Legal Notice No….. of 2017

THE BIOSAFETY ACT, 2012

(Act No. 7 of 2012)

THE BIOSAFETY REGULATIONS, 2017

(under section 34)

In exercise of the powers conferred by section 34 of the Biosafety Act, 2012 the Minister for Tourism and Environmental Affairs makes the following Regulations -

Arrangement of Regulations

PART I

PRELIMINARY

1. Citation and Commencement

2. Interpretation

3. Application

4. Application and authorization procedures

PART II

GMOs FOR CONTAINED USE AND FIELD TRIALS

5. Exemption

6. Prohibition

7. Risk assessment

8. First time users

9. Classes of contained use

10. Containment measures

11. Modifications

12. Review of decision by Competent Authority

PART III

GMOs FOR FOOD, FEED AND PROCESSING

13. GMOs for food and feed

14. Application for authorization

15. Products likely to be used as both food and feed

16. Authorization

17. Supervision

18. Modification, suspension and revocation of authorizations

19. Renewal of authorizations

PART IV

LABELLING OF GENETICALLY MODIFIED FOOD AND FEED

20. Scope of this Part

21. Labelling Requirements for food

22. Labelling Requirements for feed

23. Data protection

24. Emergency measures

25. Responsibilities of food business operators

26. Responsibilities of feed business operators

27. Unavoidable presence of GMO material

28. Food or feed aid

PART V

GMOs FOR RELEASE INTO THE ENVIRONMENT

29. GMOs for release into the environment and placing on the market

30. Application requirements

31. Advertisement of application to make an environmental release

32. Objections or Public Comments

33. Duty to inform the Competent Authority of new information, etc.

34. Reviews

35. Modification of application prior to the decision

36. Limitation on authorization

37. Submission of renewal application

PART VI

UNINTENTIONAL RELEASE

38. Emergency measures

39. Notification of accident

40. Duty to report damage

PART VII

IMPORT, EXPORT AND TRANSIT OF GMOs

41 Application and authorization for import of GMOs

42. Transportation of GMOs for export

43. Measures to be taken during transportation

44. Transportation within institutions

45. Transportation of micro organisms

46. Unintentional release while on transit

PART VIII

MISCELLANEOUS

47. Power to modify, suspend or terminate authorization

48. Public access

49. Confidentiality

50. Measures to avoid the unintended presence of genetically modified organisms

51. Guidelines and manuals

52. Fees

53. General offenses and penalties

54. Seizure and forfeiture

55. Amendment of schedules

56. Transitional Provisions

PART I

PRELIMINARY

Citation and Commencement

1. These Regulations shall be cited as The Biosafety Regulations, 2017 and shall come into force on the date of publication in the Gazette.

Interpretation

2. In these Regulations, unless the context otherwise requires -

“Act” means the Biosafety Act, 2012;

“advance informed agreement procedure’ means the procedural requirements for the transboundary movement of GMO’s provided for under section 11,12 and 13 of the Act;

“environmental risk assessment” means the evaluation of risk in accordance with the guidelines set out in the Second Schedule of the Act;

“living modified feed or feed” means feed containing or consisting of or produced from living modified organisms;

“re-packaged food or pre-packaged food or feed” means any single item for presentation as such consisting of a food and the packaging into which it was put before being offered for sale, whether such packaging encloses the food completely or only partially, provided that the contents cannot be altered without opening or changing the packaging.

“response measures” means reasonable actions to -

(a) prevent, minimize, contain, mitigate, or otherwise avoid damage, as appropriate;

(b) restore biological diversity through actions to be undertaken in the following order of preference–

(i) restoration of biological diversity to the condition that existed before the damage occurred, or its nearest equivalent; and where the competent authority determines this is not possible; and

(ii) restoration by replacing the loss of biological diversity with other components of biological diversity for the same, or for another type of use either at the same or, as appropriate, at an alternative location.

Scope of regulations

3. These regulations are applicable to–

(a) the import;

(b) the export;

(c) the introduction into the environment;

(d) the contained use;

(e) the placing on the market;

(f) the transport, including transport in transit through Swaziland; and

(g) the use or handling in any other way,

of a GMO or LMO or a product of a GMO or LMO.

Application and authorization procedures

4. (1) A person who applies for authorization for contained use or release to the environment shall submit, to the Competent Authority, an application together with a checklist as set out in the form prescribed in the First Schedule.

(2) An authorization shall not be given for the intentional release or placing on the market of GMOs or their products which are plants and seeds for agricultural purpose until the Competent Authority has received results of research on the effects of the use of such GMOs or their products.

(3) An authorization granted in terms of this Act and these Regulations shall be for the period specified in the Decision Documents unless reviewed in terms of the Act and these Regulations.

PART II

GMOs FOR CONTAINED USE AND FIELD TRIALS

Exemption

5. (1) This Part shall not apply to -

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

(b) the storage, culture, transport, destruction, disposal or use of a genetically modified micro-organism which has been placed on the market in accordance with Part VII.

(2) Paragraph (b) shall be applicable only where the conditions attached to the authorization to place the genetically modified micro-organism on the market have been complied with.

Prohibition

6. (1) A person shall not carry out contained use activities without an authorization issued by the Competent Authority in respect of class 3 and class 4 of contained use.

(2) An application to conduct contained use activity shall contain the information set out in the First Schedule.

(3) Additional information may be requested by the Competent Authority in terms of the Act.

Risk assessment

7. (1) Without prejudice to any other provision of this Part, an operator shall, before commencing a contained use activity –

(a) carry out an assessment of the risks to human health and the environment which may be associated with such use;

(b) draw up and put in place measures or plans that may mitigate any adverse effects that may arise from an accident caused by the activity.

(2) In carrying out an assessment in accordance with sub-regulation (1), an operator shall -

(a) as a minimum, use the elements of assessment and the procedures set out in the Second Schedule of the Act, and take account, in particular, of issues related to the disposal of waste and effluent;

(b) make a classification of contained use activities in accordance with the Third Schedule.

(3) In making a classification and determining the appropriate class of contained use activities in terms of sub-regulation (2) (b), the higher level of

containment shall be applied by the user unless the competent authority agrees in writing that there is sufficient evidence to justify application of a lower level.

(4) Without prejudice to any other provision of these Regulations, a record of an assessment for the purposes of sub-regulation (1) shall be kept by the operator and shall be made available to the Competent Authority on request.

(5) An operator shall periodically review the risk assessment and the containment measures applied by the operator, and the risk assessment shall be reviewed immediately if -

(a) the containment measures applied are no longer adequate or the class assigned to the contained use is no longer correct, or

(b) in the light of new scientific or technical knowledge, the assessment is no longer appropriate.

First time users

8. (1) a person shall not undertake contained use activities in premises used for the first time for contained use, without the authorization of the Competent Authority.

(2) Notwithstanding any other provisions of section 10 of the Act, A notification of intent to conduct contained use activities for the first time shall be submitted to the Competent Authority at least one hundred and twenty (120) calendar days before the activities covered by the notification are due to begin.

(3) An application to carry out contained use activities for the first time in any premise shall be in the Form set out in the First Schedule.

(4) The Competent Authority shall communicate its decision in writing to the user within two hundred and seventy (270) days after receipt of the application.

(5) For the purposes of this regulation, an authorization granted for the first time use of a premises for a particular class of contained use shall be treated as an authorization for the first time use of the premises for that class and for any lower class of contained use, and a further authorization shall be required in respect of the first time use of the premises for any higher class of contained use.

Classes of contained use

9. (1) A risk assessment carried out in accordance with these Regulations shall result in the classification of the contained use into one of the classes listed in the Third Schedule.

(2) An application to carry out Class 3 or 4 contained use activities shall be in the Form set out in sixth Schedule.

(3) A person shall not proceed with a class 3 or 4 contained use activities unless an authorization has been granted by the competent authority under this Part and the conditions, if any, attached to the authorization have been complied with.

(4) The Competent Authority shall communicate its decision in writing to the user -

(a) within two hundred and seventy (270) days after receipt of the application in the case of a premises which has been the subject of a previous application to carry out the same class or a higher class of contained use and where any associated authorization requirements have been complied with, or

(b) within two hundred and seventy (270) days after receipt of the application in other cases.

(5) Where the Competent Authority fails to issue a decision within the prescribed period, such failure shall not entitle a user to proceed with a class 3 or 4 contained use.

Containment measures

10. (1) An operator shall apply -

(a) the general principles of good microbiological practice and of good occupational safety and hygiene.

(b) the containment measures set out in the Second Schedule.

(2) Where containment measures applied to a contained use are no longer adequate or that a class assigned to a contained use is no longer correct or that a

risk assessment carried out in accordance with these Regulations is no longer appropriate, the user shall -

(a) immediately inform the competent authority in writing of the proposed review to be carried out in accordance with sub-regulation (2), and

(b) immediately on the conclusion of the review, give the competent authority a report on the outcome.

