumigated the room should be capable of being sealed by appropriate means and consideration should be given to the means of removing or extracting the fumigant	no	yes	yes	yes
39	Hygiene plan	no	yes	yes	yes
40	The animal facility has to be entered via a lock equipped with two self closing doors. hand washing basin, disinfection dispenser and shower	no	no	yes	yes
41	Acceptability of windows that open	yes	yes	no	no
42	Emergency power supply for safety relevant equipment such as ventilation system	no	no	yes	yes
43	Where mechanical ventilation	no	yes	yes	yes

	is provided, the airflow should be inwards. Air should not be recirculated to any part of the building.				
44	The ventilation system should be designed to prevent accidental reverse flow and positive pressurisation in any part of the animal unit	no	no	yes	yes
45	In case of work with airborne pathogens negative pressure relative to the pressure of the immediate surroundings, extract air should be HEPA* filtered	no	no	yes	yes
46	HEPA* filters should be sited so that they are accessible for testing and allow their safe removal, HEPA filters have to be sterilised on site or immediately sealed in an	no	no	yes	yes

	airtight plastic sack for later sterilisation				
47	Animals infected with risk group 3 microorganisms shall be housed in cages in isolators with ventilation passing through HEPA* filtration to the exterior. Alternatively, animals shall be housed in cages within ventilation units with ventilation exhausts placed behind cages.	no	no	yes	yes
48	Carcasses have to be sterilised prior to disposal. If this is not possible inside the facility, carcasses have to be transported in closed, leakproofed and disinfected containers	no	no	yes	yes
49	Waste water has to be sterilised	no	no	yes	yes

* High-efficiency particle arresting

B: CHECKLIST FOR INSPECTIONS (CONTAINED USE — GLASSHOUSES AND GROWTH-ROOMS)

		Containment level			
Specification		1	2	3	4
1	Greenhouse: permanent structure	No	yes	yes	yes
2	Internal walls, ceilings and floors shall be resistant to penetration by liquids and chemicals to facilitate cleaning and decontamination of the area. All penetrations into these structures and surfaces shall be sealed (e.g. cables, pipes)	No	Optional	yes	yes
3	Control of contaminated run-off water	Optional	Minimise run-off	Prevent run-off	Prevent run-off
4	There, must be a suitable program to control plant pests, weeds, insects and rodents	Yes	Yes	Yes	Yes
5	Measures to control undesired species such as weed, insects, rodents, arthropods	Yes	Yes	Yes	Yes
6	Procedures for transfer of living material between the glasshouse/ growth-room,	Minimise dissemination	Minimise dissemination	Prevent dissemination	Prevent dissemination

	protective structure and laboratory shall control dissemination of genetically modified micro-organisms				
7	Transport of GMOs in suitable closed non-breakable container	No	Yes	yes	yes
8	The container shall be decontaminated if organisms outside are present within the effective dissemination distance of the experimental organism, e.g. by fumigation	No	No	Yes	yes
9	The ground of the greenhouse can be of gravel or other greenhouse-typical material. At least the pavement should be solid, e.g. of concrete.	Yes	Yes	Yes	yes
10	The ground of the greenhouse should be of water impermeable	yes	yes	Not applicable	Not applicable

	material. Gravel and other porous material under the planting tables are suitable if there is only a minor possibility that reproducible biological material can be transmitted through the soil. In this case earth beds are also possible.				
11	If part of the ground consists of gravel, appropriate treatments should be made periodically to eliminate, or render inactive, any organisms potentially entrapped by the gravel	No	Yes	Not applicable	Not applicable
12	The ground of the greenhouse is made of water impermeable material with provisions to collect and sterilise wastewater.	No	No	Yes	yes
13	Escape of GMOs	Minimised	Prevent	Prevent	Prevent

14	Windows shall be closed and sealed	No	No With insect nets	Yes	Yes
15	All glazing shall be resistant to breakage	No	No	Yes	Yes
16	Biohazard sign at entry	No	Yes	Yes	Yes
17	A sign shall be posted indicating: - That a restricted experiment is in progress - Name of responsible individual - Plants (organisms) in use - Special requirements for using the area	No	Optional	Yes	Yes
18	Access is limited to the project leader and personnel authorised by him	No	Yes	Yes	Yes
19	Protective clothing shall not be worn outside the greenhouse	Yes	Yes	Yes	Yes
20	Separate facilities for storing protective and street clothing shall be available	No	Yes	Yes	Yes
21	Protective clothing has to be sterilised	No	No	Yes	Yes

	before laundry				
22	Gloves shall be worn at work	No	No	Yes	Yes
23	Injuries have to be reported immediately to the project leader	Yes	Yes	Yes	Yes
24	There must be written instructions for greenhouse practices and procedures	Yes	Yes	Yes	Yes
25	Hand disinfection apparatus and wash basin	No	Yes	Yes	Yes
26	Greenhouse to be entered via a lock with self-closing doors and hand disinfection apparatus and touch-free hand washing basin	No	No	Yes	Yes
27	Air intake screening and motorised or gravity-driven exhaust fan louvers	Yes	Yes	Not applicable	Not applicable
28	The glasshouse has to be held under negative pressure compared to the surrounding	No	No	Yes	Yes

29	If there is the danger of the dissemination of airborne pathogens, exhaust air has to be filtered through HEPA-filters	No	No	Yes	Yes
30	Before disposal genetically modified plants have to be made unable to reproduce, e.g. by cutting off blossoms	Yes	Not applicable	Not applicable	Not applicable
31	Equipment which was in contact with GMOs has to be sterilised before cleaning, if the contact may lead to the transmission of GMOs	No	Yes	Yes	Yes
32	Autoclave inside the glasshouse	No	No, but available	Yes	Yes
33	The glasshouse has to be surrounded by a security fence or equal protection system	No	No	Yes	Yes

C: CHECKLIST FOR INSPECTIONS (CONTAINED USE — LABORATORY ACTIVITIES)

I. *Physical Control Measures*

a) Facility design

	Containment level			
Specification	1	2	3	4

1	Process with viable micro-organisms separates{ from the environment (closed system)	yes	yes	yes	yes
2.	Laboratory suite isolation	no	no	yes	yes
3.	Restricted access to the facility (e.g. electronic cards, camera)	no	yes	yes	yes
4.	laboratory sealable for fumigation	no	no	yes	yes
5.	Acceptability of windows that open	yes	yes	no	no
6.	Biohazard sign on the door	no	yes	yes	yes
7.	Signs at laboratory entrance: - special hazard signs if an organism containing rDNA needs special provision for persons entering the laboratory - names of occupants who have access to the laboratory	no	yes	yes	yes
8	Ventilation system	no	no	yes	yes
a) Containment equipment					
		Containment level			
Specification		1	2	3	4
1	Surfaces resistant	yes	yes	yes	yes

	to water, acids, alkalis, solvents, disinfectants, decontamination agents and easy to clean				
2.	Suitable of equipment used for safety purposes	no	no	yes	yes
3.	Suitable chemical disinfectants in use	no	yes	yes	yes
4.	suitable position of the autoclave with respect to the genetically modified organism installation	no	no	yes	yes
5.	Autoclave provides a print-out showing the temperature and time of sterilisation	yes	yes	no	no
6.	Wash hand basin or sink that can be used for hand washing with: - dispenser containing soap - dispenser containing hand disinfectant - paper towels	no	yes	yes	yes
7.	Appropriate position and design of	no	yes	yes	yes

	biological safety hoods				
8.	Suitable design of the equipment for the safe storage of genetically modified organisms	no	no	yes	yes
9.	suitable design of waste transport containers	optional	yes	yes	yes
10.	Suitable design of containers for the transport of genetically modified organisms inside the facility	optional	yes	yes	yes
11.	Suitable design of centrifuge buckets	yes	yes	yes	Yes
12.	Entry to lab via airlock	no	no	optional	yes
13.	Air lock with two doors which are interlocked	no	no	yes	yes
14.	Air lock equipped with a hand washing basin (touch free) and hand disinfectant dispenser	no	no	yes	yes
15.	Negative pressure relative to the pressure of the immediate surroundings	no	no	optional	yes

16.	Ventilation system is alarmed to indicate a failure to generate a negative pressure	no	no	yes	yes
17.	Ventilation system connected to an emergency power supply	no	no	yes	yes
18.	Switch for ventilation system should be accessible from outside of the laboratory in case of fumigation	no	no	yes	yes
19.	Extract and input air from the laboratory should be NEPA* filtered	no	no	extract air	input and extract air
20.	Filters have to be sterilised on site or instantly sealed in a plastic bag for later sterilisation	no	yes	yes	yes
21.	Alarm systems for workers working alone	no	no	yes	yes
22.	Shower for the occupants before leaving the laboratory	no	no	optional	yes

23.	An observation window or alternative is to be present so that occupants can be seen	optional	optional	optional	yes
II. Safety Management					
a) Work procedures					
		Containment level			
Specification		1	2	3	4
1	Engineering control measures have to be exercised at source and supplement these with appropriate personal protective clothing and equipment where necessary	yes	yes	yes	yes
2	Control measures and equipment have to be tested adequately and maintained	yes	yes	yes	yes
3	Doors and windows closed while working	only doors	yes	yes	yes
4	Access to the laboratory must be restricted when experiments are in progress	no	yes	yes	yes
5	Workers should be given	yes	yes	yes	yes

	adequate information on safety matters and be suitably trained. Training should include the following points: a) the existence and application of written work procedures b) the procedures for using particular pieces of equipment c) spillage control and other emergency procedures				
6	Check at which process steps hazardous quantities of aerosols are formed	optional	yes	yes	yes
7	Prevention of aerosol formation	yes	yes	yes	yes
8	Genetically modified organisms are only to be transported within the facility in closed, robust and leakproof containers	yes	yes	yes	yes

9	Work surfaces must be decontaminated daily and after a spillage	yes	yes	yes	yes
10	Effective disinfectants and specified disinfection procedures in case of spillage of genetically modified organisms	yes	yes	yes	yes
11	Inactivation of genetically modified organisms in contaminated material and waste	optional	yes	yes	yes
12	Inactivation of genetically modified organisms in effluent from the hand washing sinks or drains and showers and similar effluents	no	no	optional	yes
13	Benches should be free from clutter	yes	yes	yes	yes
14	The identity of genetically modified organisms should be regularly checked to avoid the culturing of incorrect stains. (The	optional	yes	yes	yes

	time between these checks should be dependent upon the potential hazard).				
15	Corrective actions following the results of the controls and way to register them	yes	yes	yes	yes
16	Users should ensure that the performance of safety equipment is validated (e.g. autoclaves and safety hoods) - validation of equipment (e.g. autoclaves, safety hoods) - maintenance of the equipment - markers used to verify the efficiency of autoclaves	yes	yes	yes	yes
17	Prohibition of mouth pipetting	yes	yes	yes	yes
18	Prohibition of eating, drinking, smoking, applying cosmetics or the storing of food for human consumption	yes	yes	yes	yes

	in the work area				
19	Skin contact with rDNA material must be avoided	yes	yes	yes	yes
20	Hands must be washed after handling rDNA and before leaving the laboratory	yes	yes	yes	yes
21	Protective clothing	yes	yes	yes and optional footwear	yes, complete change of clothing & footwear
22	Decontaminate protective clothing before laundering	yes	yes	yes	yes
23	Protective clothing and street wear must be kept separate	yes	yes	yes	yes
24	Gloves	no	optional	yes	yes
25	Implementation of an insect and rodent control programme	optional	yes	yes	yes
26	Keep the workplace and environmental exposure to any physical, chemical or biological agent to the lowest practicable level	yes	yes	yes	yes
27	Tests, when necessary, for the presence of viable	yes	yes	yes	yes

	genetically modified organisms outside the primary physical containment				
28	Use of sharps should be avoided	yes	yes	yes	yes
29	Contaminated syringes / sharps must be disposed of in a 'Sharps bin' and incinerated	yes	yes	yes	yes
30	where appropriate make vaccines available	no	yes	yes	yes
31	Establish Insitutional Biosafety Committees or sub-committees as required	yes	yes	yes	yes
32	Animals must not be allowed to enter into the laboratory	yes	yes	yes	yes
33	Where appropriate serum samples must be taken from workers and stored to provide baseline information in the event of an unexplained illness	no	optional	optional	optional

