ARRANGEMENT OF REGULATIONS

Regulation

PART I – PRELIMINARY

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 organisms

Second Schedule: Approval

BIOSAFETY ACT
(No 2 of 2009)

THE BIOSAFETY (ENVIRONMENTAL RELEASE) REGULATIONS, 2011

IN EXERCISE of the powers conferred by section 51 of the Biosafety Act, the Minister for Higher Education, Science and Technology makes the following Regulations -

THE BIOSAFETY (ENVIRONMENTAL RELEASE) REGULATIONS, 2011

PART I- PRELIMINARY

Citation.

1. These Regulations may be cited as the Biosafety (Environmental Release) Regulations, 2011.

Interpretation.

2. In these Regulations unless the context otherwise requires-

applicant means a person making an application pursuant 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 and legal information and experience with genetically modified organism;

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.

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

higher plants means plants, which belong to the taxonomic group Spermatophytae (Gymnospermae and Angiospermae);

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 animal health 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 and such evaluation is carried out in accordance with the Second Schedule to these Regulations and the Fifth Schedule to the Act;

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

Objective.

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

Exceptions.

4. These Regulations shall not apply to genetically modified organisms that are pharmaceuticals for human use provided that their environmental release is authorised by written law.

PART II- APPLICATIONS

Environmental Release.

5. (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) the prescribed fee; 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 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) 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.

Placing on the market.

6. (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) the prescribed fee; and

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

(3) An applicant may-

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

(d) 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 sub-regulation (1) commits an offence.

Consideration of an application

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

(2) The Authority shall 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 within fourteen days of receipt of an application from an applicant-

(a) forward the application to the relevant regulatory agency, which may, within fourteen days, ;and

(b) make available the application to the public who may, within twenty one days,.

in writing submit comments on the application to the Authority.

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

(5) 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.

(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.

Non-assessment of risks.

8. The Authority may opt not to undertake risk assessment where it determines that sufficient experience or information exists to conclude that the environmental release of a genetically modified organism does not pose a significant.

Approval.

9. (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 risk to human health or the environment, the Authority may amend or revoke the approval.

Validity and Renewal of approval

10. (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 a person intending to continue to release into the environment or place on the market genetically modified organisms shall submit an application for the renewal of an 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) a copy of the approval under regulation 9 (1);

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

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

(d) 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;
(b) approve the application with conditions; or
(c) reject the application stating the reasons for rejection.

(5) An applicant may continue 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 approval from the Authority, and the Authority establishes that monitoring data has 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.

Handling of new information

11. (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.

Public awareness and Participation

12. (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, information on applications for environmental release of genetically modified organisms.

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

Decision document.

13. (1**)** The decision on the application shall be recorded in a decision document.

(2)The decision document 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 that 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 organism;

(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 that may arise from the use of genetically modified organism 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 can be released into the environment or placed on the market, and under which conditions, or

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

Monitoring.

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

(2) A monitoring report shall be submitted to the Authority by the relevant regulatory agency.

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

(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 was granted, the Authority shall ensure that-

(a) necessary measures are taken to terminate the release or placing on the market of the genetically modified 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

Registration of decisions in the National Biosafety Clearing House.

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

Confidentiality.

16. (1) The Authority shall not disclose to a third party any confidential information exchanged under these Regulations and shall protect Intellectual Property rights relating to the data received.

(2) An applicant may indicate the information in the application submitted under these Regulations, the disclosure of which might harm his competitive position and which should be treated as confidential provided that an applicant shall give verifiable justification to show that the information is confidential.

(3) The Authority shall, after consultation with the applicant, decide which information may be kept confidential and shall inform the applicant of its decision provided that the following information shall not be considered as confidential-

(a) name and address of the applicant;

(b) general description of the genetically modified organism;

(c) purpose of the release;

(d) location of release and intended uses;

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

(f) risk assessment report**.**

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

Offences and penalties

17. A person who contravenes any of the provisions of these Regulation**s** 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 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).

This application form shall be accompanied by a declaration of correctness

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
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 Abiotic environmental tolerance	2.5.2 Altered growth, development and product quality
Altered photoperiod sensitivity Cold or heat tolerance Drought or water tolerance Other	Altered ripening or flowering Coloration Fertility restoration 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	2.5.4Medical products
Herbicide tolerance Other chemical tolerance	Animal vaccines 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* Electric shock polarisation Other- specify	Biolistic methods Osmotic shock
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	6.3 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 each 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	
2.0 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 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

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 }

at }

_____

DECLARANT

Before me
Commissioner for Oaths/Magistrate/Judge

SECOND SCHEDULE ... (r 9 (1))

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, of the Biosafety Act 2009, 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	
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

Dated the ……, 2011

HELLEN SAMBILI,
Minister for Higher Education, Science and Technology.