(3) If, following a review and consideration of the report, the competent authority is not satisfied that -

(a) the containment measures applied are adequate;

(b) the class assigned is correct; or

(c) the risk assessment carried out is appropriate, the competent authority shall -

(i) undertake a review of the contained use, or

(ii) require the user to make a new application.

Modifications

11. An operator shall not modify an activity -

(a) in a way which could result in the classification of the containment which has been approved by the Competent Authority, being amended to a higher level, or

(b) in any other way which could have significant consequences for the risks posed for human health or the environment,

without an authorization granted by the Competent Authority in writing.

Review of decision by Competent Authority

12. (1) The Competent Authority may review a contained use permit at any time by notice to the operator or at a time not less than three (3) years from the date the contained use commenced.

(2) Notwithstanding sub-regulation (1), the competent authority may review a contained use at any time if, in the light of information which was not known to it previously, there is reason to consider that the risks posed by the contained use for human health or the environment are altered to a significant degree.

(3) The Competent authority may as soon as may be, after it has completed a review under this regulation, -

(a) amend any authorization granted under this Part or otherwise require the user to modify the contained use, or

(b) require the user to suspend or terminate the contained use.

(4) Where the competent authority has suspended a contained use activity, an operator shall not resume the activity the conditions, unless the required conditions have been complied with.

PART III

GMOs FOR FOOD, FEED AND PROCESSING

GMOs for food and feed

13. (1) A person shall not import genetically modified organisms for food or feed or for processing –

without an authorization granted by the Competent Authority.

(2) Genetically modified organisms for food, feed or processing shall not be authorized unless the applicant has sufficiently demonstrated that the GMO does not -

(a) have adverse effects on the environment and human health, ;

(b) mislead the consumer;

(c) differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer.

(3) A person who contravenes this regulation commits an offence.

Application for authorization

14. (1) An application for authorization for import of genetically modified organisms for food or feed or for processing shall be made to the Competent Authority and shall include where applicable the following information as near as may be in accordance with the First Schedule-

(a) the designation of the food, and its specification, including the transformation event(s) used;

(b) where applicable, the information set out in the First Schedule;

(c) where applicable, a detailed description of the method of production and manufacturing;

(d) a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out and any other material which is available to demonstrate that the food complies with the requirements referred to in regulation 19(1);

(e) either an analysis, supported by appropriate information and data, showing that the characteristics of the food are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics or a proposal for labelling the food;

(f) either a reasoned statement that the food does not give rise to ethical or religious concerns, or a proposal for labelling;

(g) where appropriate, the conditions for placing on the market the food or foods produced from it, including specific conditions for use and handling;

(h) methods for detection, sampling (including references to existing official or standardized sampling methods) and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food or in foods produced from it;

(i) samples of the food and their control samples, and information as to the place where the reference material can be accessed;

(j) where appropriate, a proposal for post-market monitoring regarding use of the food for human consumption; and

(k) a summary of the dossier in a standardized form.

(2) An application relating to a genetically modified organism for food use, references to 'food' in sub-regulation 3 shall be interpreted as referring to food containing, consisting of or produced from the genetically modified organism in respect of which an application is made.

(3) An application the application shall also be accompanied by for genetically modified organisms or food containing or consisting of genetically modified organisms, the application shall also be accompanied by -

(a) the complete technical dossier supplying the risk assessment where the placing on the market of the genetically modified organism has been authorized and a copy of the authorization decision;

(b) a monitoring plan for environmental effects including a proposal for the duration of the monitoring plan; this duration may be different from the proposed period for the consent.

Products likely to be used as both food and feed

15. Where a product is likely to be used as both food and feed, a single application may be submitted.

Authorization

16. (1) The Competent Authority shall make a decision within two hundred and seventy (270) days after receiving the application, taking into account the opinion of the public and any relevant government departments or agencies and other legitimate factors relevant to the matter under consideration.

(2) The Competent Authority shall without delay inform the applicant of the decision taken and enter the decision in the registry.

Supervision

17. (1) After an authorization has been issued in accordance with this regulation, the operator shall comply with any conditions or restrictions which have been imposed in the authorization and shall in particular make sure that products not covered by the authorization are not imported as food or feed.

(2) If the operator proposes to modify the terms of the authorization, the operator shall submit an application for such modification.

(3) The operator shall forthwith inform the Competent Authority of any new scientific or technical information which might influence the evaluation of the safe use of the GMO. In particular, the operator shall forthwith inform the Competent Authority of any prohibition or restriction imposed by the competent authority of any third country in which the food is placed on the market.

Modification, suspension and revocation of authorizations

18. (1) The Competent Authority shall on its own initiative or following a request from a member of the public issue an opinion on whether an authorization for a product still meets the conditions set by this regulation.

(2) Where the operator fails to meet a condition imposed on the authorization by the Competent Authority, the Competent Authority may modify, suspend or revoke the authorization.

(3) An operator who continues to place the food on the market after revocation of a licence commits an offence.

Renewal of authorizations

19. (1) An authorization granted under this Part shall be valid for ten (10) years and may be renewable.

(2) An authorization shall not be granted, refused, renewed, modified, suspended or revoked except on the grounds and under the procedures set out in this Part.

(3) An operator may make an application for renewal of an authorization one (1) year before the expiry date of the authorization.

(4) The application for the renewal of an authorization shall be made to the Competent Authority and shall be accompanied by the following -

(a) a copy of the Decision Document;

(b) any other new information which has become available with regard to the evaluation of the safety in use of the food and the risks of the food to the consumer or the environment;

(c) where appropriate, a proposal for amending or complementing the conditions of the original authorization.

PART IV

LABELLING OF GENETICALLY MODIFIED FOOD AND FEED

Scope of this Part

20. (1) This Part shall not apply to food or feed containing material which contains, consists of or is produced from genetically modified organisms in a proportion not higher than 0.9 per cent of the food or feed consisting of a single ingredient provided that this presence is adventitious or technically unavoidable.

(2) In order to establish that the presence of this material is adventitious or technically unavoidable, every operator shall be in a position to supply evidence to satisfy the Competent Authority that the operator has taken appropriate steps to avoid the presence of such materials.

Labelling Requirements for food

21. (1) Foods falling within the scope of this Part shall be subject to the following specific labelling requirements -

(a) where the food consists of more than one ingredient, the words ‘genetically modified’ or ‘produced from genetically modified (name of the ingredient)’ shall appear in the list of ingredients in parentheses immediately following the ingredient concerned;

(b) where the ingredient is designated by the name of a category, the words ‘contains genetically modified (name of organism)’ or ‘contains (name of ingredient) produced from genetically modified (name of organism)’ shall appear in the list of ingredients;

(c) where there is no list of ingredients, the words ‘genetically modified’ or ‘produced from genetically modified (name of organism)’ shall appear clearly on the labelling;

(d) the indications referred to in (a) and (b) may appear in a footnote to the list of ingredients. In this case they shall be printed in a font of at least the same size as the list of ingredients. Where there is no list of ingredients, they shall appear clearly on the labelling;

(e) where the food is offered for sale to the final consumer as non-pre-packaged food, or as pre-packaged food in small containers of which the largest surface has an area of less than 10 cm2, the information required under this paragraph shall be permanently and visibly displayed either on the food display or immediately next to it, or on the packaging material, in a font sufficiently large for it to be easily identified and read.

(2) In addition to the labelling requirements referred to in sub-regulation (1), the labelling shall also mention any characteristic or property, as specified in the authorization, in the following cases -

(a) where a food is different from its conventional counterpart as regards the following characteristics or properties -

(i) composition;

(ii) nutritional value or nutritional effects;

(iii) intended use of the food;

(iv) implications for the health of certain sections of the population;

(b) where a food may give rise to ethical or religious concerns.

(3) In addition to the labelling requirements referred to in sub-regulation (1) and as specified in the authorization, the labelling of foods falling within the scope of this Part which do not have a conventional counterpart shall contain appropriate information about the nature and the characteristics of the foods concerned.

Labelling Requirements for feed

22. (1) No person shall place feed produced from a genetically modified organisms on the market without a written authorization granted by the Competent Authority.

(2) Each feed of which a particular feed is composed shall be subject to the following rules -

(a) for the feed referred to in regulation 23(1) (a) and (b), the words 'genetically modified (name of the organism)' shall appear in parentheses immediately following the specific name of the feed. Alternatively, these words may appear in a footnote to the list of feed. It shall be printed in a font of at least the same size as the list of feed;

(b) for the feed referred to in regulation 23 (1) (c), the words 'produced from genetically modified (name of the organism)' shall appear in parentheses immediately following the specific name of the feed. Alternatively, these words may appear in a footnote to the list of feed. It shall be printed in a font of at least the same size as the list of feed;

(c) as specified in the authorization, any characteristic of the feed referred to in regulation 14(1) such as those indicated hereunder, which is different from its conventional counter-part -

(i) composition;

(ii) nutritional properties;

(iii) intended use;

(iv) implications for the health of certain species or categories of animals;

(d) as specified in the authorization any characteristic or property where a feed may give rise to ethical or religious concerns.