34	Sample collection, addition of materials to closed system and transfer of viable microorganisms to another closed system, should be performed appropriate	yes	yes	yes	yes
35	Safe storage of biological agents	yes	yes	yes	yes
36	Safe storage of contaminated laboratory equipment and materials, when appropriate	yes	yes	yes	yes
		containment level			
Specification		1	2	3	4
1	Keep adequate records	yes	yes	yes	yes
2	Hygiene plan	no	yes	yes	yes
3	Provide written standard operating procedures where appropriate to ensure safety	yes	yes	yes	yes
4	Provide documentation of the appointment of the BioSafety Officer (BSO)	yes	yes	yes	yes
5	The appointment	yes	yes	yes	yes

	of project leader				
6	A description of the tasks of the BioSafety Officer (BSO) with respect to safety; internal control; accident/ incident; response and preparedness; internal counselling, advice and education; and, reporting	yes	yes	yes	yes
7	A description of the tasks of the project leader with respect to: - everyday management - drawing-up and executing work-protocol	yes	yes	yes	yes
8	A clear description of the separation of responsibilities and tasks between the BioSafety Officer and the project leader	yes	yes	yes	yes
9	The status of the BioSafety Officer should be defined	yes	yes	yes	yes
10	There should be written procedures	yes	yes	yes	yes

	that cover the following: - undertaking risk assessments - the training of new staff - emergency procedures including the treatment of spillages with disinfectants - cleaning and disinfection of equipment - transport of GMOs - operation, testing and maintenance of containment equipment - measures for limiting access to facilities - health surveillance of workers				
11	Written instructions should be in both national languages	yes	yes	yes	yes
12	Documents that should be centrally held within an institution undertaking contained use: (a) records indicating working areas and their containment	yes	yes	yes	yes

	levels (these records may include plans of buildings) (b) all of the documents listed in point 10 above (c) these records should also cover any sites for storage Genetically modified organisms outside of containment facilities (d) records of internally organised inspections (e) records of accidents, including evaluation and any remedial action (f) a list of other data and documents that are held at other locations within the institution				
13	Documents that can be held separately from the main records (see 12 above): (a) records of staff involved in contained use	yes	yes	yes	yes

		indicating their experience and training and the type of projects in which they have been employed (b) results of procedures for checking the purity and identity of the genetically modified organisms (c) results of the testing of containment equipment (e.g. autoclaves and safety cabinets) (d) a list of stored genetically modified organisms for each storage facility (e) work protocols for particular expermental procedures			

b) Institutional matters and documentation relating to the safe handling of genetically modified organisms

NB: Risk assessment of the genetically modified organisms that will be handled in every facility will be evaluation during application to the Authority.

III - Contingency Plan

		Containment level			
Specification		1	2	3	4
1	Check contingency plans for protection of the environment and the	no	no	optional	no

	public outside of the facility				
2	Check information on accidents (reporting of accidents and near — misses and records of corrective actions that have been taken)	yes	yes	yes	yes
3	Provide written procedures for: - a procedure for internal notification of incidents (e.g. spillages) - a procedure for external notification in case of serious risk - a procedure accident response (measures, reporting, evaluation) - emergency preparedness actions and countermeasures in case of accidents or incidents	no	yes	yes	yes

THIRD SCHEDULE

[r. 7(3)]

APPLICATION FORMS FOR CONTAINED USE ACTIVITIES

This Schedule comprises of application forms for contained use activities. The forms are as follows:

1. Laboratories, Green houses and Growth chambers

2. Confined field trials for Animals, animal health inputs and microorganisms

3. Confined field trials for plants.

PART I

APPLICATION FORM FOR CONTAINED USE ACTIVITY (LABORATORY, GREENHOUSE AND GROWTH CHAMBERS)

GENERAL REQUIREMENTS FOR THE APPLICATIONS

This application form must be completed for each individual genetically modified organism for the intended contained use activity. The application may include more than one experiment (genetic modification of that particular species) or protocols and all sections must be completed. Additional pages can be attached if the space provided is not sufficient. Applications for new and renewal of previously authorized contained use should be submitted separately.

1.0 Name and Contact Address of Applicant

1.1 Date of Submission

1.2 Name of applicant	1.3 Name of Institutional Biosafety Committee (IBC)
1.4 Institution of applicant	1.5 Registration Status in Kenya 1.6 Affiliating institution (*if institution of applicant is not registered in Kenya)*
1.4.1 Address of applicant's institution	1.6.1 Address of affiliating institution
1.4.2 Telephone 1.4.3 Facsimile /email	1.6.2 Telephone 1.6.3 Facsimile/email

2.0 Nature and purpose of contained use

2.1 Brief Description of Proposed contained use activity

2.2 Purpose of contained use - character of the activity that will be carried out by applicant (e.g. research, laboratory control, manufacture)

2.3 If the contained use work is successful, indicate whether a general release of the GMO is planned

2.4 Total period of contained use and date of its expected starting-up

3.0 Risk assessment

3.1 Summary of the risk assessment for the genes and species of GMO involved.

3.2 Description of potential risks associated with the transformed organism, transformation genes or gene elements.

3.3 Description of potential risks associated with the activities to be undertaken

4.0 Location where contained use activities are to be undertaken

4.1 Contained Use Facility: Laboratory and growth chambers

4.1.1 Facility Location	4.1.2 Approval No. or reference	4.1.3 Number of other contained use activities currently approved within the same facility

4.1.4 Biosafety level assigned to facility during approval (*Level 1, or level 2, or level 3 or level 4)*

4.1.5 Layout of-premises and of the location of main facilities (*Attach additional annex if more space is required*)
4.1.6 Code of practice of a workplace (*Indicate type)*
4.1.7 Emergency Response Plan in the event of an accident
4.1.8 Characteristics of the workplace *(Tick as appropriate)*
4.1.8.1 Microbiological laboratory 4.1.8.2 Pilot plant
4.1.8.3 Production facilities 4.1.8.4 Glasshouse/growth room
4.1.8.5 Animal breeding facility 4.1.8.6 Other (*Specify*)
4.1.9 Species and amount of used organism and the used genetic modifications including nominally mentioned validated methods for detection of occurrence of genetically modified organisms.
4.1.10 Waste management plan
4. 2 Contained Use Facility: Greenhouse Facility

4.2.1 Facility Location	4.2.2 Approval No. or reference.	4.2.3 Number of other activities currently approved within the same facility.

4.2.4 Protocol: Fully describe the following
4.2.4.1 Purpose of the greenhouse trial
4.2.4.2 Experimental design
4.2.4.3 Nature and type of data to be collected
4.2.5 Arrangements for transporting the GMO to the greenhouse
4.2.6 Proposed herbicide/pesticide use, if any

4.2.6.1 Name of the pesticide / herbicide	4.2.6.2 Active ingredient	4.2.6.3 Total area to be sprayed (m^2/ *hectarage)*

4.2.7 Provide work schedule *(post approval)* of key activities including but not limited to:

4.2.7.1 Dates of movement of material	4.2.7.2 Planting (*anticipated*)	4.2.7.3 Harvest/ Sampling (*anticipated*)

4.2.8 Describe your plan for recording the quantities of seed planted/GMO used and accounting for any excess
4.2.9 Describe the disposition plan, including how and where any excess, or non-planted seed/GMO will be disposed of or stored.
4.2.10 State whether plants will he allowed to set seed or to reproduce
Yes # No #

4.2.11 Indicate whether any harvested plant material will be retained from the trial		4.2.11.1 If yes, Type (*e.g. seed, leaves, etc*.)
Yes #	No #	
4.2.11.2 Quantity to be retained		4.2.11.3 Purpose of retaining material

4.2.12 For harvested plant material, describe the following if applicable:

4.2.12.1 The storage method. 4.2.12.2 Storage location

4.2.12.3 Person in the institution responsible for the storage of the material

4.2.12.3.1 Name 4.2.12.3.2 Telephone

4.2.12.4 Proposed storage records

5.0. Nature and identity of Genetically modified organism

5.1 Name of GMO

5.2 Modified trait(s) Identification

# Herbicide Tolerance	# Modified Oil Composition	# Pharmaceutical
# Male sterility/ restoration	# Virus Resistance	# Genetic Research
# Insect Resistance	# Stress Tolerance	# Generation of mutants
# Nutritional change	# Fungal Resistance	# Other (Specify)

5.3 Modified Trait(s)

Describe each specific new trait associated with this GMO.

5.4 For each gene construct, describe all genes regulatory elements, gene products, non-translated DNA sequences and, where applicable, affected metabolic pathways.

5.5 Provide Information on the donor organism including its origin

5.6 Provide Information on recipient and parental organism including origin

5.7 Provide Information on the vector including its origin

5.8 Provide the name of plasmid (*construct*) and genetic map (*map of each genetic construct is required)*.

5.9 Describe Mode of action of traits (*gene product, metabolic pathways*).

5.9.1 Is the vector naturally pathogenic? # Yes # No	5.9.2 Is the vector disarmed? # Yes # No	5.9.3 If yes, how was the vector disarmed?

5.10 Description of elements of the constructs(s): This area should be filled for all constructs and GMO gene elements

5.10.1 Genetic Element	5.10.2 Size (bp)	5.10.3 Source	5.10.4 Function

5.11 Method of introduction of the insert

5.12 Method for detection of genetically modified organism

5.13 Amount of genetically modified organism to be used (*volume of the culture, number of plants or animals)*

5.14 Information on whether the genetically modified organism has already been approved in some other country and for what purpose.

6.0 Nature and purpose of the contained use activities

6.1 In case of import or export of the genetically modified organism intended for contained use

6.1.1 The country of origin or destination, as appropriate 6.1.2 Importer or exporter, as appropriate
6.1.3 Maximum amount of genetically modified organism to be imported or exported 6.1.4 Means of transportation
6.1.5 Means of packaging and labeling
6.2 Measures to protect human health and the environment and biological diversity
6.3 Frequency and the manner of carrying out control of the occurrence of genetically modified organism inside and outside of the contained space
6.4 Description of waste management plan
7.0 Containment measures
7.1 List all protocols proposed to be used at this facility for this application (*Separate sheets may be annexed*.)
7.2 Attach inspection report if facility is not yet assigned a biosafety level
7.3 State proposed documentation procedures on the use of genetically modified organisms
7.4 Plan of training of employees prior to the commencement of the use of geneticilly modified organisms, and the plan of their refresher training
8.0 Declaration of correctness of information
I certify that the above information is true to the best of my knowledge.
Principal Investigator
Name_____
Signature _____ Date _____

Collaborator(s)
Name(s) _____ Date _____
Signature _____ Date _____

Institutional Biosafety Committee (IBC) Review
This application has been reviewed by IBC
Name of IBC _____
Name of Chairperson _____
Signature _____ Date _____

PART II
APPLICATION FORM FOR CONTAINED USE AND CONFINED FIELD TRIALS (GENETICALLY MODIFIED ANIMALS, ANIMAL HEALTH INPUTS AND MICRO-ORGANISMS)
This application form must be completed for each individual animal/organism species. Applications for new and renewal of previously authorized contained or confined research field trials should he submitted separately.
Sections 1, 2 and 3 must he completed for all contained use (laboratory and animal units) trials.
For all confined field trials, Section 4 must be completed, in addition to Sections 1, 2 and 3.
Section 1: General Information
1.0 Title of Planned Introduction
1.1 Application Type 1.2 Animal/Organism Species Name
New 1.2.1 Latin Name(s)

Renewal 1.2.2 Common Name(s)
1.3 Feed Section
Indicate whether any animal/organism material generated in the contained or confined research trials will be used as research material for livestock feed. # Yes # No
1.4 Applicant 1.5 Co-Applicant - Complete if the applicant is not a Kenyan resident
1.4.1 Name 1.5.1 Name
1.4.2 Address 1.5.2 Address (Affiliate Institution)
1.4.3 Telephone 1.4.4 Facsimile \Email 1.5.3 Telephone 1.5.4 Facsimile/ Email
1.6 Facility Manager (*Name, Address and Telephone Number*)
1.7 Name of Institutional Biosafety Committee (IBC) - (Attach confirmed minutes of IBC)
1.8 The Proposed Contained or Confined Trial
1.8.1 Brief description of proposed trial
1.8.2 What are the aims and objectives of the proposal?
1.8.3 What is the intended eventual use(s) of the products?
Description of the Unmodified Animal/Organism
1.9 Fertility
1.9.1 Describe mechanisms and frequency of intra-and inter-specific out-crossing.
1.9.2 Describe the mechanism of infertility
1.10 Habitat
1.10.1 What is the natural. habitat of the parent animal/organism and its distribution in Kenya?
1.10.2 Where is the origin of the parent animal/organism?
1.10.3 Is the parent animal/organism already present at or near the site of the planned genetically modified organism introduction (s)?
1.10.4 Is the parent animal/organism exotic to Kenya?
1.10.5 Does the unmodified form(s) have any adverse effect on: (*please indicate adverse effects*)
1.10.5.1 Humans, animals, or plants?
1.10.5.2 Agricultural production? (*e.g. pests*)
1.10.5.3 Any other aspect of the environment? (*e.g. invasiveness*)
1.10.5.4 List any locations in Kenya or elsewhere where the animal/organism is a known pest.
1.11 Phenotypic Characteristics
Provide information on animal/organism mechanisms responsible for:
1.11.1 Tendency to propagate uncontrollably
1.11.2 Dormancy
1.11.3 Body tissues/fluid dispersal (*animals only*)
1.11.4 Persistence or dispersal of reproductive structures such as larvae and eggs
1.11.5 Other dispersal mechanisms
1.12 Toxins
1.12.1 List any known toxins produced by this animal/organism, including natural defence compounds.
1.12.2 Indicate the levels at which these compounds induce toxicity.
1.12.3 Indicate the species affected by these toxins.
1.13 Allergens
1.13.1 List any known allergens that emanate from this animals/organisms, including natural defence compounds.

1.14 Please describe any other pathological, ecological and physiological traits that relate to the animal/organism Novel Trait (NT) but not the unmodified animal/ organism. A few suggestions of the required information are as described below:
• Generation time in natural ecosystems, sexual and asexual reproductive cycle
• Pathogenicity: infectivity, virulence, infective dose, communicability, possibility of survival outside of human, (toxigenicity, allergenicity = already given), carrier (vector) or means of dissemination of pathogen, biological stability, host range including non-target organisms. Possible activation of latent viruses (proviruses), availability of possible therapies, etc.
• Antibiotic resistance and potential use of the antibiotics in humans and domestic organisms
• Involvement in environmental processes, e.g. primary production, nutrient turnover, decomposition of organic matter, etc
Section 2: Submission
Please fill out Section 2 for each individual Submission included in the application.
2.1 Name or Designation of animal or organism Novel Trait (NT)
2.2 Novel Trait(s) Identification (Tick as appropriate)

# Genetic Research.	# Pharmaceutical.	# Generation of mutants.
# Insect Resistance.	# Stress Tolerance	# Fungal Resistance.
# Nutritional change.	# Increased production of milk or wool	# Genes knocked out to allow xeno transplantation
# Faster, more efficient growth rates	# Increased tolerance to cold water for fish.	# Improved meat, milk or wool quality
# Leaner, more tender beef and pork.	# Resistance to diseases caused by viruses, bacteria and other pathogens.	# Milk that lacks allergenic proteins, or results in increased amounts of cheese and yogurt.
# Development of animals that serve as models for human diseases to help scientists better understand prevention and treatment strategies.	# Possession of characteristics which are environmentally friendly e.g. improved use of dietary phosphorous to lessen the environmental impacts	# In the phylogenetic analysis of the amplified nucleic acid sequences to provide novel information on the evolution of pathogens.

	of animal manure	
# Animal vaccines rationally designed for the specific control and eradication of diseases, including the implementation of DIVA (differentiating infected from vaccinated animals) strategies.	# Development of diagnostic kits that can not only be used in the laboratory but pen-side tests that can be used in the field to make decisions about the exposure of animals during a disease outbreak.	# In epidemiology to characterize pathogens through determination of their nucleotide sequence. The possibility of pinpointing the source of infection can significantly contribute to improved disease control.
# Cloning to enable the rapid dissemination of superior genotypes from nucleus breeding flocks and herds, directly to commercial farmers. Genotypes could be provided that are ideally suited for specific product characteristics, disease resistance, or environmental conditions.	# Cloning to help salvage the germplasm of indigenous species that are near extinction, including intra-species nuclear transfer procedures which can be used to rescue genes from endangered species.	# New and improved medicines for animals. e.g. Gene therapy which involves the insertion of a functional gene or another molecule that contains an information sequence into a cell to achieve a therapeutic effect. Thus, the gene serves as a drug.
# Producing large amounts of therapeutic - proteins in animal milk or meat (biopharm animals or transgenic animal bioreactors) may be an efficient, relatively low cost method to manufacture many proteins used to treat human diseases or proteins that have industrial value.	# In the development of novel diagnostic assays, e.g. PCR and isothermal	# Other (Specify)

		amplification methods, microarrays, protein detection by nucleic acid amplification, recombinant proteins, synthetic proteins, biosensors etc. to detect the pathogens and/or the immune responses after infection.

2.3 Novel Trait(s)
Describe each specific novel trait associated with this animal or organism.
2.4. Is GMO Imported or generated locally.
2.4.1 Import Permit No. If the animal or organism novel trait is imported, provide the import permit number issued under the *Animal Diseases Act (Cap. 364*) or any other appropriate legislation.
2.5 History
Has this genetically modified organism been previously tested in Kenya? If yes, please provide information on trial (s), year(s) of authorization and location(s) tested.
Yes # No
2.6 Trait Introduction and Selection Method
2.6.1 Describe Induction Method (mutagenesis) or Transformation Method (*recombinant techniqu*es).
2.6.2 Describe Selection Method.
2.6.3 Describe Mode of action of traits (*gene product, metabolic pathways*).
2.6.4 Other
Provide details of modification by means other than mutagenesis or recombinant techniques.
2.7 Gene Donor
Indicate the gene's donor organism (*for animals or organisms transformed using recombinant techniques*).
2.8 Transformation Plasmids
Please provide the following information:
2.8.1 Name of plasmid (construct) and genetic map (*map of each genetic construct required*).

2.8.2 Is the vector naturally pathogenic?	2.8.3 Is the vector disarmed? (*Tick as appropriate*) #Yes #No	2.8.4 If yes, how was the vector disarmed?

(*Tick appropriate)*
Yes
No
2.8.5 For each gene construct, describe all genes, regulatory elements, gene products, non-translated nucleic acid (DNA/RNA) sequences and, where applicable, affected metabolic pathways.
2.8.5.1 Description of elements of the constructs(s): This area should be filled for all constructs and GMO gene elements

2.8.5.1.1 Genetic Element	2.8.5.1.2 Size (bp)	2.8.5. 1.3 Source	2.8.5.1.4 Function

2.9.1 Spatial and Temporal Trait Expression

Trait	Expression		
	2.9.1.1 Constitutive (Yes/ No) If not constitutive, indicate the specific tissue(s) in which the trait is expressed (green tissue, seed, pollen, roots, other)	2.9.1.2 Is the trait expressed during specific developmental stage? If yes, when?	2.9.1.31s the trail inducible? If yes, how?

2.10 Toxicity and Allergenicity of the Novel Trait(s)
2.10.1 To what extent are novel gene products toxic when ingested by native fauna populations, including mammals, birds, reptiles, and insects? How has this been determined?
2.10.2 To what extent are novel gene products allergens? How has this been determined?
2.11 Altered Animal or Organism Characteristics
Please indicate any changes with respect to the following:
2.11.1 Tendency to propagate uncontrollably
2.11.2 Dormancy
2.11.3 Body tissues/fluid dispersal (*animals only*)
2.11.4 Persistence or dispersal of reproductive structures such as larvae and eggs
2.11.5 Other dispersal mechanisms
2.11.6 What is the frequency of reversion, i.e., loss of genetic modification?
2.11.7 How do you verify that you have the desired GMO?
2. 11.8 What methods are to be used to test for batch-to-batch consistency'?
2.12 Facility Inspection
2.12.1 Has the facility been inspected by the relevant regulatory agency?
#Yes # No
Please attach the facility inspection approval letter/certificate
2.13 Trial Site Locations and Trial Protocols

Town and Province	Legal land and location	Trial Protocol(s) — Attach trial Protocol

Please note: Section 3 must be completed for each Trial Protocol listed above and, for confined field trials. Section 4 must be completed for each Trial Site Location listed above.
Section 3: Contained Use Trial Protocol
Please fill out Section 4 for each Trial Protocol included in the application.
1 Trial Protocol *(Study)*
Title:

2 Protocol
Prescribe fully the purpose of the trial, the experimental design, the nature and type of data to to be collected and arrangements for transporting the GMO to the trial site. Please dude proposed, if any, herbicide/pesticide use.
3 Provide work schedule (*post approval)* to include:
3.1 3.3.2 Sampling (*anticipated*)
Intervention
(*anticipated*)
3.4 Isolation
Site the isolation measures being implemented for this trial and give details.
3.5 Method of introduction of GMO into parent where applicable
3.6 Spraying/Dipping*
Please complete this section if the trial site is subject to the use of an unregistered product, or a registered product used for a non-registered purpose.
3.6.1 Name of the pesticide 3.6.2 Total area sprayed (Square meters) 3.6.3 Active ingredient
* *This information is also required to determine compliance with the Pest Control Products Act*
3.6.4 Unregistered Pesticide Use Indicate whether the trial site location will be subject to unregistered pesticide use.
#Yes #No
3.7 Harvesting
3.7.1 Will animal/ organism be allowed to reproduce?
Yes No
# #
3.7.2 Describe the method of harvest for microbial cultures, embryos and other animal material
3.7.3 Will any material be retained from the trial?
Yes No
# #
3.7.4 If yes,
3.7.4.1 Type of material to be retained
3.7.4.2 Quantity to be retained
3.7.4.3 Purpose of retaining material.
3.7.5 Describe the storage method and storage location of harvested material.
3.7.6 Provide the name, address and phone number of the contact person responsible for the storage of the material and the proposed storage records.
3.7.7 Describe your management plan to avoid escape of GMO from the trial site
3.8 Disposal Plan
3.8.1 Describe your disposal plan for all material; including how and where the material will be disposed of.
3.8.2 Provide the name, address and phone number of the contact person responsible for the disposal of the material and the proposed disposal records.
3.9 Contingency Plans
3.9.1 Describe your contingency plan in the case of accidental release of GMO material or the breakdown of isolation/quarantine.
3 .10 Monitoring the Trial Site
3.10.1 Describe the extent.and frequency of trial site monitoring during the course of the trial.
3.10.2 Describe the extent and frequency of trial site monitoring during the post-trial period.

3.10.3 Describe what monitoring results will be recorded, how they will he recorded and who is responsible for them.
3.10.4 If any controlled monitoring procedures are proposed for this trial, detail these.
3.10.5 Describe the provisions to remove or eliminate the GMO from the test site or any other place where it may be found upon completing the trial release and to restore the test site and any such other place to its status quo.

Section 4: Field Trial Site Location
(*To be completed for confined field trials only)*
Please fill out Section 3 for each Trial Site Location included in the application.

4.1 Town/ City (Nearest city)

4.2 Province

4.3 Legal Land Location (*The NBA will not authorize a confined field trial unless the trial site has been inspected and approved*)

4.4 Field Manager (*Must be a Kenyan resident and responsible for the trial site location*)

4.4.1 Name

4.4.2 Address

4.4.3 Telephone

4.4.4 Facsimile

4.5 Trial Size Trial size in meters^2

4.6 Map location
Has a complete map location of the trial site been provided?
Yes # No #
A map and GPS coordinates of the trial site must be received by the NBA within 7 days following commencement of the trial.