Data protection

23 (1) The scientific data and other information in the application dossier may not be used for the benefit of another applicant for a period of ten (10) years from the date of the authorization, unless the other applicant has agreed with the operator that such data and information may be used.

(2) On the expiry of period of ten (10) years, the findings of all or part of the evaluation conducted on the basis of the scientific data and information contained in the application dossier may be used by the Authority for the benefit of another applicant if the applicant can demonstrate that the food or feed for which it is seeking authorization is essentially similar to a food or feed already approved under this regulation.

Emergency measures

24. (1) Where it is evident that food or feed imported into Swaziland is likely to constitute a serious risk to human health or the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the operator, the Competent Authority, shall immediately adopt one or more of the following measures, depending on the gravity of the situation -

(a) suspension of the placing on the market or use of the food or feed in question;

(b) laying down special conditions for the food or feed in question;

(c) any other appropriate interim measure.

(2) As soon as possible, and at most within ten (10) working days, the Competent Authority shall confirm, amend, revoke or extend the measures taken

and the Competent Authority shall make the reasons for its decision public without delay.

Responsibilities of food business operators

25. (1) If a food business operator considers or has reason to believe that a food which the operator has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, the operator shall-

(a) immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the Competent Authority of the action taken.

(b) effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.

(2) A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and the Competent Authority.

(3) A food business operator shall immediately inform the Competent Authority if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health.

(4) Every operator shall inform the Competent Authority of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the Competent Authority where this may prevent, reduce or eliminate a risk arising from a food.

(5) Every operator shall collaborate with the Competent Authority on action taken to avoid or reduce risks posed by a food which they supply or have supplied.

Responsibilities for feed business operators

26. (1) Where a feed business operator has reason to believe that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the feed safety requirements, the operator shall immediately initiate procedures to withdraw the feed in question from the market and inform the Competent Authority thereof.

(2) In these circumstances or, where the batch, lot or consignment does not satisfy the feed safety requirement, the Competent Authority shall destroy the feed.

(3) Every operator shall effectively and accurately inform users of the feed of the reason for its withdrawal, and if necessary, recall from them products already supplied when other measures are not sufficient to achieve a high level of health protection.

(4) A feed business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the feed shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the feed-safety requirements and shall participate in contributing to the safety of food by passing on relevant information necessary to trace a feed, cooperating in the action taken by producers, processors, manufacturers or the competent authorities.

(5) A feed business operator shall -

(a) immediately inform the Competent Authority if it considers or has reason to believe that a feed which it placed on the market may not satisfy the feed safety requirements.

(b) inform the National Competent authorities of the action taken to prevent risk arising from the use of that feed and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the Competent Authority where this may prevent, reduce or eliminate a risk arising from a feed.

(6) Every Feed business operators shall collaborate with the Competent Authority on action taken in order to avoid risks posed by a feed which they supply or have supplied.

Unavoidable presence of GMO material

27. (1) An operator who has been producing GMOs food or feed shall not transitions to producing non-GMO food or feed material which contains, or consists of or is produced from genetically modified organisms in a proportion no higher than 0.9% except where

(a) the presence of that product is adventitious or technically unavoidable;

(b) the application for its authorization has not been rejected; and

(c) detection methods are publicly available.

(3) In order to establish that the presence of this material is adventitious or technically unavoidable, operators shall demonstrate to the Competent Authority that they have taken appropriate steps to avoid the presence of such materials.

Food or feed aid

28. (1) Genetically modified food and feed assistance introduced into Swaziland shall comply with the prior informed consent principle and the notification requirement in accordance with Article 8 of the Cartagena Protocol on Biosafety.

(2) Food and feed consignment involving grain that contain GMOs shall be milled prior to distribution to the beneficiaries.

(3) An operator who administers GMO food aid into Swaziland shall be responsible for creating awareness among users or consumers on the handling of such food products.

PART V

GMOs FOR RELEASE INTO THE ENVIRONMENT

GMOs for release into the environment and placing on the market

29. (1) A person shall not release a genetically modified organism into the environment prior to an authorization in writing has been issued by the Competent Authority under this Part and any conditions attached to the authorization have been complied with.

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

Application Requirements

30. (1) An application for release into the environment or placing in the market shall be in the form set out in the First Schedule and shall be accompanied by-

(a) a technical dossier on the proposed environmental release;

(b) an environmental risk assessment, and

(c) the conclusions arrived at by the applicant together with any bibliographic references and details of the methods used;

(d) an emergency response plan; and

(e) the prescribed fee.

(2) The applicant may, in making an application, refer to data or results from an application previously given by another applicant provided that the data or results are not confidential information or that the said other applicant has agreed in writing to such reference and a copy of this agreement is included in the application.

(3) The Competent Authority may accept an application for the environmental release of -

(a) a combination of genetically modified organisms on the same site, or

(b) a genetically modified organism or a combination of genetically modified organisms on different sites,

(4) The notification may be made in a single application provided that the proposed release is for the same purpose and will be carried out within a defined period of time.

(5) The applicant shall, not more than (fourteen) 14 days after the date of receipt by the Competent Authority, of the application, send a copy of the notice to -

(a) the owner of the site of the proposed environmental release, if the said owner is a person other than the applicant; and

(b) the local authority in whose functional area the proposed environmental release is to be carried out.

(6) The Competent Authority shall respond in writing to the applicant in terms of section 18 (5) of the Act.

(7) The applicant shall not make an environmental release prior to furnishing the Competent Authority with additional information or complying with conditions attached to the authorization.

(8) Where a person who has been granted an authorization to make an environmental release, wishes to modify the release in a manner that could have adverse effects to human health or the environment, that person shall make an application to the Competent Authority for such modification.

Advertisement of application to make an environmental release

31. (1) An applicant who wishes to apply for a proposed environmental release or placing on the market shall, not more than fourteen (14) days after the date of receipt by the Competent Authority of the application, cause to be published in a newspaper and national television the proposed environmental release notice with the heading "PROPOSED ENVIRONMENTAL RELEASE OF A GENETICALLY MODIFIED ORGANISM" and containing the following information—

(a) the name and address of the applicant;

(b) the description of the genetically modified organism proposed to be released,

(c) the fact that an application has been submitted to the Competent Authority, and the location and purpose of the proposed environmental release.

(d) the period of time in which the proposed environmental release is to be carried out,

(e) the fact that further information on the environmental release may be obtained from the Competent Authority,

(f) the full title and address of the Competent Authority;

(g) that any person may, within the period of (twenty eight) 28 days beginning on the day of publication of the notice, object or comment in writing to the Competent Authority regarding the application.

Objections or Public Comments

32. (1) A person who wishes to make an objection or comment on an application in terms of this part may make a written request of that application to the Competent Authority.

(2) Competent Authority shall make available to that person portion of any application subject to recognition of confidential information as provided for in regulation 52 and Section 14 of the Act for purposes of public analysis.

(3) A person may, within the period of twenty-eight (28) days beginning on the day of publication, make a written objection or comment to the Competent Authority in relation to the application.

(4) The Competent Authority shall, within seven (7) days from date of receipt, forward such objections or comments to the applicant for a response.

(5) The applicant shall respond to the objection or comment and forward that response to the Competent Authority within five (5) days.

(6) In the response the applicant may include a proposal for modification of the application.

(7) The Competent Authority shall on receipt of the response of the applicant make a formal response to the objection or comment and make that response public.

Duty to inform the Competent Authority of new information, etc.

33. (1)Where the Competent Authority has granted an authorization in writing, and there is an unintended change to the environmental release, or new information relevant to the release becomes available, which could have adverse effects to human health or the environment, the person granted the authorization shall -

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

(b) inform the Competent Authority as soon as the unintended change is known or the new information becomes available; and

(2) inform the Competent Authority as soon as possible of such further measures he or she has taken or proposes to take in relation to the matters concerned.

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

Reviews

34. (1) Where, as a result of either -

(a) new or additional information made available after the granting of the authorization and affecting the environmental risk assessment in respect of the product concerned, or

(b) a reassessment of existing information in respect of that product on the basis of new or additional scientific information, the Competent Authority has detailed grounds for considering that the product constitutes a risk to human health or the environment,

(2) The Competent Authority may by notice in writing, restrict or prohibit the use, or placing on the market, of the genetically modified organism.

(3) Where, the Competent Authority considers that a product constitutes a severe risk to human health or the environment, the Competent Authority shall by notice in writing to the person granted the authorization, require such measures to be taken as it considers appropriate including suspension or termination of the placing on the market of the genetically modified organism.