4.7 Habitat
4.7.1 Describe the biological diversity of the trial site, including:
4.7.1.0 Potential impacts resulting from the field test
4.7.1.1 Soil
4.7.1.2 Groundwater level
4.7.1.3 Topography
4.7.1.4 Flora and fauna
4.7.1.5 Climate, especially prevailing winds and temperature
4.7.1.6 Former use of the facility
4.7.1.7 Distance from nearest human settlements
4.7.1.8 Distance from surface water body

4.7.2 Is the trial site part of a managed ecosystem
Yes #
No #

4.7.3 If yes, how close is the nearest natural

4.7.4 How close is the site from an area of special ecological interest, including protected areas and sanctuaries?
4.8 Indigenous Species
4.8.1 Specify the related wild and domesticated species/organisms present at the trial site and how close they are to the novel animal/organism material under test.
4.8.2 Are there any endangered species on or near the site?
4.8.3 If yes, please list.

Yes	No
#	#

For information on endangered species that may be near the trial site location, contact the Kenya Wildlife Service; P.O. Box 40241 NAIROBI, Email: kws@kws.org, Website: www.kws.org, Langata Road, Telephone (+245-20-501081.

4.8.4 What mechanisms are in place to prevent the local fauna from removing novel plant/animal/organism material from the site?
4.9 Post-Trial Land Use
4.9.1 Name and address of the person(s) having control over the site during the post-trial land use period.
4.9.2 What is the anticipated post-trial land use?
4.9.3 Describe how the site boundaries will be marked to facilitate subsequent inspection.
4.10 Submissions and Trial Protocols
Please list all submissions and trial protocols used at this site.

Submission (Animal or organism novel trait designation — List of possible designations/unique identifier)	Trial Protocol(s)

<u>Please note</u>: Section 2 must be completed for each Submission listed above and Section 4 must be completed for each Trial Protocol listed above.

4.11 Public Notice
4.11.1 How will you provide public notification of your proposed field trial?
Section 5: Certification
I certify that the above information is true to the best of my knowledge.
Principal Investigator
Name _____ Date_____
Signature _____ Date _____

Collaborator(s)
Name(s) _____
Signature _____ Date _____

Institutional Biosafety Committee (IBC) Review
This application has been reviewed by IBC
Name of IBC _____
Name of Chairperson _____
Signature _____ Date _____

PART III
APPLICATION FORM FOR CONFINED FIELD TRIAL (PLANTS)
This application form must be completed for each individual genetically modified plant. The application may include more than one submission of a genetic modification of that particular species, Trial site Location and/or Trial Protocol.

Complete section 2 for each submission, section 3 for each trial site and section 4 for each trial protocol included in the application. All sections must be completed. Additional pages can be attached if the space provided is not sufficient. Applications for new and renewal of previously authorized confined research field trials should be submitted separately.

Section 1.0 General Information

1.1 Application Type	1.2 Plant Species Name
	1.2.1 Latin Name(s)
# New	1.2.2 Common Name(s)
# Renewal# Date of submission of the application	
	(Indicate if perennials, annuals, trees etc.)

1.3 Feed Section

Indicate whether any plant material generated in the confined field trials will be used as research material for livestock feed.

Yes # No #

1.4 Applicant		1.5 Name of Institutional Biosafety Committee. *(Attach signed minutes of Institutional Biosafety Committee discussions)*	
1.4.1 Name			
		1.5.1 Institution of applicant	
		1.5.2 Registration Status in Kenya	
		1.5.2.1 Affiliating institution *(if institution of applicant is not registered in Kenya)*	
1.4.2 Address		1.5.3 Address	
1.4.3	1.4.4	1.5.3	1.5.4 Facsimile/ email
Telephone	Facsimile/email	Telephone	

1.6 Summary of trial

1.6.1 Brief Description of Proposed Trial

1.6.2 Objective

1.6.3 What is the aim of the proposed trial of the genetically modified organism?

1.6.4. What are the benefits of this approach compared with other possible methods, especially those not involving planned trial?

1.6.5 If the trial is successful, do you intend to propose a general release of the GMO?

1.6.6 Summary of the risk assessment

1.7 Description of unmodified plant species

1.7.1 Describe mechanisms and frequency of intra-and inter-specific out-crossing.

1.7.2 Describe the mechanism of infertility

1.8 Phenotypic Characteristics

Provide information on plant mechanisms responsible for:

1.8.1 Tendency to weediness

1.8.2 Allelopathy

1.8.3 Dormancy

1.8.4 Pollen dispersal

1.8.5 Seed dispersal

1.8.6 Vegetative dispersal
1.8.7 Other dispersal
1.8.8 Other Characteristics
1.9 Toxins
1.9.1 List any known toxins from this species, including natural defence compounds.
1.9.2 Indicate the levels at which these compounds induce toxicity.
1.9.3 Indicate the species affected by these toxins.
1.10 Allergens
1.10.1 List any known allergens for this species, including natural defence compounds.
1.11 Describe any pathological, ecological and physiological traits that relate to the
genetically modified organism but not to the unmodified plant.
Section 2: Submission
Fill out section 2 for each individual submission (genetic modification of that particular species) included in the application.
2.1 Name or Designation of genetically modified organism
2.2 Modified trait(s) Identification

# Herbicide Tolerance	# Modified Oil Composition	# Pharmaceutical
# Male sterility/ restoration	# Virus Resistance	# Genetic Research
# Insect Resistance	# Stress Tolerance	# Generation of mutants
# Nutritional change	# Fungal- Resistance	# Other (Specify)

2.3 Modified Trait(s)
Describe each specific novel trait associated with this genetically Modified organism.
2.4 Status of authorization
2.4.1 Is genetically modified organism Imported or generated locally.
2.4.2 If imported, provide the import permit number issued under any other authorization.
2.5 History
Has this Genetically Modified Organism been previously tested in Kenya?
Yes
No
If yes, please provide information on trial (s), year(s) of authorization and location(s) tested.
2.6 Trait Introduction and Selection Method
2.6.1 Describe Introduction Method(s).
2.6.2 Describe Trait Selection Method.
2.6.3 Describe Mode of action of traits (gene product, metabolic pathways).
2.6.4 Other techniques of modification
Provide details of modification by means other than mutagenesis or recombinant DNA techniques.
2.7 Gene Donor (s)
Indicate the gene donor organism(s) (*for plants transformed using rDNA techniques*).

2.8 Transformation Vectors and/or Plasmids
Please provide the following information:
2.8.1 Name of plasmid (construct) and genetic map (*map of each genetic—construct required).*

2.8.2 Is the vector naturally pathogenic? # Yes # No	2.8.3 Is the vector disarmed?# Yes # No	2.8.4 If yes, how was the vector disarmed?

2.8.5 For each gene construct, describe all genes, regulatory elements, gene products, non-translated DNA sequences and, where applicable, affected metabolic pathways.
2.9 Characteristics of the transformed Trait(s)
2.9.1 Spatial and Temporal Trait Expression

Trait	Expression		
	2.9.1.1 Constitutive # Yes # No If not constitutive, indicate the specific tissue(s) in which the trait is expressed (green tissue, seed, pollen, roots, other	2.9.1.2 Is the trait expressed during specific developmental stage? # Yes # No If yes, when?	2.9.1.3 Is the trait inducible? # Yes # No If yes, how'?

2.10 Toxicity and Allergenicity of the Transformed Trait(s)
2.10.1 To what extent are transformed gene products toxic when ingested by native fauna
Populations, including mammals, birds, reptiles, and insects?
2.10.1.1 How has this been determined?
2.10.2 To what extent are transformed gene products allergens?
2.10.2.1 How has this been determined?
2.11 Altered Plant Characteristics
Please indicate any changes with respect to the following:
2. 11.1 Persistence and invasiveness
2.11.2 Allelopathy
2.11.3 Dormancy
2.11.4 Pollen Dispersal
2.11.5 Seed Dispersal
2.11.6 Vegetative Dispersal
2.11.7 Any other Dispersal Mechanism
2.11.8 Any other altered characteristic (s)
Are any of the likely gains directly linked to losses in other characteristics of the species?
2.11.9 Please describe if any toxins and allergens are produced by the GMO that were not
produced by the unmodified plant
2.11.10 What is the frequency of reversion, i.e., loss of genetic modification?
2.11.11 How do you verify that you have the desired GMO?
2.11.12 What methods are to be used to test for batch-to-batch consistency?
2.12 Trial Site Locations and Trial Protocols

2.12.1 Town and Province	2.12.2 Legal land location	2.12.3 Trial Protocol(s)

(Attach trial Protocol)

//Please note: Section 3 must be completed for each Trial Site Location listed above and
Section 4 must be completed for each Trial Protocol listed above.//

Section 3: Confined Field Trial Site

Please fill out Section 3 for each Trial Site Location included in the application.

3.1 Town/City (*Nearest city*)	3.2 Province	3.3 Legal Land Location (*The National Biosafety Authority will not authorize a confined field trial until the legal land location of the trial site has been given*)
3.4 Field Manager responsible for the trial site		3.4.2 Address
3.4.1 Name (*Must be affiliated to a research institution registered in Kenya*)		
3.4.3 Telephone		3.4.4 Facsimile
3.5 Trial Size Trial size in meters^2/Hectarage		3.6 Location Map Attach a complete map *(including GPS coordinates)* of the location of the trial site

3.6.1 Has the suitability of the contained use facility to conduct contained use activity been assessed.

3.7 Habitat

3.7.1 Describe the biological diversity of the trial site, including:

3.7.1.0 Potential impacts resulting from the field test

3.7.1.1 Soil

3.7.1.2 Groundwater level

3.7.1.4 Topography

3.7.1.5 Flora and fauna

3.7.1.6 Climate, especially prevailing winds direction and Temperate

3.7.1.7 Previous use of the facility

3.7.1.8 Distance from nearest human settlements

3.7.1.9 Distance from surface water body

3.7.2 Is the trial site part a of a managed ecosystem?	3.7.3 If yes, how close is the nearest natural ecosystem?
Yes # No #	

3.7.4 How close is the site from an area of special ecological interest, including protected areas and sanctuaries?

3.8.1 Specify the related wild and domesticated species/organisms present at the trial site and how close they are to the modified plant material under test.

3.8.2 Are there any endangered species on or near the site? 3.8.3 If yes, list
Yes# No #
NB: For information on endangered species that may be near the trial site location, contact the Kenya Wildlife Service, P.O. Box 40241 NAIROBI, Email: kws@kws.org, Website: www.kws.org, Langata Road, Telephone +245-20-501081.
3.8.4 What mechanisms are in place to prevent the local fauna from removing the modified plants material from the site?
3.9 Post-Trial Land Use
3.9.1 Person(s) having control over the site during the post-harvest/trial land use period, including the isolation area
3.9. 1.1 Name 3.9.1.2 Address
3.9.1.3 Telephone 3.9.1.4 Facsimile
3.9.2 Describe how the site boundaries will be marked to facilitate subsequent inspection.
3.10 Submissions and Trial Protocols
Please list all submissions and trial protocols used at this site.
3.10.1 Submission (*genetically modified organism designation — List of possible designations/unique identifier)* 3.10.2 Trial Protocol(s)
//Please note: Section 2 must be completed for each Submission listed above and Section 4 must be completed for each Trial Protocol listed above.//
Section 4: Confined Field Trial Protocol
Please fill out Section 4 for each Trial Protocol included in the application.
4.1 Trial Protocol (Study)
Title:
4.2 Protocol
4.2.1 Fully describe the following
4.2.2 Purpose of the field trial
4.2.3 Experimental design
4.2.4 Nature and type of data to be collected
4.2.5 Arrangements for transporting the GMO to the trial site
4.2.6 Proposed, if any, herbicide/pesticide use
4.3 Provide work schedule (*post approval*) to include:
4.3.1 Planting (*anticipated)* 4.3.2 Harvest/Sampling (*anticipated)*
4.4 Isolation
State the isolation measures being implemented for this trial and give details
4.4.1 If using bags or nets, please provide the mesh size of the material being used and justify the effectiveness.
4.5 Seeding
4.5.1 Material will he planted by: 4.5.2 Will any unmodified plants of the same or a related species be planted at the trial site location?
4.5.1.1 Hand # 4 5.3 if yes, state reason
Or

4.5.1.2
Mechanically #
4.5.4 Describe your management plan to avoid the dissemination, e.g. of seed, from the trial site.
4.5.5 Describe your plan for recording the quantities of seed planted/GMO used and accounting for any excess
4.5.6 Describe the disposition plan, including how and where any excess. or non-planted seed/G MO will be disposed of or stored.
4.6 Spraying*
Complete this section it the trial site is subject to the use of an unregistered product, or a registered product used for a non-registered purpose.
4.6.1 Registered pesticide for unregistered use

4.6.1.1 Name of the pesticide	4.6.1.2 Total area to be sprayed (*m^2/hectarage)*	4.6.1.3 Active ingredient

4.6.2 Unregistered Pesticide Use Yes # No #

4.6.2.1 Name of the pesticide	4.6.2.2 Total area to be sprayed (//m^2 /hectarage//)	4.6.2.3 Active ingredient

** This information is required to determine compliance with the Pest Control Products Act (Cap 346).*
4.7 Harvesting

4.7.1 Will plants be allowed to set seed or to reproduce? Yes# No #	4.7.2 Describe the method of harvest for seed and other plant material (e.g. by hand, small plot combine, etc.)
4.7.3 Will any harvested plant material be retained from the trial? Yes # No #	4.7.4 Material retention If yes 4.7.4.1 Type *(e.g. seed, leaves, etc.*) 4.7.4.2 Quantity to be retained 4.7.4.3 Purpose of retaining material

4.7.5 For harvested plant material, describe the following if applicable:4.7.5.1 The storage method.
4.7.5.2 Storage location
4.7.6 Person responsible for the storage of the material

4.7.6.1 Name	4.7.6.2 Address
4.7.6.3. Telephone	4.7.6.4 Facsimile

4.7.6.5 Proposed storage records
4.7.7 Describe how the site boundaries will be marked to facilitate subsequent inspection.
4.7.8 Describe your management plan to avoid dissemination of seed/GMO from the trial site during harvesting.
4.8 Disposal
4.8.1 Describe your disposal plan for all propagules and non-propagule plant material; including how and where the material will be disposed of.
4.8.2 Person responsible for the disposal of the material

4.8.2.1 Name	4.8.2.2 Address
4.8.2. Telephone	4.8.2.4 Facsimile

4.8.2.5 Proposed disposal records

4.9 Contingency Plans
4.9.1 Describe your contingency plan in the case of accidental release of seed/ GMO plant material (e.g. spills), or the breakdown of isolation.
4.9.2 Describe your contingency plans if after accidental release there is unexpected spread of the transformed plant material.
4.10 Monitoring the Trial Site
4.10.1 Describe the extent and frequency of trial site monitoring during the course of the
Field trial.
4.10.2 Describe the extent and frequency of trial site monitoring during the post-trial
period.
4.10.3 Person responsible for monitoring
4.10.3.1 Describe what monitoring results will be recorded
4.10.3.2 Describe how monitoring results will be recorded
4.10.4 If any controlled monitoring procedures are proposed for this trial (e.g. planting of unmodified plants of a related species to determine possibility and frequency of gene flow), detail these.
4.10.5 Describe the provisions to remove or eliminate the GM° from the test site or any other place where it may be found upon completing the trial and to restore the test site and any such other place to its status quo.
4.11 Public Notice
4.11.1 How will you provide public notification of your proposed field trial?
Section 5: Hectarage
Please indicate the number of hectares per submission per province (Limit of 5 ha cumulative per submission per province)
Province A:
Submission (genetically modified organism designation):

Trial site location		
Legal land location	Town	Number of hectares

Total number of hectares:
Add other tables for any other Province, if applicable
Section 6: Certification
I certify that the above information is true to the best of my knowledge.

Principal Investigator
Name
_____
Signature _____ Date
_____
Collaborator(s)
Name(s) _____
Signature _____ Date
_____
Institutional Biosafety Committee (IBC) Review
This application has been reviewed by IBC
Name of IBC _____

Name of Chairperson
_____
Signature _____ Date
_____

FOURTH SCHEDULE
[r. 9]

FORM FOR APPROVAL TO CONDUCT CONTAINED USE ACTIVITY USING GENETICALLY MODIFIED ORGANISM

THE NATIONAL BIOSAFETY AUTHORITY

APPROVAL TO CONDUCT CONTAINED USE ACTIVITY USING GENETICALLY MODIFIED ORGANISM

APPROVAL NUMBER _____ DATE OF ISSUE _____
VALID UP TO _____

In accordance with regulation 9 of the Biosafety (Contained Use) Regulations, of the Biosafety Act, I hereby grant the approval to undertake contained use activity of the genetically modified organism herein stated in the research institution mentioned in this approval.

Name of the Applicant/ Research Institution
Specification of the genetically modified organism
Quantity approved
Specification of the genetic modification
Risk category
Purpose of the use

This approval is granted subject to the following Conditions-

1. _____
2. _____
3. _____
4. _____

This approval is not transferrable and is valid for:

Place: Name:
Date Signature:
The Chief Executive Officer National Biosafety Authority

FIFTH SCHEDULE
[rr. 13, 14]

CONTINGENCY PLAN

1.0 Name of the Applicant 2.0 Address of the Work place

3.0 Accurate identification of premises, sites and facilities where the genetically modified ' organisms are used and the accurate identification of the place, premises, sites or facilities are situated (*describe and attach map*)

4.0 Plan of the workplace with identification of places that are important for the reduction of accident consequences, places of storage of genetically modified organisms, protective measures of the contained space

5.0 Description of an accident that can occur in space or place where the genetically modified organism is used
6.0 Review on possible accident impacts on human health and the environment, including the methods for detection of such impacts and effective protection from the impacts

7.0 Validated procedures for the detection of presence of genetically modified organisms	8.0 Validated methods and procedures available for liquidation of genetically modified organisms and for decontamination of an affected space
9.0 Methods of isolation of spaces and facilities affected by accident including methods of control of isolation effectiveness	10. Methods of disposal or remediation of plants and animals that were in the affected area at the time of the accident

11. Description and layout of decontamination agents available to liquidate genetically modified organisms and decontaminate an affected space
12. Procedures for protection of human health and the environment in case of undesirable effects of an accident
13. Description of the procedure of subsequent monitoring of sites and premises after the termination of a decontaminated process

14. Persons to whom the contingency plan is submitted to	15. Manner of notification of an accident to the Authority and relevant regulatory agency including the manner of warning the inhabitants on its possible consequences

16.0 Undertaking of the applicant (*attach affidavit)*
16.1 Name Signature
DECLARATION BY APPLICANT
I, ... of P.O. Box No. ..... of (Company/ Institution) ..... ID No. .....;
hereby declare that to the best of my knowledge and belief the particulars given in this application are true and correct.
Declared by } _____
this day of } DECLARANT
at }
Before me
Commissioner for Oaths/Magistrate/Judge

THE BIOSAFETY (ENVIRONMENTAL RELEASE) REGULATIONS

ARRANGEMENT OF REGULATIONS

PART I – PRELIMINARY

Regulation

1. Citation
2. Interpretation
3. Objective
4. Exceptions

PART II – APPLICATIONS

5. Environmental release
6. Placing on the market
7. Consideration of an application
8. Non-assessment of risks
9. Approval
10. Validity and renewal of approval
11. Handling of new information
12. Public awareness and participation
13. Decision document
14. Monitoring

PART III – MISCELLANEOUS

15. Registration of decisions in the National Biosafety Clearing House
16. Confidentiality
17. Offences and penalties

SCHEDULES

FIRST SCHEDULE — APPLICATION FORM FOR ENVIRONMENTAL RELEASE AND/OR PLACING ON THE MARKET OF GENETICALLY MODIFIED ORGANISM(S)

APPROVAL FOR ENVIRONMENTAL RELEASE/PLACING ON THE MARKET OF A GENETICALLY MODIFIED ORGANISMS

THE BIOSAFETY (ENVIRONMENTAL RELEASE) REGULATIONS

[Legal Notice 98 of 2011]

PART I – PRELIMINARY

1. Citation

These Regulations may be cited as the Biosafety (Environmental Release) Regulations.

2. Interpretation

In these Regulations unless the context otherwise requires—

"applicant" means a person making an application under to these Regulations;

"Authority" means the National Biosafety Authority established under section 5 of the Act;

"Biosafety Clearing-House" means a mechanism for exchange of scientific, technical, environmental, socio-economic and legal information and experience with genetically modified organisms;

"environmental release" means introduction into the environment of a genetically modified organism for which an approval has been granted in accordance with these Regulations and—

(a) for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment; and

(b) includes making genetically modified organisms available to the public for purposes other than sale;

"genetically modified organism" means an organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology techniques;

"placing on the market" means making a genetically modified organism available for sale;

"regulatory agency" means a regulatory agency as set out in the First Schedule to the Act, or such other agency as the Minister may, by order in the Gazette, determine;

"risk assessment" means the evaluation of risks to human and the environment, whether direct or indirect, immediate or delayed, which the environmental release or placing on the market of genetically modified organisms may pose;

"screening for completeness" means the evaluation of an application to ensure that all the administrative as well as technical requirements are met.

3. Objective

The objective of these Regulations is to ensure that potential adverse effects of genetically modified organisms are addressed to protect human health and the environment when conducting environmental release.

4. Exceptions

These Regulations shall not apply to genetically modified organisms that are pharmaceuticals for human use.

PART II – APPLICATIONS

5. Environmental release

(1) A person shall not make an environmental release without the written approval of the Authority.

(2) An application for environmental release shall be made to the Authority in the form set out in Part A of the First Schedule to these Regulations and shall be accompanied by—

(a) an application fee of Kenya shillings eight hundred and fifty thousand; and

(b) where necessary, an additional risk assessment report.

(3) An applicant may—

(a) refer to data or results from an application previously submitted by another applicant; or

(b) submit additional information that the applicant considers relevant, provided that the information, data and results are non-confidential or such applicants have given their agreement in writing.

(4) The Authority may allow an application for release of the same genetically modified organism on the same site or on different sites for the same purpose and within a definite period to be made in a single application.

(5) Where the Authority, after a risk assessment, considers that it is necessary for the genetically modified organism to be subjected to contained use, the Authority shall communicate its decision to the applicant in writing and the provisions of the Contained Use Regulations shall apply.

(6) Where the application is for introduction into the environment of a genetically modified organism that is not locally developed, the Authority, after a risk assessment, may require that the applicant carries out field trials of the genetically modified organism and the provisions of the Contained Use Regulations shall apply.

(7) A person who contravenes sub-regulation (1) commits an offence.

6. Placing on the market

(1) A person shall not place on the market a genetically modified organism without the written approval of the Authority.

(2) An application to place on the market a genetically modified organism shall be made to the Authority in the form set out in Part B of the First Schedule to these Regulations and shall be accompanied by—

(a) an application fee of Kenya shillings eight hundred and fifty thousand; and

(b) where necessary, a risk assessment report.

(3) An applicant may—

(a) refer to data or results from an application previously submitted by other applicants; or

(b) submit additional information that the applicant considers relevant, provided that the information, data and results are non-confidential or such applicants have given their agreement in writing.

(4) A person who contravenes subregulation (1) commits an offence.

7. Consideration of an application

(1) Upon receiving an application, the Authority shall within fourteen days screen for completeness and circulate to the relevant regulatory agencies for further information, comments or reasoned objections.

(2) The Authority shall in considering an application, examine—

(a) the conformity of an application with the requirements of these Regulations;

(b) the accuracy and completeness of the information given;

(c) the risk assessment submitted by the applicant; and

(d) the uses of the genetically modified organism.

(3) The authority shall publicize an application received hereunder and invite written comments from members of the public within twenty one days.

(4) Where necessary, the Authority may ask an applicant to provide further information.