(4) The Competent Authority shall inform the public, by notice in a newspaper with nationwide circulation, radio or television of its decision and the reasons for its decision.

Modification of application prior to the decision

35. (1) Where new information relevant to the proposed release into the environment or placing on the market becomes available, which could have adverse effects to the environment the applicant may modify the application and shall -

(a) inform the Competent Authority immediately in writing; and

(b) submit an amended application to the Competent Authority and the first application shall not be further considered by the Competent Authority.

(2) Where the Competent Authority receives an amended application, it shall deal with the amended application as if it were a new application in relation to the proposed release into the environment and placing on the market.

Limitation on authorization

36. An authorization granted under this Part shall be for a period not exceeding ten (10) years beginning on the date on which the authorization is granted.

Renewal application

37. A person seeking to renew an authorization shall submit an application to the Competent Authority no later than twelve (12) months before the expiry of the authorization that it is proposed to have renewed.

PART VI

UNINTENTIONAL RELEASE

Emergency measures

38. The Biosafety Registrar shall ensure that, where necessary, before any release is made or contained use carried out -

(a) an emergency plan is drawn up for the protection of human and animal health, biological diversity and the environment in the event of an accident and the appropriate emergency and other services are informed of this plan in writing; and

(b) Information on safety measures and procedures to adopt in the case of an accident is supplied to persons likely to be affected by the accident. The information shall be updated and supplied periodically. It shall also be made available to the general public.

Notification of an accident

39. (1) The operator shall immediately inform the Competent Authority of any accident and shall (a) furnish the Competent Authority with the following -

(i) full and detailed information on the circumstances of the accident;

(ii) full and detailed information on the identity and quantities of the genetically modified micro-organism concerned;

(iii) any information necessary to assess the effects of the accident on the health of the general public or on the environment;

(iv) full and detailed information on the measures taken.

(2) The operator shall also

(a) inform relevant emergency services of the accident;

(b) inform persons likely to be affected by the accident; and

(c) activate other relevant provisions of the emergency plan.

(3) Competent Authority is notified of an accident, it shall -

(a) collect, where possible, the information necessary for a full analysis of the accident and, where appropriate, make recommendations to avoid a similar accident in the future and to limit the effects of any such future accident, and

(b) ensure that any measures necessary are taken.

(4) The operator shall contribute towards the costs incurred due to the accident.

Duty of operator to report damage

40. (1) Where damage has occurred or there is a threat of damage occurring, response measures shall be undertaken without undue delay to ensure that biodiversity loss is minimized.

(2) In the event of damage or accident, the operator(s), subject to any requirements of the competent authority, shall -

(a)immediately inform the Competent Authority of the nature, circumstances and location of the damage or accident including potential damage that is likely to occur as a result of the GMO activity or accident involving GMO under his control;

(b) evaluate the damage; and

(c) take appropriate response measures to avert any adverse effect from occurring as a result of the activity or accident.

(3) Where damage occurs and the operator is not yet known by the Competent Authority, the Competent Authority shall -

(a) identify the operator which has caused the damage;

(b) evaluate the damage; and

(c) determine which response measures should be taken by the operator.

(4) Where relevant information, including available scientific information or information available in the Biosafety Clearing-House, or any other credible source of information, indicates that there is a sufficient likelihood that damage will result if timely response measures are not taken, the operator shall be required to take appropriate response measures so as to avoid such damage.

(5) The Competent Authority shall implement appropriate response measures, including, in particular, when the operator has failed to do so through funding from the Environment Fund.

(6) The Competent Authority shall issue an order to recover from the operator, the costs and expenses of, and incidental to, the evaluation of the damage and the implementation of any such appropriate response measures.

(7) Decisions of the competent authority requiring the operator to take response measures should be reasoned and communicated in writing to the operator immediately after the operator is known.

(8) If the operator decides to appeal the decision of the Competent Authority, he shall, pending such appeal, deposit security to be determined by the Competent Authority.

(9) In implementing this regulation and with a view to defining the specific response measures to be required or taken by the operator, the Competent Authority, as appropriate, assess whether response measures are already addressed by any other law on civil liability regarding environmental damage.

PART VII

IMPORT, EXPORT AND TRANPORTATION OF GMOs

Application and authorization for transboundary movement of GMOs

41. (1) A person who intends to import export or transport a genetically modified organism or a product of a genetically modified organism for the first time shall ensure that an advance informed agreement is issue.

(2) In the event of an import of a genetically modified organism for which no authorization has been granted, the Competent Authority may inform and advise the public, of the existence of the genetically modified organism within the country.

Transportation of GMOs for, export

42. (1) A person who intends to export a genetically modified organism or a product of a genetically modified organism shall provide to the Competent Authority a written advance informed agreement or authorization of the competent authority of the importing country.

(2) The presentation of the advance informed agreement by an exporter does not in any manner absolve the exporter from complying with any other laws governing foreign trade.

(3) A person shall not re-export a genetically modified organism or a product of a genetically modified organism that is banned by the laws of the exporting country.

(4) An exporter shall -

(a) package any genetically modified organism or any product of a genetically modified organism in the prescribed manner so as to prevent any unintentional release in transit; and

(b) comply with any other requirements imposed by the competent authority of the importer as to labelling or other relevant measures to protect human and animal health, non-genetically modified crops, biological diversity or the environment from any risk or adverse effect from any genetically modified organism or the product of any genetically modified organism.

Measures to be taken during transportation

43. (1) An operator shall, in accordance with the provisions governing the transportation of GMOs, take sufficient measures to -

(a) prevent the escape of GMOs, given such possibilities as accidents on the way so that they are not crossed with domesticated indigenous populations;

(b) be sure that they are well identified and that they reach their destination as intended;

(c) ensure that the process is supervised by a competent authority with experience in the management related problems.

(2) A person transporting GMOs shall not use a cage or container for transportation of genetically modified organisms unless it is approved by the Competent Authority.

(3) A person transporting GMOs shall, during the transportation take the measures to ensure that no damage or dispersal of the contents including ensuring that -

(a) the GMOs are put in an unbreakable lockable container clearly labelled and sealed in order to avoid leakages;

(b) the locking container is put in another container clearly labelled and properly sealed for transportation;

(c) the transport equipment is decontaminated by autoclave after the transported GMOs are transferred into new container; and

(d) recording keeping system is set up to ensure that the number of containers exported are the same upon delivery.

Transportation within institutions

44. (1) Any GMOs to be transported within and between institutions, shall first be put in a primary container and placed in unbreakable secondary container.

(2) The container shall contain a label bearing the address of the sender to be contacted in case of loss or damage of the parcel.

(3) The parcels shall contain labels indicating the quantity transported.

Transportation of micro-organisms

45. Micro-organism shall be transported in accordance with international norms in force and shall not, for any reason, be transported in personal luggage by public or private transport.

Unintentional release while on transit.

46. (1) In the event of an accident involving a genetically modified organism on transit, the person transporting the GMO's shall –

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

(b) notify the Competent Authority immediately verbally and in writing of the accident; and

(2) The Competent Authority shall record a statement of the accident as follow-

(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.

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

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

PART VIII

MISCELLANEOUS

Power to modify, suspend or terminate an Authorization

47. (1) Where an authorization has been granted in terms of the Act and the Competent Authority -

(a) becomes aware of information which, in its view, could have significant consequences for the risks to human health or the environment, or

(b) is notified of a proposed modification; or

(c) is informed of an unintended change or new information relevant to the genetically modified organism,

the Authority may, following an evaluation of the matters concerned, require the person granted the authorization to modify the conditions of, suspend or terminate the authorized activities.

(2) Where the Competent Authority has suspended an activity authorized in terms of this these Regulations, the person granted an authorization shall ensure that the necessary conditions are complied with before the resumption of the activity.

(3) The Competent Authority shall, within fourteen (14) days of indicating its decision to the applicant, publish a notice in a newspaper of nationwide circulation, to inform the public of its decision to suspend an authorization.

Public access

48. The Competent Authority shall avail to the public, any information relating to the application for authorization, supplementary information from the applicant, opinions from the public, monitoring reports and information from the authorization holder, excluding confidential information.

Confidentiality

49. (1) An applicant may indicate which information submitted that the applicant wishes to be treated as confidential on the ground that its disclosure might significantly harm its competitive position.

(2) The Competent Authority shall determine, after consultation with the applicant, which information should be kept confidential and shall inform the applicant of its decision.

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

(a) name and composition of the genetically modified organisms, where appropriate, indication of the substrate and the micro-organism;

(b) general description of the genetically modified organism and the name and address of the operator;

(c) physio-chemical and biological characteristics of the genetically modified organisms;

(d) effects of the genetically modified organisms on human and animal health and on the environment;

(e) effects of the genetically modified organisms referred on the characteristics of animal products and its nutritional properties;

(f) methods for detection, including sampling and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the GMO;

(g) information on waste treatment and emergency response.

(4) The Competent Authority shall take the necessary measures to ensure appropriate confidentiality of the information received under this regulation except for information which shall be made public if circumstances so require in order to protect human health, and or the environment.

(5) If an applicant withdraws or has withdrawn an application, the Competent Authority, shall respect the confidentiality of commercial and industrial information, including research and development information, as well as information as to the confidentiality of which the Authority and the applicant disagree.

Measures to avoid the unintended presence of genetically modified organisms

50. (1) Every operator shall take appropriate measures to avoid the unintended presence of genetically modified organisms in other products.

(2) The Competent Authority shall gather and coordinate information, observe the developments regarding coexistence and, on the basis of the information and observations, develop guidelines on the coexistence of genetically modified organisms and conventional crops.

Guidelines and manuals

51. The Competent Authority may develop guidelines and manual in relation to any matter under the Act and these regulations to facilitate ease of implementation of the Act.

Fees

52. (1) Fees shall be charged for the handling of application requests and other administrative matters required under these Regulations based on the table contained in the Eighth Schedule.

(2) The amounts paid by the applicant shall not be refundable even in case where a decision not issue an authorization has been the outcome or there has been refusal for entry or use of the consignment.

General offenses and Penalties

53. (1) A person who contravenes a provision of this Act or fails to comply with a cessation order or regulation issued pursuant to this Act commits an offence and shall, on conviction be liable to a fine not exceeding one hundred thousand Emalangeni (E100 000.00) or a term of imprisonment not exceeding two (2) years or both, including additional penalties not exceeding five hundred Emalangeni (E500) for each day that the offence is continued after legal service of a cessation order upon that person.

(2) A person who repeatedly and knowingly commits offences under this Act and is convicted for such offences may be prohibited from engaging in any further activities under this Act.

(3) An administrative fine prescribed under these Regulations shall be payable demand to the Competent Authority within a specified period not exceeding twenty-one (21) working days).

Seizure and Forfeiture

54. A person who is found guilty of contravening subsection (1) shall be liable to return the imported products to the country of origin, or its seizure and subsequent destruction by the State and shall bear the costs of measures taken to redress the infringement.

Amendment of schedules

55. The Minister may, by notice in the Gazette, amend the schedules to these Regulations for the better carrying out of the purposes and provisions of these Regulations.

Transitional Provisions

56. (1) All operators conducting activities relating to GMOs OR GMO Products falling within the scope the Act which have been lawfully been carried on the date of commencement of these Regulations shall, within six (6) months after the date of application of these Regulations, notify the Competent Authority of that activity.

(2) The notification required in sub-regulation (1) shall contain the information required in terms of the First Schedule.

(3) Within one (1) year from the date of application of these Regulations and after verification that all the information required has been submitted and examined, the products concerned shall be entered in the Register.

FIRST SCHEDULE

SUPPLIMENTARY INFORMATION

I. INFORMATION REQUIRED FOR THE APPLICATION	**A. General information**
	1. Name and address of the applicant
	B. Information on personnel and training
	1. Name of person(s) responsible for the planning and carrying out the release, including those responsible for supervision, monitoring and safety, in particular, name and qualification(s) of the responsible scientist(s).
	2. Information on training and qualification(s) of personnel involved in carrying out the release.
II. INFORMATION RELATING TO THE GENETICALLY MODIFIED ORGANISM(S) OR PRODUCTS THEREOF	**A Characteristics of -** (a) the donor; (b) the recipient; or (c) (where appropriate) parental organism(s)
	1. Scientific name.
	2. Taxonomy.
	3. Other names (usual name, strain name, cultivars name, local name etc.).
	4. Phenotypic and genetic markers.
	5. Degree of relatedness between donor and recipient or parental organisms.
	6. Description of identification and detection techniques.
	7. Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques.
	8. Description of the geographic distribution and of the natural habitat of the organisms including information on natural predators, preys, parasites and competitors, symbionts and hosts.
	9. Potential for genetic transfer and exchange with other organisms.

	10. Verification of the genetic stability of the organisms and factors affecting it, taking into account the relevance of the laboratory experiments undertaken for the authentic ecological conditions under which the organisms live or are used.
	11. Pathological, ecological and physiological traits: (a) classification of hazard according to existing national rules concerning the protection of human and animal health and/or the environment; (b) generation time in natural ecosystem, sexual and asexual reproductive cycle; (c) information on survival, including the season and the ability to form survival structures e.g.: seeds, spores or sclerotia; (d) pathogenicity: infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organisms. Possible activation of latent viruses (proviruses). Ability to colonize other organisms; (e) antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for therapy and prophylaxis; (f) involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc.
	12. Nature of indigenous vectors: (a) Sequence; (b) Frequency of mobilisation; (c) Specificity;
	13. History of previous modifications.
	B. Characteristics of the vector
	1. Nature and source of the vector.
	2. Sequence of transposons, vectors and other non-coding genetic segments used to construct the genetically modified organism (s) and products thereof and to make the introduced vector and insert function in the genetically modified organism (s) and products thereof.
	3. Frequency of mobilisation of inserted vector and/or genetic transfer capabilities and methods of determination.
	4. Information on the degree to which the vector is limited to the DNA required to perform the intended function.

	5. Factors (chemical, biological, climatic, etc.) influencing the functional level of the promoter / enhancer, and how the functional level is changed.
	C. Characteristics of the genetically modified organism (s) and products thereof
	1. Information relating to the genetic modification: (a) method used for the modification; (b) methods used to construct and introduce the insert(s) into the recipient or to delete a sequence; (c) description of the insert and / or vector construction; (d) purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function; (e) number of intact and truncated vector inserts. Sequence, functions identity and location of the altered /inserted/deleted nucleic acid segment(s) in question with particular reference to any known sequence; and (f) sequence and methylation pattern of the recipient DNA as far as 100 kbp up and downstream from all DNA inserts.
	2. Information on the final genetically modified organism(s) and products thereof: (a) description of the genetic trait(s) of phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed; (b) structure and amount of any vector and / or donor nucleic acid remaining in the final construction of the genetically modified organism (s) and products thereof; (c) stability of the organism in terms of genetic traits; (d) rate and level of expression of the new genetic material. Methods and sensitivity of measurement; (e) activity of the expressed protein(s); (f) expression levels for the recipient's genes situated as far as 100 kbp up and downstream from all DNA inserts; (g) sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques; (h) history of previous releases or uses of the genetically modified organism (s) or products thereof;

	(i) health considerations: (i) toxic or allergenic effects of the viable or non-viable genetically modified organism(s) or product thereof or their metabolic products; (ii) product hazards; (iii) comparison of the genetically modified organism (s) or products thereof to the donor, recipient or (where appropriate) parental organism regarding pathogenicity; (iv) capacity for colonisation; (v) if the organisms is pathogenic to humans who are immuno competent: (a) disease caused and mechanism of pathogenicity including invasiveness and virulence; (b) communicability; (c) infective dose; (d) host range, possibility of alteration; (e) possibility of survival outside human; (f) presence of vectors or means of dissemination; (g) biological stability; (h) antibiotic resistance patterns; (i) potency of allergen; (j) Availability of appropriate therapies.
III. INFORMATION RELATING TO THE CONDITIONS OF RELEASE AND THE RECEIVING ENVIRONMENT	**A. Information on the release**
	1. Description of the proposed deliberate release, including the purpose(s) and foreseen products;
	2. Foreseen dates of the release and time planning of the experiment including frequency and duration of releases;

	3. Preparation of site prior to the release;
	4. Size of the site;
	5. Method(s) to be used for the release;
	6. Quantities of genetically modified organism (s) or products thereof to be released;
	7. Disturbance on the site (type and method of cultivation, mining, irrigation or other activities);
	8. Workers protection measures taken during the release;
	9. Post-release treatment of the site;
	10. Techniques foreseen for elimination or inactivation of the genetically modified organism (s) or products thereof at the end of the experiment;
	11. Information on, and results of, previous releases of the genetically modified organism (s) or products thereof, especially at different scales and in different ecosystems.
	B. Information of the environment (both on site and in the wider environment)
	1. Geographical location and grid reference of the site(s) (in case of notification the site(s) of release will be the foreseen areas of use of the product).
	2. Physical and biological proximity to humans and other significant biota.
	3. Proximity to significant biotopes or protected areas.
	4. Size of local population.
	5. Economic activities of local populations which are based on the natural resources of the area.
	6. Distance to closest areas protected for drinking water and/ or environmental purposes.
	7. Climatic characteristics of the region(s) likely to be affected.
	8. Geographical, geological and pedological characteristics.
	9. Flora and fauna, including crops, livestock and migratory species.
	10. Description of target and non-target ecosystems likely to be affected.
	11. A comparison of the natural habitat of the recipient organism with the proposed site(s) of release.