(5) The Authority shall communicate its final decision to the applicant within one hundred and fifty days of receipt of the application, but not earlier than ninety days of such receipt.

(6) For the purpose of calculating the periods, any period of time during which the Authority is awaiting any further information that it may have requested from the applicant shall not be taken into account.

8. Non-assessment of risks

(1) The Authority may opt not to undertake risk assessment where it determines that sufficient experience or information exists to conclude that an environmental release does not pose a significant risk.

(2) Once an approval has been granted by the Authority for release of a genetically modified organism, subsequent release of the same species, or the same species modified with the same gene or combination of genes, may be exempted from risk assessment.

9. Approval

(1) An approval for environmental release shall be in the Form set out in the Second schedule to these Regulations.

(2) If information becomes available that an approved activity poses a risk to human health or the environment, the Authority may amend or revoke the approval.

10. Validity and renewal of approval

(1) An approval granted under these Regulations shall be for a period not exceeding ten years.

(2) At least nine months before the expiry of an approval period, a person intending to continue to release into the environment or placing genetically modified organisms on the market shall submit an application for the renewal of the approval.

(3) An application for renewal of an approval under these Regulations shall contain the information set out in the First Schedule to these Regulations and shall be accompanied by—

(a) an application fee of eight hundred and fifty thousand shillings;

(b) a copy of the approval under regulation 9(1);

(c) a report on the results of the monitoring which was carried out in accordance with these Regulations;

(d) any new information which has become available with regard to the risks of the genetically modified organism to human health and the environment; and

(e) a proposal for amending or complementing the conditions of the original approval and any other conditions concerning future monitoring.

(4) The Authority shall consider an application for renewal within thirty days of receiving the application and may—

(a) approve the application with or without conditions; or

(b) reject the application stating the reasons for rejection.

(5) Pending the renewal of an approval, an applicant may continue operating under the conditions of approval granted under regulation 9(1) until a final decision has been taken on the application for renewal.

(6) An approval for renewal from the Authority shall be valid for a period of ten years.

(7) Where a genetically modified organism has been released into the environment or placed on the market for twenty years with the approval from the Authority, and the Authority establishes that monitoring data indicates no risk to human health and the environment, the genetically modified organism may continue to be released to the environment or placed on the market without further approval.

11. Handling of new information

(1) Where there are any changes to a genetically modified organism or of a combination of genetically modified organisms as a result of the environmental release which could have

adverse effects on human health and the environment after the Authority has given its written approval, the applicant shall immediately—

(a) take the measures necessary to protect human health and the environment;

(b) inform the Authority in advance of any change or as soon as the unintended change is known or the new information is available; and

(c) revise the measures specified in the application or approval.

(2) Where there are any changes to a genetically modified organism or of a combination of genetically modified organisms as a result of the environmental release which could have adverse effects on human health and the environment after the Authority has given its written approval the Authority—

(a) shall evaluate such information and may make it available to the public; and

(b) may require the applicant to, modify the conditions of, suspend or terminate the environmental release.

12. Public awareness and participation

(1) The Authority shall promote public awareness and participation on the proposed environmental release.

(2) In carrying out public awareness and participation, the Authority shall publish guidance documents.

(3) The Authority shall—

(a) by notice in the Gazette;

(b) in at least two newspapers of wide circulation; and

(c) on its website, make available to the public, non-confidential information on applications for environmental release of genetically modified organisms.

(4) Any person may within thirty days of the publication of a notice under paragraph (3), submit written comments on the proposed decisions for any application for placing a genetically modified organism on the market.

13. Decision document

(1) A decision on the application shall be recorded in a decision document.

(2) The decision document shall be in such form as the Authority may determine and shall contain a statement to the proposed manner of the use, risk management and proposed requirements for monitoring and shall include the following information—

(a) identification of properties of a recipient which are important for the use of the genetically modified organism;

(b) any known risks to health and the environment arising from the introduction of non-modified recipient into the environment or on the market;

(c) description of results of genetic modification in genetically modified organisms;

(d) evaluation of the sufficiency of characterising genetic modification in the request to assess risks;

(e) identification of risks to the health of humans, animals, plants and the environment which may arise from the use of genetically modified organisms in comparison with the use of corresponding non-modified organism, based on the risk assessment conducted;

(f) a conclusion as to whether—

(i) a genetically modified organism may be released into the environment or placed on the market, and under which conditions; or

(ii) a genetically modified organism shall not be released into the environment or placed on the market, in which case the reasons shall be stated.

14. Monitoring

(1) A person granted an approval under these Regulations together with the relevant regulatory agency shall monitor and report on the release in accordance with the approval.

(2) The relevant regulatory agency shall submit the monitoring report to the Authority.

(3) The Authority shall ensure that all appropriate measures are taken to avoid adverse effects on the health of humans, animals and the environment which might arise from the environmental release or the placing on the market of genetically modified organisms.

(4) The Authority shall develop and issue an inspection manual and guidelines to ensure that the relevant regulatory agency organises inspections and other control measures as appropriate for purposes of compliance with this regulation.

(5) In the event of a release of a genetically modified organism or the placing on the market of a genetically modified organism for which no approval has been granted, the Authority shall ensure that—

(a) necessary measures are taken to terminate the release or placing on the market of such organism;

(b) remedial action is taken, if necessary; and

(c) the public is informed and appropriately advised on such release or placing on the market.

PART III – MISCELLANEOUS

15. Registration of decisions in the National Biosafety Clearing House

The Authority shall register all decisions made under these Regulations in the National Biosafety Clearing House within thirty days of making the decision.

16. Confidentiality

(1) The Authority shall not disclose to a third party any confidential information exchanged under these Regulations and shall protect intellectual property rights of the applicant.

(2) An applicant may indicate with verifiable justification, information in the application submitted under these Regulations, the disclosure of which might harm the applicant's competitive position and which should be treated as confidential.

(3) The Authority shall, after consultation with the applicant, decide which information may be kept confidential and shall inform the applicant accordingly.

(4) The following information shall not be considered to be confidential—

(a) the name and address of the applicant;

(b) the general description of the genetically modified organism;

(c) the purpose of the release;

(d) the location of release and intended uses;

(e) the plans for monitoring of the genetically modified organism and for emergency response; and

(f) the risk assessment report.

(5) If, an applicant withdraws an application, the Authority shall respect the confidentiality of the information supplied.

17. Offences and penalties

A person who contravenes any of these Regulations commits an offence and shall be liable on conviction to a fine not exceeding twenty million shillings or to imprisonment for a term not exceeding ten years, or both.

FIRST SCHEDULE

APPLICATION FORM FOR ENVIRONMENTAL RELEASE AND/OR PLACING ON THE MARKET OF GENETICALLY MODIFIED ORGANISM(S)

(r. 5(2), 6(2))

Part A of this schedule shall be filled by an Applicant making an application for either Environmental Release or Placing on the market of genetically modified organism(s), or both.

Part A and B of this schedule shall be filled by an Applicant making an application for Placing on the market of genetically modified organism(s).

APPLICATION FORM FOR ENVIRONMENTAL RELEASE AND /OR PLACING ON THE MARKET OF GENETICALLY MODIFIED ORGANISM(S)

PART A

1.0 General information

1.1 Name of applicant	1.2 Physical Address
1.3 Telephone	1.4 Email
1.5 Title of the Application	1.6 Application Type of # New # Renewal

2.0 Information on the Genetically modified organism

2.1 Name and identity of the genetically modified organism (*Differences between the biological characteristics of the genetically modified organism and those of the recipient organism or parental organisms*)	2.2 Transformation event(s)
2.3 Intellectual property ownership of the novel trait, if any	2.4 Unique identifier for the genetically modified organism if any

2.5 Introduced or modified trait (Choose the trait from the following list)

2.5.1 A biotic environmental tolerance	2.5.2 Altered growth, development and product quality
# Altered photoperiod sensitivity	# Altered ripening or flowering
# Cold or heat tolerance	# Coloration
# Drought or water tolerance	# Fertility restoration
# Other	# Growth rate or yield # Male sterility # Nutritional composition (including allergenicity) # Selectable marker genes and reporter genes # Uptake or degradation of environmental pollutants # Other growth, development and product quality
2.5.3 Chemical tolerance	2.5.4 Medical products
# Herbicide tolerance	# Animal vaccines
# Other chemical tolerance	# Development of transplant organs # Production of pharmaceuticals # Other medical products
2.5.5 Pest resistance	2.5.6 Other — specify
# Bacterial resistance	

Fungus resistance
Insect resistance
Nematode resistance
Virus resistance
Other pest resistance
2.6 Technique used for modification. (*Please select techniques used for the transformation*)
Plasmid carried by *Agrobacterium tumefaciens*
Biolistic methods
Osmotic shock
Electric shock
polarisation
Other- specify
2.7 Description of gene modification
2.8 Summary of contained use and confined field trial data (*provide information on key results of trials at both contained level and confined field trials whether conducted in Kenya or outside Kenya*)
3.0 *Characteristics of genetic modification*
3.1 Vector characteristics

3.1.1 vector(s) identity	3.1.2 source(s) or origin	3.1.3 host range

3.2 Insert or inserts
(Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced)

3.3 Description of phenotypic characteristics (in particular any new traits and characteristics which may be expressed or no longer expressed)	3.4 Rate and level of expression of the new genetic material. Method and sensitivity of measurement

3.5 Activity of the expressed protein(s)
3.6 Description of identification and detection techniques of the inserted sequence and vector
4.0 Recipient organism or parental organisms

4.1 Taxonomic name/status of recipient organism or parental organisms	4.2 Common name of recipient organism or parental organisms
4.3 Point of collection or acquisition of parental organisms	4.4 Center(s) of origin of the recipient organism or parental organisms (*Describe the exact location and give geographical coordinates*)
4.5 Center(s) of genetic diversity, if known, of Centre's of genetic Diversity, if known, of Recipient organism or Parental organisms Describe the exact location and give geographical coordinates)	4.6 Habitats where the recipient organism or Parental organism may persist or proliferate

4.7 Description of the habitat where the genetically modified organism may persist or proliferate
5.0 Donor organism(s)

5.1 Taxonomic name/status of the donor organism or parental organisms	5.2 Common name of donor organism
5.3 Point of collection or acquisition of donor organism (*Describe the exact location and geographical coordinates*)	5.4 Biological characteristics of donor organisms

6.0 Intended use and receiving environment
6.1 Description of the proposed deliberate release, including the purpose(s) and foreseen products
6.2 Foreseen dates of the release
Quantities of genetically modified organisms to be released
6.4 Suggested method(s) for, safe handling, transport and storage during release
6.5 History and results of previous environmental releases, as well as uses of the genetically modified organism - (country, region, dates of releases especially at different scales and in different ecosystems, any adverse effects on the health of human, animal and plant, and environment)
6.6 Intended use of the Genetically modified organism (*Information relating to the intended use of the genetically modified organism, including new or changed use compared to the recipient organism or parental organisms*)
6.7 Receiving environment (*Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment*)
7.0 Risk assessment summary (Cite references)
7.1 Detection/Identification method of the genetically modified organisms (*Suggested detection and identification methods and their specificity, sensitivity and reliability)*
7.2 Evaluation of the likelihood of adverse effects (*An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential to the health of human, plant and animal, and the receiving environment to the genetically modified organism*)
7.3 Evaluation of the consequences
(*An evaluation of the consequences should these adverse effects be realized)*
7.4 Overall risk
(*An estimation of the overall risk posed by the genetically modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized*)
7.5 Recommendation
(*A recommendation as to whether or not the risks are acceptable or, manageable, including, where necessary, identification of strategies to manage these risks*)
7.6 Information on post release monitoring and emergency response plans
(*describe post release monitoring methods, recall procedures*)
8.0 Additional information
8.1 Availability of detailed risk assessment information (*Please indicate whether more details on the risk assessment are available and how they can be accessed*)
8.2 Any other relevant information
8.3 Additional notes
PART B
1.0 General information
1.1 Name or names, as appropriate, and surname *(trade company*), if the applicant is the natural person authorised to operate a business
1.2 Title (*trade company*) and the legal form, if the applicant is legal person
1.3 Nationality (*in case of natural persons*)
1.4 Place of business (*in case of legal persons*) or place of business and place of residence (*in case of natural persons*)
1.5 Company registration number (if assigned
1.6 Tax identification number (if assigned)

1.7 Subject of activity

1.8 Name of person(s), who represents a statutory body of the applicant, including the manner of acting on behalf of the applicant *(in case of legal persons*), as appropriate

1.9 Address of residence

1.10 Contact address

1.11 Telephone number

1.12 Fax number

1.13 E-mail

2.0 Information on the genetically modified organism

2.1 Name of beach constituent genetically modified organism contained in a package

2.2 Origin of each constituent genetically modified organism contained a package

2.3 The properties of each constituent genetically modified organism contained in a package

3.0 Purpose and procedure of the placing of genetically modified organism

3.1 The purpose of placing of the genetically modified organism on the market

3.2 Date of expected commencement of the placing genetically modified organism placing on the market and its binding schedule (*details and the periods of the individual stages*)

3.3 Expected amount of the genetically modified organism that will be used in the individual stages including information on whether the production comes from Kenya or whether it's imported.