	12. Any known planned developments or changes in land use in the region, which could influence the environmental impact of the release.
IV. ADDITIONAL INFORMATION REQUIRED IN THE CASE OF APPLICATION FOR PLACING ON THE MARKET OF PRODUCTS CONTAINING OR CONSISTING OF GENETICALLY MODIFIED ORGANISMS	**A: The following information shall be provided in the application for placing on the market of a product containing or consisting of a genetically modified organism.**
	1. Proposed commercial name(s) of the product and name(s) of genetically modified organisms contained and any specific identification, name or code used by the applicant to identify the GMO.
	2. Name and full address of the person established in the country who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor,
	3. Name and full address of the supplier(s) of control samples,
	4. Description of how the product and the genetically modified organism as or in product are intended to be used. Differences in use or management of the genetically modified organism compared to similar non-genetically modified products should be highlighted.
	5. description of the geographical area(s) and types of environment where the product is intended to be used within the Lao PDR including where possible, estimated scale of use in each area,
	6. Intended categories of users of the product (e.g. industry, agriculture and skilled trades, consumer use by public at large).
	7. Proposed labelling on a label or in an accompanying document. This shall include, at least in summarised form, a commercial name of the product, a statement that "This product contains genetically modified organisms", the name of the genetically modified organism and the information referred to at 2 above. The labelling should indicate how to access the information in the publicly accessible part of the register
	B The following information shall be provided in the application, in accordance with the Regulations, when relevant, in addition to that required by Part I of this schedule:

	1. measures to take in case of unintended release or misuse;
	2. specific instructions or recommendations for storage and handling;
	3. specific instructions for carrying out monitoring and reporting to the applicant and, if required, the Competent Authority;
	4. proposed restrictions on the approved use of the genetically modified organism, for example, where the product may be used and for what purposes;
	5. proposed packaging;
	6. estimated production in and/or imports
	7. proposed additional labelling to include, at least in summarised form, the information referred to in points 4 and 5 of Part I of this schedule and points 1, 2, 3 and 4 of this Part.
V. INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GENETICALLY MODIFIED ORGANISM(S) OR PRODUCTS THEREOF AND THE ENVIRONMENT	**A. Characteristics and factors affecting survival, multiplication, gene expression and dissemination**
	1. Biological features which affect survival, multiplication and dispersal.
	2. Known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, pollutants such as pesticides, heavy metals and others, etc.)
	3. Sensitivity to specific agents
	B. Interactions with the environment
	1. Predicted habitat of the genetically modified organism (s) or products thereof.
	2. Studies of the behaviour and characteristics of the genetically modified organism (s) or products thereof and their ecological impact carried out in simulated natural environments, such as microorganisms, growth rooms, green houses.
	4. Likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the genetically modified organism (s) or products thereof.

	5. Measures employed to ensure and verify genetic stability. Description of genetic traits, which may prevent or minimise dispersal or genetic material. Methods to verify stability.
	6. Routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing, etc.
	7. Description of ecosystems to which the genetically modified organism (s) or products thereof could be disseminated.
	C. Potential environmental impact
	1. Potentials for excessive population increase in the environment.
	2. Competitive advantage of the genetically modified organism (s) or products thereof in relation to the unmodified recipient or parental organism(s).
	3. Identification and description of the target organisms.
	4. Anticipated mechanism and result of interaction between the released genetically modified organism (s) or products thereof and the target organism.
	5. Identification and description on non-target organisms, which may be affected unwittingly.
	6. Likelihood of post release shifts in biological, or in host range.
	7. Known or predicted effects on non-target organisms in the environment, impact on population levels of competitors, preys, hosts, symbionts, predators, parasites and pathogens.
	8. Known or predicted involvement in biogeochemical processes.
	9. Other potentially significant interactions with the environment.
VI. INFORMATION ON MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS	**A. Monitoring techniques**
	1. Methods for tracing the genetically modified organism (s) or products thereof, and for monitoring their effects.
	2. Specificity (to identify the genetically modified organism (s) or products thereof, and to distinguish them from the donor, recipient or, where appropriate, the parental

	organisms), sensitivity and reliability of the monitoring techniques.
	3. Techniques for detecting transfer of the donated genetic material to other organisms.
	4. Methods to detect aberrant gene expression.
	B. Control of the release
	1. Methods and procedures to avoid and/or minimise the spread of the genetically modified organism (s) or products thereof beyond the site of release or the designated area for use.
	2. Methods and procedures to protect the site from intrusion by unauthorised individuals.
	3. Methods and procedures to prevent other organisms from entering the site.
	C. Waste treatment
	1. Type of waste generated;
	2. Expected amount of waste;
	3. Possible risks;
	4. Description of treatment envisaged.
	D. Emergency response plan
	1. Methods and procedures for controlling the genetically modified organism (s) or products thereof in case of unexpected spread.
	2. Methods for decontamination of the areas affected, e.g. eradication of the genetically modified organism (s) or products thereof.
	3. Methods for disposal or sanitation of plants, animals, soils, etc. that was exposed during or after the spread.
	4. Methods for the isolation of the area affected by the spread.
	5. Plans for protecting human health and the environment in case of the occurrence of an undesirable effect.
VII. INFORMATION REQUIRED IN THE NOTIFICATION OF A FIRST TIME USE OF PREMISES OR OF A	**A. Information required for applications**

CONTAINED USE	
	1. name of user, including those responsible for supervision and safety;
	2. information on the training and qualifications of the persons responsible for the activity;
	3. supervision and safety;
	4. details of any biological committees or subcommittees;
	5. address and general description of the premises;
	6. a description of the nature of the work which will be undertaken;
	7. the class of the contained use;
	PART B : **Information required for the notification**
	1. date of submission of the application;
	2. the names of the persons responsible for supervision and safety and information on their training and qualifications;
	3. the recipient, donor and/or parental micro-organism(s) used and, where applicable;
	4. the host-vector system(s) used;
	5. the source(s) and the intended function(s) of the genetic material(s) involved in the modification(s);
	6. identity and characteristics of the genetically modified micro-organism;
	7. the purpose of the contained use including the expected results;
	8. approximate culture volumes to be used;
	9. description of the containment measures to be applied, including information about waste management including the wastes to be generated, their treatment, final form and destination;
	10. a summary of the risk assessment;
	11. the information necessary for the Directorate to evaluate any emergency response plans if required.
	PART C: Information required for application
	1. the date of submission of the application;
	2. the names of the persons responsible for supervision and safety and information on their training and qualifications;
	3. the recipient or parental micro-organism to be used;
	4. the host-vector system to be used (where applicable);

	5. the source and intended function of the genetic material involved in the modification,
	6. identity and characteristics of the genetically modified micro-organism;
	7. the culture volumes to be used;
	8. description of the containment measures to be applied, including information about waste management including the type and form of wastes to be generated, their treatment, final form and destination;
	9. the purpose of the contained use including the expected results;
	10. description of the parts of the premises;
	11. information about accident prevention and emergency response plans, if any;
	12. any specific hazards arising from the location of the premises;
	13. the preventive measures applied such as safety equipment, alarm systems and
	14. containment methods;
	15. procedures and plans for verifying the continuing effectiveness of the containment measures,
	16. a description of information provided to workers;
	17. the information necessary for the competent authority to evaluate any emergency
	18. response plans if requires; and
	19. a copy of the risk assessment

SECOND SCHEDULE

CHECKLISTS

FORM FOR AUTHORIZATION FORCONTAINED USE AND RELEASE INTO THE ENVIRONMENT

Information required	**Response/Comments**
1. Name, address and contact details of the exporter.	
2. Name, address and contact details of the importer.	
3. Name and identity of the genetically modified organism, as well as the domestic classification, if any, of the biosafety level of the genetically modified organism in the State of	

export.	
4. Intended date or dates of the transboundary movement, if known.	
5. Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or the parental organisms related to biosafety.	
6. Centres of origin and centres of genetic diversity, if known, of the recipient organism or the parental organisms and a description of the habitats where the organisms may persist or proliferate.	
7. Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.	
8. Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the genetically modified organism.	
9. Intended use of the genetically modified organism or products thereof, namely, processed materials that are of genetically modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.	
10. Quantity or volume of the genetically modified organism to be transferred.	
11. Is there previous and existing risk assessment report conducted on the GMO. Please annex summary of same and confirm whether you have annexed and marked it as such.	
12. Proposed methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.	
13. Regulatory status of the genetically modified organism within the State of export, i.e. whether the GMO has been approved, banned or restricted and the reasons for its decision.	
14. Result and purpose of any notification by the exporter to other States regarding the genetically modified organism to	

be transferred.	
15. Have you annexed a declaration that the above-mentioned information is factually correct?	
16. Have you indicated on written annex herein information that you consider confidential (if any) for evaluation and protection.	
Applicant's signature:	
FOR OFFICIAL USE: **Comments by NBAC:**	
Registrar's Stamp on date of receipt of notification _____ **Signature**	