4.0 Summary of the Risk assessment of genetically modified organism to be placed on the market

5.0 Information, data or results from placing on the market if any, of the same genetically modified organism previously or currently applied for or carried out by the applicant

5.1 Additional information

DECLARATION BY APPLICANT

1, ... of P.O.Box No. ..... of (Company/ Institution) ..... ID No. ....., hereby declare that to the best of my knowledge and belief the particulars given in this application are true and correct.

Declared by ..... } _____

this ..... day of } DECLARANT

at }

Before me

Commissioner for Oaths/Magistrate/Judge

SECOND SCHEDULE

[s. 9]

APPROVAL FOR ENVIRONMENTAL RELEASE/PLACING ON THE MARKET OF A GENETICALLY MODIFIED ORGANISMS

(r. 9(1)

THE BIOSAFETY ACT

(Cap. 320)

THE NATIONAL BIOSAFETY AUTHORITY

APPROVAL FOR ENVIRONMENTAL RELEASE/PLACING ON THE MARKET* OF A GENETICALLY MODIFIED ORGANISMS

APPROVAL NUMBER _____ DATE OF ISSUE _____

VALID UP TO _____

In accordance with Regulation 9 of the Biosafety (Environmental Release) Regulations, approval is hereby granted for environmental release/placing on the market* of the genetically modified organism herein stated. The approval is granted to the applicant/research institution* mentioned in this approval.

Name of the Applicant/ Research Institution

Scope of the approval

Identity of the genetically modified organism

Quantity approved

Specification of the genetic modification

Purpose

This approval is granted with to the following requirements:

1. _____
2. _____
3. _____

This approval is granted with the following monitoring requirements:

1. _____
2. _____
3. _____

Place: Name:

Date Signature:

The Chief Executive Office National Biosafety Authority

N.B - The applicant shall make samples available to the Authority on request

-This approval is not transferrable

* - Please delete as appropriate

THE BIOSAFETY (IMPORT, EXPORT AND TRANSIT) REGULATIONS

ARRANGEMENT OF REGULATIONS

PART I – PRELIMINARY

Regulation

1. Citation
2. Interpretation
3. Objective

PART II – APPLICATIONS

4. Application and requirements for import
5. Unauthorized importation
6. Application and requirements for export
7. Application and requirements for transit
8. Conditions for transit
9. Unauthorized transit
10. Unintentional release while on transit
11. Approval

PART III – MISCELLANEOUS

12. Monitoring for compliance
13. Genetically modified organisms register
14. Review of decisions
15. Registration of decisions in the National Biosafety Clearing House
16. Confidential information
17. Products derived from genetically modified organisms
18. Offences and penalties

SCHEDULES

FIRST SCHEDULE — APPLICATION FORM FOR IMPORT, EXPORT AND TRANSIT OF GENETICALLY MODIFIED ORGANISMS

SECOND SCHEDULE — APPROVAL TO IMPORT/ EXPORT /TRANSIT GENETICALLY MODIFIED ORGANISMS

THIRD SCHEDULE — INFORMATION REQUIRED FOR SAFETY ASSESSMENT

THE BIOSAFETY (IMPORT, EXPORT AND TRANSIT) REGULATIONS

[Legal Notice 97 of 2011]

PART I – PRELIMINARY

1. Citation

These Regulations may be cited as the Biosafety (Import, Export and Transit) Regulations.

2. Interpretation

In these Regulations unless the context otherwise requires—

"accident" means the unintended release of genetically modified organisms in the course of import, export or transit, which could pose present an immediate or delayed hazard to human health and the environment;

"Authority" means the National Biosafety Authority established under section 5 of the Act;

"Biosafety Clearing House" means a mechanism for exchange of scientific, technical, environmental, socio-economic and legal information and experience with genetically modified organism;

"competent authority" means an agency of another country responsible under its national law for the control or regulation of genetically modified organisms;

"contained use" means any activity undertaken within a facility, field, installation or other physical structure, which involves genetically modified organisms that are controlled by specific measures to provide safety for humans and the environment;

"contained use premises" includes a facility, field, installation or other physical structure in which contained use is undertaken;

"environmental release" means introduction into the environment of a genetically modified organism for which an approval has been granted in accordance with the Biosafety (Environmental Release) Regulations (sub. leg);

"export" means to take out of Kenya a genetically modified organism;

"genetically modified organism" means an organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology techniques;

"import" means to bring into Kenya a genetically modified organism;

"transit" means the movement of genetically modified organism through Kenya to another country.

3. Objective

The objective of these Regulations is to ensure safe movement of genetically modified organisms into and out of Kenya while protecting human health and the environment.

PART II – APPLICATIONS

4. Application and requirements for import

(1) A person wishing to import a genetically modified organism shall apply for and obtain written approval from the Authority.

(2) An application to import a genetically modified organism shall be in the form set out in the First Schedule to these Regulations and shall be accompanied by—

(a) a cover letter; and

(b) an application fee of twenty five thousand shillings.

(3) An application under Regulation 4 shall specify—

(a) the species or identity and amount of the genetically modified organism proposed to be imported; and

(b) the proposed port of entry into Kenya;

(c) the intended purpose for the genetically modified organism:

Provided that—

(i) where the intended purpose is for contained use the provisions of the Biosafety (Contained Use) Regulations (sub. leg) shall apply;

(ii) where the intended purpose is for the environmental release the provisions of the Biosafety (Environmental Release) Regulations (sub. leg) shall apply.

(4) The Authority may opt not to undertake risk assessment in cases where it previously gave approval for importation of the same genetically modified organisms from the same source.

(5) A person who contravenes subregulation (1) of this regulation commits an offence.

5. Unauthorized importation

In the event of an import of a genetically modified organism for which no authorization has been granted, the Authority—

(a) shall initiate remedial action such as refusal of entry, destruction or set conditions of use; and

(b) may inform and advise the public, of the existence of the genetically modified organism within the country.

6. Application and requirements for export

(1) A person wishing to export a genetically modified organism shall apply for and obtain written approval from the Authority.

(2) An application to export a genetically modified organism shall be made to the Authority in the form set out in the First Schedule and shall be accompanied by—

(a) consent or approval for import issued by the competent authority of the importing country; and

(b) an application fee of twenty five thousand shillings.

(3) An application to export genetically modified organisms shall specify—

(a) the species or identity and amount of the genetically modified organism that is to be exported; and

(b) the proposed port of exit from Kenya.

(4) The Authority shall, upon receipt of an application under this regulation, confirm that the proposed export meets the requirements of the importing country and may issue the approval in the manner prescribed in the Second Schedule.

(5) The Authority shall give a copy of the approval to the relevant regulatory agency for authorization of export.

(6) A person who contravenes subregulation (1) of this regulation commits an offence.

7. Application and requirements for transit

(1) A person wishing to transit a genetically modified organism shall apply for and obtain written approval from the Authority.

(2) An application under subregulation (1) shall be in the form set out in the First Schedule.

(3) A person transiting a genetically modified organism shall ensure that the genetically modified organisms are packaged and transported in accordance with Kenyan and International standards.

(4) A person who contravenes subregulation (1) commits an offence.

8. Conditions for transit

(1) A person transiting a genetically modified organism shall provide a copy of the approval granted by the Authority at the port of entry and exit.

(2) An approval to transit shall include—

(a) approved methods for packaging and handling of genetically modified organisms imported through conveyor shipment which should comply with the relevant international and national requirements for repackaging and handling of conveyor shipped commodities;

(b) a requirement that conveyor shipment shall meet import conditions under these Regulations; and

(c) a copy of the import permit issued by the receiving country indicating the quantities or volumes involved from the country of origin and confirming that the consignment may contain genetically modified materials.

(3) The Authority shall liaise with the relevant regulatory agency to ascertain that the consignment at the port of entry and exit is consistent with accompanying documents.

9. Unauthorized transit

If a person transits or is in the process of transiting a genetically modified organism for which no approval has been granted, the Authority may—

(a) confisticate the genetically modified organism;

(b) destroy the genetically modified organism; or

(c) set conditions for transit of the genetically modified organism; and

(d) inform and advice the public on the genetically modified organism.

10. Unintentional release while on transit

(1) In the event of an accident involving a genetically modified organism on transit it shall be the responsibility of the person transiting and the importer to—

(a) notify the Authority immediately both verbally and in writing of the accident; and

(b) as soon as possible provide the Authority with information regarding—

(i) the circumstances of the accident;

(ii) the identity and the quantity of genetically modified organism released;

(iii) the type of accident; and

(iv) any emergency measures taken or that ought to be taken to avoid or mitigate any adverse effects of the accident;

(c) take all appropriate short term, medium term and long term measures to avoid or mitigate any adverse effects of the accident.

(2) The Authority shall inform and advise the public of the accident.

(3) The Authority in consultation with the relevant regulatory agency shall undertake necessary action to minimize risk to human health and environment.

11. Approval

An approval granted by the Authority under these Regulation shall be in the form set out in the Second Schedule to these Regulations.

PART III – MISCELLANEOUS

12. Monitoring for compliance

The Authority shall liaise with the relevant regulatory agency to monitor any imported genetically modified organisms for compliance with the requirements of these Regulations.

13. Genetically modified organisms register

The Authority shall maintain a register, which shall contain all applications made to and decisions made by the Authority regarding genetically modified organisms.

14. Review of decisions

Where the Authority or a person granted an approval under these Regulations considers that—

(a) a change in circumstances has occurred which may influence the approval or the conditions issued under the approval; or

(b) additional relevant scientific or technical information has become available, the Authority may on its own volition or on the request of the person granted the approval, review its decision.

15. Registration of decisions in the National Biosafety Clearing House

The Authority shall register all decisions made under these Regulations in the National Biosafety Clearing House within thirty days of making the decision.

16. Confidential information

(1) The Authority shall not disclose to a third party any confidential information exchanged under these Regulation and shall protect the intellectual property rights of the applicant.

(2) The applicant may indicate, with verifiable justification, information in the application the disclosure of which might harm the competitive position of the applicant and which should be kept confidential.

(3) The following information shall not be considered confidential—

(a) the name and address of the exporter and importer;

(b) the unique identifier of the genetically modified organism;

(c) a summary of the risk assessment; and

(d) any method and plans for emergency response.

(4) Where an applicant withdraws an application, the authority shall respect the confidentiality of the information supplied.

17. Products derived from genetically modified organisms

(1) A person intending to export, import or transit a product derived from genetically modified organisms whose safety has been established in accordance with Kenya Standards for food and feed safety assessment shall notify the Authority in writing indicating proof of safety.

(2) The information required under subregulation (1) shall be provided in the format prescribed in the Third Schedule.

(3) Upon receipt of such notification, the Authority shall, in consultation with the relevant regulatory agency, review the information provided and communicate its decision.

18. Offences and penalties

A person who contravenes the provisions of these Regulations commits an offence and is liable on conviction to a fine not exceeding twenty million shillings or to imprisonment for a term not exceeding ten years or both.