CHECKLIST FOR CONTAINMENT INSPECTION: – ANIMAL UNITS

Specification		Containment level			
		L1	**L2**	**L3**	**L4**
1	Isolation of animal unit optional	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)	optional	optional	yes	yes
4	Floor and/or walls easily washable	optional	floor	floor and walls	floor and walls
5	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	no	yes	yes	yes

	regularly.				
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 have to be transported so that the environment is not contaminated	yes	yes	yes	yes
11	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 the facility. Separate male and female of the species to avoid reproductive transmission, unless reproductive studies are part of the experiment	yes	yes	yes	yes
17	Measures to control undesired species such as insects and rodents	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	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 genes, about the breeding experiments and the disposal of animals	yes	yes	yes	yes
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 escape of animals	yes	yes	yes	yes
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	37 Genetically modified organisms must only be transported in break proofed and closed containers	no	yes	yes	yes
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	no	yes	yes	yes

	should be given to the means of removing or extracting the fumigant				
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 is provided, the airflow should be inwards. Air should not be re-circulated to any part of the building.	no	yes	yes	yes
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 airtight plastic sack for later sterilisation	no	no	yes	yes
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 trans-ported in closed, leak proofed and disinfected containers	no	no	yes	yes
49	Waste water has to be sterilised	no	no	yes	yes

*High-efficiency particle arresting

1. CHECKLIST FOR CONTAINMENT INSPECTION – GLASSHOUSES AND GROWTH-ROOMS

Specification		Containment level			
		L1	**L2**	**L3**	**L4**
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 runoff Water	Optional	Minimise run-off	Prevent runoff	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, protective structure and laboratory shall control dissemination of genetically modified micro-organisms	Minimise Disseminati on	Minimise dissemina tion	Prevent dissemina tion	Prevent dissemination
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	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 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.	No	Yes	N/A	N/A
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	N/A	N/A
12	The ground of the greenhouse is made of water impermeable material with provisions to collect and sterilise waste water.	No	No	Yes	yes

13	Escape of GMOs	Minimised	Prevent	Prevent	Prevent
14	Windows shall be closed and sealed With insect nets.	No	No	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	20 Separate facilities for storing protective and street clothing shall be available	No	Yes	Yes	Yes
21	Protective clothing has to be sterilised before laundry	No	No	Yes	Yes
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	27 Air intake screening and motorised or gravity-driven exhaust fan louvers	Yes	Yes	N/A	N/A
28	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	N/A	N/A	N/A
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	Yes	Yes

			available		
33	The glasshouse has to be surrounded by a security fence or equal protection system	No	No	Yes	Yes

1. CHECKLIST FOR CONTAINMENT INSPECTION – LABORATORY ACTIVITIES

I. Physical Control Measures

a) Facility design

Specification		Containment level			
		L1	**L2**	**L3**	**L4**
1	Process with viable micro-organisms separated 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	no	no	yes	yes
6	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

b) Containment equipment

Specification		Containment level			
		L1	**L2**	**L3**	**L4**
1	Surfaces resistant to water, acids, alkalis, solvents, disinfectants, decontamination agents and easy to clean	yes	yes	yes	yes
2	Suitable of equipment used for safety purposes	no	yes	yes	yes
3	Suitable chemical disinfectants in use	optional	yes	yes	yes
4	suitable position of the autoclave with respect to the genetically modified organism installation	on site	in the building	in suite in lab	double closed
5	Autoclave provides a print-out showing the temperature and time of sterilisation	no	no	yes	yes
6	6 Wash hand basin or sink that can be used for hand	yes	yes	yes	yes

	washing with: - dispenser containing soap - dispenser containing hand disinfectant - paper towels				
7	Appropriate position and design of biological safety hoods	optional	yes	yes	yes
8	Suitable design of the equipment for the safe storage of genetically modified organisms	yes	yes	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 HEPA* filtered	no	no	extract air input	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

I. Physical Control Measures

a) Facility design

Specification		Containment level			
		L1	**L2**	**L3**	**L4**
1					
2					
3					
4					

5					
6					

I. Physical Control Measures
a) Facility design

Specification		Containment level			
		L1	**L2**	**L3**	**L4**
1					
2					
3					
4					
5					
6					

I. Physical Control Measures
a) Facility design

Specification		Containment level			
		L1	**L2**	**L3**	**L4**
1					
2					
3					
4					
5					
6					

I. Physical Control Measures
a) Facility design

Specification		Containment level			
		L1	**L2**	**L3**	**L4**
1					
2					
3					
4					
5					
6					

THIRD SCHEDULE

CLASSIFICATION OF CONTAINMENT LEVELS

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 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.

FOURTH SCHEDULE

CONTAINMENT MEASURES AND LEVELS

Table IA Containment measures for contained use of genetically modified organisms in a laboratory					
Measures		**Containment levels (Classes)**			
		1	2	3	4
1	Laboratory suite: isolation	Not required	Not required	Required	Required
2	Laboratory: sealable for fumigation	Not required	Not required	Required	Required
Equipment					
3	Surfaces resistant to water, acids, alkalis, solvents, disinfectants, decontamination agents and easy to clean	Required for bench	Required for bench	Required for bench and floor	Required for bench, floor, ceiling and walls
4	Entry to laboratory via airlock	Not required	Not required	Optional	Required
5	Negative pressure relative to the pressure of the immediate	Not required	Not required	Required	Required

	environment				
6	Extract and input air from the laboratory should be HEPA–filtered	Not required	Not required	Required	Required for input and extract air
7	Microbiological safety cabinet	Not required	Optional	Required	Required
8	Autoclave	On site	In the building	En suite	Double-ended autoclave in laboratory
System of work					
9	Restricted access	Not required	Required	Required	Required
10	Biohazard sign on the door	Not required	Required	Required	Required
11	Specific measures to control aerosol dissemination	Not required	Required to minimize	Required to prevent	Required to prevent
12	Shower	Not required	Not required	Optional	Required
13	Protective clothing	Suitable protective clothing	Suitable protective clothing; footwear optional	Suitable protective clothing and footwear	Complete change of clothing and footwear before entry and exit
14	Gloves	Not required	Optional	Required	Required
15	Efficient vector control (e.g. for rodents and insects)	Optional	Required	Required	Required

Measures		**Containment levels (Classes)**			
		1	2	3	4
Waste					
16	Inactivation of genetically modified organisms in effluent from hand-washing sinks or drains and showers and similar effluents	Not required	Not required	Optional	Required
17	Inactivation of genetically	Optional	Required	Required	Required

	modified organisms in contaminated material and waste				
Other measures					
18	Laboratory to contain its own equipment	Not required	Not required	Optional	Required
19	Observation window or alternative to enable occupants to be seen	Optional	Optional	Optional	Require

Table IB Containment measures for contained use of genetically modified organisms in plant growth facilities

In addition to the measures specified in Table 1 A, the following measures shall apply:

Measures		**Containment levels (Classes)**			
		1	2	3	4
Building					
1	Permanent structure	Not required	Required	Required	Required
Equipment					
2	Entry via a separated room with two interlocking doors	Not required	Optional	Optional	Required
3	Control of contaminated run-off water	Optional	Required to minimise run-off	Required to prevent run-off	Required to prevent run-off
System of work					
4	Measures to control undesired species such as insects, rodents, arthropods	Required	Required	Required	Required
5	Procedures for transfer of living material between the plant growth facility and laboratory to	Required to minimise dissemination	Required to minimise dissemination	Required to prevent dissemination	Required to prevent dissemination

	control dissemination of genetically modified micro-organisms				

Table IC Containment measures for contained use of genetically modified organisms in animal units

In addition to the measures specified in Table 1 A, the following measures shall apply:

Measures		**Containment levels (Classes)**			
		1	2	3	4
Facilities					
1	Isolation of animal unit	Optional	Required	Required	Required
2	Animal facilities separated by lockable doors	Optional	Required	Required	Required
3	Animal facilities designed to facilitate decontamination	Optional	Optional	Required	Required
4	Floor and walls easily washable	Optional	Required for floor	Required for floor and walls	Required for floor and walls
5	Animals kept in appropriate containment facilities	Optional	Optional	Optional	Optional
6	Filters on isolators or isolated room	Not required	Optional	Required	Required

Table 1D

Containment measures for contained use of genetically modified organisms in facilities other than those covered by tables IA, IB or IC of this Schedule