FIRST SCHEDULE

APPLICATION FORM FOR IMPORT, EXPORT AND TRANSIT OF GENETICALLY MODIFIED ORGANISMS

(r. 4(2) 6(2), 7(2))

APPLICATION FORM FOR IMPORT, EXPORT AND TRANSIT OF GENETICALLY MODIFIED ORGANISMS

1. Name, address *(including physical address*) and contact details of the importer/exporter	Type of application (*Tick as appropriate*) # Import # Export # Transit
2. Contact details of the competent authority as applicable.	2.1 Importing /Destination country 2.2 Exporting country
3. Name. address and contact details of the supplier.	4. Country of origin 5. Expected date of import/export/ transit
6. Common name, scientific name, commercial name or unique identifier code of the genetically modified organism.	7. Port: 7.1 Entry into Kenya 7.2 Exit from Kenya
8. Evidence of approval of the genetically modified organism from the exporting country (Attach)	9. Consent for import from the destination country (in case of export or transit).
10. The intended use of the genetically modified organism in Kenya and what it was used for in the exporting country	1 1. The quantity of the genetically modified organism to be imported into Kenya

12. A summary of the risk assessment report
13. Methods and plans for safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures.
14. Describe the emergency response plan in Kenya in the event of an accident with the genetically modified organisms

DECLARATION BY APPLICANT

1, ... of P.O. Box No. ..... of (Company/ Institution) ..... ID No. ....., hereby declare that to the best of my knowledge and belief the particulars given in this application are true and correct.

Declared by } _____
this day of } DECLARANT
at }

Before me
Commissioner for Oaths/Magistrate/Judge

SECOND SCHEDULE

APPROVAL TO IMPORT/ EXPORT /TRANSIT GENETICALLY MODIFIED ORGANISMS (r. 4(1), 6(1), 7(11))

APPROVAL TO IMPORT/ EXPORT /TRANSIT* GENETICALLY MODIFIED ORGANISMS

APPROVAL NUMBER _____	DATE OF ISSUE _____ VALID UP TO _____

In accordance with regulation 4, 6, 7 and 11 of the Biosafety (Import, export end transit) Regulations 2011, approval is hereby granted to export, import or transit* the genetically modified organism herein stated. The approval is granted to the applicant mentioned in this approval.

1.0 Name of the Applicant	2.0 To import/export/transit from/to 2.1 Name and address of supplier:

2.2 Country of supplier:
2.3 Country of destination:

3.0 Identity of the genetically modified organism
4.0 Specification of the genetic modification
5.0 Quantity approved
6.0 Purpose
This approval is granted subject to the following conditions-1. _____
2. _____
3. _____
4. _____
7.0 The applicant should meet the following requirements for conveyor shipment
1. _____
2. _____
3. _____
4. _____
Name: Place:
Signature: Date
The Chief Executive Office
National Biosafety Authority
Note:
- the applicant shall make samples available to the Authority on request
- This approval is not transferrable
- ensure that any other relevant legal requirements have been met
* - Please delete as appropriate

THIRD SCHEDULE

INFORMATION REQUIRED FOR SAFETY ASSESSMENT

(r. 17(2))

INFORMATION REQUIRED FOR SAFETY ASSESSMENT

1. Name, address (//including physical address)// and contact details of the Applicant — include email and telephone.	Type of application (*Tick as appropriate)* # Import # Export # Transit # Other
2. Contact details of the competent authority responsible for safety assessment	2.1 Importing /Destination country 2.2 Exporting country
3. Name, address and contact details of the supplier.	4. Country of origin 5. Expected date of import/export/ transit
6. Name of manufacturer or distributor if different from applicant	7. Port: 7.1 Entry into Kenya

8.0 Description of the Product and its intended use	7.2 Exit from Kenya
9.0 Evidence of prior approval for use as food/feed and source or indication of where detailed information on the approval can be obtained.	10. Instructions and conditions of use, storage
II. Quantity of the product	12. Proposed labeling and packaging

THE BIOSAFETY (LABELLING) REGULATIONS

ARRANGEMENT OF REGULATIONS

Regulation

1. Citation
2. Interpretation
3. Objective
4. Application
5. Exemptions
6. Food safety assessment before labelling
7. Labelling and packaging requirements
8. Claims
9. Traceability
10. Monitoring inspection and compliance
11. Genetically modified organisms labelling register
12. Offences and penalties

THE BIOSAFETY (LABELLING) REGULATIONS

[Legal Notice 40 of 2012]

1. Citation

These Regulations may be cited as the Biosafety (Labelling) Regulations.

2. Interpretation

In these Regulations unless the context otherwise requires—

"altered characteristic" of a genetically modified food means that when the genetically modified food is compared to its conventional counterpart, it is different in:

composition or nutritional values, anti-nutritional factors or natural toxicants, factors known to cause allergic responses in particular sections of the population, its intended use, or any other material differences;

"Authority" means the National Biosafety Authority established under section 5 of the Act;

"competent authority" means an agency of a country outside Kenya responsible under its national law for the control or regulation of genetically modified organisms;

"conventional counterpart" means a related organism or variety, its components or products for which there is experience of establishing safety based on common use as food, feed or for processing;

"food, feed or ingredient derived from genetically modified organism" means a food, feed, or ingredient produced, in whole or in part from genetically modified organisms;

"genetic modification-free" means the complete absence of any genetically modified material, or use of a genetic modification process, in a food or food product and

"non-genetically modified organism" shall be construed accordingly;

"genetically modified food or feed" means food or feed that is, or contains as an ingredient, including a processing aid, produced using modern biotechnology which—

(a) contains novel DNA or novel protein; or

(b) has altered characteristics;

"genetically modified organism" means an organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology techniques;

"labeling" means any written, printed, or graphic matter that accompanies a food or is displayed near the food, including that for the purpose of promoting its sale or disposal;

"novel DNA or novel protein" means DNA or a protein which, as a result of the use of genetic modification, is different in chemical sequence or structure from DNA or protein present in counterpart food which has not been produced using genetic modification;

"operator" means a natural or legal person who places a product on the market at any stage of the production and distribution chain, but does not include the final consumer;

"placing on the market" means making a genetically modified organism available for sale;

"product" means genetically modified food, feed and ingredients as defined under these Regulations;

"traceability" means the ability to trace genetically modified organisms and products of genetically modified organisms at all stages of their placing on the market through the production and distribution chains;

"unique identifier" means a simple numeric or alphanumeric code which serves to identify a genetically modified organism on the basis of the authorized transformation event from

which it was developed and providing the means to retrieve specific information pertinent to that genetically modified organism.

3. Objective

The objective of these Regulations is—

(a) to ensure that consumers are made aware that food, feed or a product is genetically modified so that they can make informed choices; and

(b) to facilitate the traceability of genetically modified organism products to assist in the implementation of appropriate risk management measures where necessary.

4. Application

The labelling requirements shall include, but not be limited to—

(a) products consisting of, or containing, genetically modified organisms; or

(b) food or feed produced from genetically modified organisms, placed on the market in accordance with the Act.

5. Exemptions

These Regulations shall not apply to—

(a) food, feed or their ingredients containing approved genetically modified organisms and derived products where there is inadvertent presence of genetically modified material in proportions of less than 1% of the total weight;

(b) highly refined food, where the effect of the refining process is to remove novel DNA or novel protein;

(c) a processing aid or food additive, except where novel DNA or novel protein from the processing aid or food additive remains present in the food to which it has been added above the threshold level;

(d) food intended for consumption prepared and sold from food premises and vendors.

6. Food safety assessment before labelling

Labelling and packaging of food, feed or ingredients containing genetically modified organisms or products derived from genetically modified organisms shall be considered after they have undergone appropriate food safety assessment in accordance with the Act.

7. Labelling and packaging requirements

(1) In labelling products consisting of or containing genetically modified organisms, operators shall ensure that—

(a) for pre-packaged products, the words "genetically modified (name of ingredient)" or "genetically modified (name of food)" appears on the label;

(b) for non-pre-packaged products the words "genetically modified organisms" or "genetically modified (name of organism)" shall appear on, or in connection with, the display of the product.

(2) In addition to the inclusion of the words "genetically modified" as required under subregulation (1), there shall be additional labelling and information requirements for genetically modified foods that have altered characteristics in relation to—

(a) one or more significant composition or nutritional parameters having values outside the normal range of values compared to conventional counterpart food or feed or ingredient thereof not produced using modern biotechnology techniques;

(b) the level of anti-nutritional factors or natural toxicants that are significantly different in comparison to the existing counterpart food, feed or ingredient not produced using gene technology;

(c) the food produced using modern biotechnology that contains a new factor known to cause an allergic response in particular sections of the population;

(d) the intended use of the food produced using modern biotechnology if it is different from the existing counterpart food produced using gene technology;

(e) the food derived from genetically modified organisms which contains any other characteristics or properties that differ from the conventional counterpart not mentioned in paragraph (a) to (d) above; or

(f) the genetic modification raises significant ethical, cultural and religious concerns regarding the origin of the genetic material used in the genetic modification.

8. Claims

(1) Genetically modified organisms shall not be described or labelled in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding their character in any respect.

(2) Any claim on a label that a product is genetic modification free shall have a clear printed statement indicating that the claim is true and not misleading, and shall be supported by validated testing and documentation of the handling practices and procedures.

(3) Validated testing shall be carried out in appropriate accredited laboratories and analytical procedures used shall be required to be consistent with national and internationally laid down procedures and protocols.

9. Traceability

(1) An operator shall at all stages of placing on the market a product consisting of or containing genetically modified organisms, including bulk quantities, ensure that the following information is transmitted in writing to the subsequent operator—

(a) that it contains or consists of genetically modified organisms; and

(b) the unique identifier assigned to those genetically modified organisms in accordance with these Regulations.

(2) At all subsequent stages of the placing on the market of the products referred to in subregulation (1), operators shall ensure that the information received in accordance with that subregulation is transmitted in writing to all other operators receiving the products along the supply chain.

(3) In the case of products consisting of or containing mixtures of genetically modified organisms to be used only and directly as food or feed or for processing, the information referred to in subregulation (1)(b) may be replaced by a list of the unique identifiers for all those genetically modified organisms that have been used to constitute the mixtures.

(4) Each operator shall maintain a register describing the systems and procedures for each transaction to be kept for a minimum period of five years.

(5) The Authority shall establish a mechanism for development and assignment of unique identifiers where such identifiers are useful in traceability of genetically modified organisms.

10. Monitoring inspection and compliance

(1) The Authority shall liaise with the relevant regulatory agency to monitor any genetically modified organisms for compliance with the requirements of these Regulations.

(2) Where the Authority is satisfied that a product consisting of or containing genetically modified organisms has not been labelled in accordance with Regulation 7, the inspector shall serve the operator with a notice in writing—

(a) prohibiting the placing on the market of the product until it is correctly labelled;

(b) prohibiting the removal of the product from the premises described in the notice other than to facilitate the correct labelling of the product;

(c) requiring that the product be labelled in accordance with these Regulations within such period as the inspector may deem reasonable.

(3) A notice under subregulation (1) may contain such conditions as the inspector is satisfied are reasonable and may be amended, suspended or revoked by a further notice in writing by the inspector at any time.

(4) A notice under this Regulation shall be complied with at the cost of the operator on whom it is served.

(5) If a notice under this Regulation, or an action required by the notice to be taken, is not complied with within the period specified in the notice, an inspector may arrange for it to be complied with and all reasonable costs of taking such action shall be recoverable by the Authority as a penalty due from the operator on whom the notice was served.

(6) Where the product has been placed on the market prior to the date of the notice, the inspector may require the withdrawal of the product within such period as he may reasonably believe to be necessary.

11. Genetically modified organisms labelling register

The Authority shall maintain a register of all applications made to, and decisions made by, the Authority on labelling of genetically modified organisms.

12. Offences and penalties

A person who contravenes the provisions of these Regulations commits an offence and is liable on conviction, to a fine not exceeding twenty million shillings or to imprisonment for a term not exceeding ten years, or both.