Measures		**Containment levels (Classes)**			
		1	2	3	4
General					
1	Viable organisms contained in a	Optional	Required	Required	Required

	system which separates the process from the environment , i.e. a closed system				
2	Control of exhaust gases from the closed system	Not required	Required to minimise dissemination	Required to prevent dissemination	Required to prevent dissemination
3	Control of aerosols during sample collection, addition of material to a closed system or transfer of material to another closed system	Optional	Required to minimise dissemination	Required to prevent dissemination	Required to prevent dissemination
4	Inactivation of bulk culture fluids before removal from the closed system	Optional	Required, by validated means	Required, by validated means	Required, by validated means
5	Seals designed to minimise or prevent release	No specific requirement	Required to minimise dissemination	Required to prevent dissemination	Required to prevent dissemination
6	Designation of controlled area to contain spillage of the entire contents of the closed system	Optional	Optional	Required	Required
7	Controlled area sealable to permit fumigation	Not required	Optional	Optional	Required
Equipment					
8	Entry via airlock	Not required	Not required	Optional	Required
9	Surfaces resistant to water, acid, alkalis, solvents, disinfectants, decontamination agents and easy to clean	Required for bench	Required for bench	Required for bench and floor	Required for bench, floor, ceiling and walls
10	Specific measures adequately to ventilate the controlled area in order to minimise air contamination	Optional	Optional	Optional	Required
11	Controlled area maintained at an air pressure negative to the immediate surroundings	Not required	Not required	Optional	Required

12	Extract and input air from the controlled area to be high efficiency particulate air filtered	Not required	Not required	Required for extract air and optional for input air	Required for input and extract air
Measures		**Containment levels (Classes)**			
		1	2	3	4
System of work					
13	Closed systems located within a controlled area	Not required	Optional	Required	Required
14	Access restricted to nominated personnel only	Not required	Required	Required	Required
15	Biohazard signs posted	Not required	Required	Required	Required
16	Personnel to shower before leaving the controlled area	Not required	Not required	Optional	Required
17	Personnel to wear protective clothing	Required (work clothing)	Required (work clothing)	Suitable protective clothing	Complete change before entry and exit
Waste					
18	Inactivation of genetically modified micro-organisms in effluent from hand-washing sinks or showers or similar effluents	Not required	Not required	Optional	Required
19	Inactivation of genetically modified organisms in contaminated material and waste including those in process effluent before final discharge	Optional	Required, by validated means	Required, by validated means	Required, by validated means

FIFTH SCHEDULE

RENEWAL APPLICATION FOR CONFINED FIELD TRIAL (PLANTS)

This application form must be completed for each individual genetically modified plant. **Applications for new and renewal of previously authorized confined research field trials should be submitted separately.**

<table>
<tr><td colspan="2">1. General Information</td></tr>
<tr><td>1.1 Application Type</td><td>1.2 Plant Species Name:

1.2.1 Latin Name:</td></tr>
<tr><td rowspan="2">□ New
□ Renewal
□ Date of submission of the application</td><td>1.2.2 Common Name(s)</td></tr>
<tr><td></td></tr>
<tr><td colspan="2">(Indicate if perennials, annuals, trees etc.)</td></tr>
<tr><td colspan="2">1.3 Feed Section
Will any plant material generated in the confined field trials be used as research material for livestock feed?

Yes __

No __</td></tr>
<tr><td>1.4 Applicant
1.4.1 Name</td><td>1.5 Name of Institutional Biosafety Committee.
(Attach signed minutes of Institutional Biosafety Committee discussions)</td></tr>
<tr><td>1.4.2 Address</td><td>1.5.1 Institution of applicant</td></tr>
<tr><td>1.4.3 Telephone</td><td>1.5.2 Registration Status in Swaziland</td></tr>
<tr><td>1.4.4 Facsimile/email</td><td>1.5.2.1 Affiliating institution (if institution of applicant is not registered in Swaziland)</td></tr>
<tr><td colspan="2">1.6 Summary of trial</td></tr>
</table>

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 weed
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 Swaziland? □ 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 pathway
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 Allergen potency 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)***

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 Competent 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 3.4.1 Name (*Must be affiliated to a research institution registered in Swaziland*)	3.4.2 Address	
3.4.3 Telephone	3.4.4 Facsimile	

3.5 Trial Size Trial size in m^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. Explain	
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 of a managed ecosystem? Yes □ No □	3.7.3 If yes, how close is the nearest natural Ecosystem?
3.7.4 How close is the site from an area of special ecological interest, including protected areas and sanctuaries?	
3.8 Indigenous Species 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? Yes □ No □	3.8.3 If yes, list
NB: For information on endangered species that may be near the trial site location, contact the ***Swaziland National Trust Commission, Lobamba Swaziland***	
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 **P**erson(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 be planted by: 4.5.1.1 Hand □ Or 4.5.1.2Mechanically □	4.5.2 Will any unmodified plants of the same or a related species be planted at the trial site location? 4.5.3 If yes, state reason
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/GMO will be disposed of or stored.

4.6 Spraying*

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.

4.6.1 Registered pesticide for unregistered use Yes □ No □		
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 relevant Pest Control Products Act*

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 Email:
. 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
4.8.2.3 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 GMO 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
(The limit is 5 ha cumulative per submission per Region)

District A:
Submission (Genetically modified organism designation):

Trial site location		
Legal land location	Town	Number of hectares

Total number of hectares:

District B:
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) Institutional Research Committee (IRC) Review

This application has been reviewed by IBC/IRC

Name of IBC/IRC_____

Name of chairperson _____

Signature_____ Date_____

PART F

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 on sequences.
16.0 Undertaking of the applicant *(attach affidavit)*	
16.1 Name	16.2 Signature

DECLARATION BY APPLICANT

I, …… of P.O. Box. …… of ..... (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

Dated …….....……, 20....

Minister for Environment and Tourism.

SIXTH SCHEDULE

APPROVALS
TO CONDUCT CONTAINED USE ACTIVITY USING GENETICALLY MODIFIED ORGANISM

APPROVAL NUMBER_____	DATE OF ISSUE_____ VALID UP TO_____
In accordance with the Biosafety Regulations of 2013 on contained Use of the Biosafety Act of 2012, 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: Date	Name: Signature: *The Executive Director* *Swaziland Environment Authority*

APPROVAL TO IMPORT, EXPORT AND TRANSIT GENETICALLY MODIFIED ORGANISMS

	DATE OF ISSUE _____

APPROVAL NUMBER _____	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: The Chief Executive Office National Biosafety Authority	Date

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

SEVENTH SCHEDULE

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
	2.1 Exporting country
3. Name, address and contact details of the supplier.	4. Country of origin
	5.Expected date of import/export/ transit organism.
6. Common name, scientific name, commercial name or unique identifier code of the genetically modified organism	7. Port: 7.1 Boarder Post for Entry into Swaziland
	7.2 Boarder Post for Exit from Swaziland
8. Evidence of approval of the genetically modified	9. Consent for import from the destination country (in case

organism from the exporting country (Attach)	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	11. The quantity of the genetically modified organism to be imported into Swaziland
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 Swaziland in the event of an accident with the genetically modified organisms	

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

EIGHTH SCHEDULE

FEES AND FINES

A. FEES

	Service Fee	**(SDE)**
1.	Handling of general application form for importation of genetically modified organisms and their products	**120. 00**

2.	Handling of risk assessment form of genetically modified organisms and their products intended for direct use as for food, feed or processing	**3000. 00**
3.	Handling of risk assessment form for genetically modified organisms and their products destined for research conducted in laboratories and green houses	**500. 00**
4.	Handling of risk assessment form for genetically modified organisms and their products destined for field trials	**500. 00**
5.	Handling of risk assessment form for genetically modified organisms and their products destined for the deliberate release into environment	**5000, 00**
6.	Issuing of certificate of transit	**100. 00**
7.	Permit for field trials	**100. 00**
8.	Request for inspection at the entry points and storage and/or re-packaging sites of genetically modified organisms and their products within the country	**100. 00**
9.	Request for authorisation of re-packaging of genetically modified organisms within country.	**100. 00**

B: FINES

Breach	**Fine (SDE)**
The importation and placing on the marketing of GMOs and their products destined for food, feed or processing without an authorization from the Competent Authority	**25 000. 00 to 100 000, 00**
The handling, manipulation, production and possession of GMOs and their products without authorization from the Competent Authority	**10 000 to 50 000. 00**
The execution of field experiments with GMOs and its products without an authorisation from the Competent Authority	**25 000. 00 to 100 000. 00**
To provide false declarations or biased information	**10 000. 00**
The obstruction of the work of the inspectors	**5000. 00**
The lack of labelling and correct identification of products containing GMOs	**5 000. 00**
The failure to report to the competent authority about any accident involving GMOs that have occurred	**5000. 00 to 10 000. 00**
The utilisation of GMOs for purposes different from what was indicated in the import authorization	**20 000. 00**

The introduction of GMOs and their products in the country through an entry point different from what was stipulated in the import authorization	**20 000. 00**