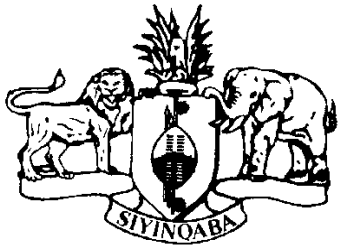
Legal Notice No……..

THE BIOSAFETY ACT, 2012

THE BIOSAFETY REGULATIONS, 2013



CHAPTER 1

PART I

PRELIMINARY

1. Citation

These regulations shall be cited as The Biosafety Regulations, 2013.

2. Interpretation

In these Regulations, unless the context otherwise requires:

" Act" means the Biosafety Act, 2012;

“Damage” means an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health, that:

(i) Is measurable or otherwise observable taking into account, wherever available, scientifically-established baselines recognized by a competent authority that takes into account any other human induced variation and natural variation; and

(ii) Is significant

“environmental risk assessment” means an evaluation, carried out in accordance with the Second Schedule, of risk to human health or the environment, whether direct or indirect, immediate or delayed, which the environmental release or the placing on the market of a genetically modified organism may pose;

‘living modified food’ means food containing, consisting of or produced from living modified organisms;

‘living modified feed’ means feed containing, consisting of or produced from living modified organisms;

‘living modified organism for food use’ means a living modified organism that may be used as food or as a source material for the production of food;

“re-packaged food” 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.

“pre-packaged food” 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:

(i) Prevent, minimize, contain, mitigate, or otherwise avoid damage, as appropriate;

(ii) Restore biological diversity through actions to be undertaken in the following order of preference:

(a) 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;

(b) Restoration by, *inter alia*, 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.

3. Scope of regulations

These regulations are applicable to the following activities involving a GMO or GMO products, namely -

(a) the import of a GMO or GMO product;

(b) the export of a GMO or GMO product;

(c) the release into the environment of a GMO or GMO product;

(d) the contained use of a GMO or GMO product;

(e) the placing on the market of a GMO or GMO product;

(f) the transport of a GMO or GMO product, including transport in transit through Swaziland; and

(g) the use or handling in any other way of a GMO or GMO product.

4. Application and authorization

(1) Application procedures

Notwithstanding the prescribed information required for any application, the general information set out in the 1st Schedule shall apply in relation to the regulation of activities relating to GMOs.

(2) The applicant shall present a checklist set out in a form in the 2nd Schedule to satisfy himself of the extent of supply of relevant information to the Competent Authority together with the application for authorization of an application for contained use or release to the environment.

5. Guiding principles

In implementing these regulations, any entity shall be guided by, and give effect to, the principles provided by the Environment Management Act, 2002 and the following:

(1) The *precautionary principle* which entails that where there is a reason to believe that harm or damage may result from any undertaking involving GMOs or its products, lack of scientific evidence or certainty shall not be used as a basis for not taking preventive measures including refusing the application or imposing any condition or limitation on an authorization.

Authorization shall not be given for the deliberate 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 the results of research on the effects of the use of such GMOs or their products.

(2) The *preventative principle* which means that all authorizations shall be made subject to compliance by the applicant of the principle of prevention that involves the use of special techniques such as risk assessment, or environmental impact assessment of potential effects of the planned activity followed by a decision to allow it or to prohibit it.

(3) All authorizations for introduction of GMO or their products shall be subject to a condition that the applicant is strictly liable for any damage caused to any person or entity.

(4) 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 minimised.

CHAPTER 2

PART II

GMOs FOR CONTAINED USE AND FIELD TRIALS

6. Application of the part

(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 of these Regulations, provided that any conditions attached to the authorization to place the genetically modified micro-organism on the market have been complied with.

7. Prohibitions

(1) No person shall carry out contained use activities without an authorization issued by the Competent Authority.

(2) An application to conduct contained use activity shall contain the information set out in the 1st Schedule to these Regulations, provided that additional information may be requested by the Competent Authority in terms of the Act.

8. Risk assessment

(1)Without prejudice to any other provision of this Part, an operator shall, before commencing a contained use, carry out an assessment of the risks to human health and the environment which may be associated with such use.

(2) In making an assessment in accordance with sub-regulation 8(1), an operator shall, as a minimum, use the elements of assessment and the procedures set out in the Third Schedule, and take account, in particular, of issues related to the disposal of waste and effluent.

(3) Without prejudice to any other provision of these Regulations, a record of an assessment for the purposes of sub-regulation 8(1) shall be kept by the user and shall be made available to the Competent Authority on request.

9. First time users

(1) Notwithstanding any other provisions of these Regulations, no person shall undertake contained use activities in premises used for the first time for contained use, without the authorization of the Competent Authority.

(2) An application to carry out contained use activities for the first time in any premise shall be in the Form set out in Part A of the Fourth Schedule.

(3) The Competent Authority shall communicate its decision in writing to the user at the latest 270 days after receipt of the application.

(4) 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 accordingly a further authorization shall be required in respect of the first time use of the premises for any higher class of contained use.

10. Classes of contained use

(1) A risk assessment carried out in accordance with these Regulations shall result in the classification of the contained use into one of the following classes –

a) Class 1: activities for which level one containment, as set out in the Fourth Schedule, is appropriate. Where the conditions, if any, attached to an authorization granted by the competent authority have been complied with, a class 1 contained use or a subsequent such contained use may proceed without further application;

b) Class 2: activities for which level two containment, as set out in the Fourth Schedule, is appropriate. No person shall carry out Class 2 contained use activities without an authorization granted by the competent authority. An application to carry out Class 2 contained use activities shall be in the Form set out in Part B of the Fourth Schedule;

c) Class 3: activities for which level three containment, as set out in the Fourth Schedule, is appropriate; and

d) Class 4: activities for which level three and four containment, as set out in the Fourth Schedule, is appropriate.

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

(3) No person shall proceed with a class 3 or 4 contained use 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 at the latest:

(a) 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) 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

(6) In the event of doubt as to the appropriate class for a proposed contained use, 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 the lower level.

11. Principles to be applied by users

(1) Every user shall apply:

(a) the general principles of good microbiological practice and of good occupational safety and hygiene set out in Part A of the Fourth Schedule, and

(b) except to the extent that Part B of the Fourth Schedule allows other measures to be applied, the containment measures set out in the tables in the said Part B which correspond to the class of the contained use, in order to keep the exposure of humans and the environment to genetically modified organisms to the lowest practicable level, and to ensure a high level of safety.

(2) An operator shall periodically review the risk assessment and the containment measures applied by the operator, and the risk assessment shall be reviewed forthwith if there is reason to consider that:

(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.

(3) Where a user has reason to consider that 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.

(4) 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 give a new application.

12. Notifications under this category

(1) Any person may, within the period of 28 days beginning on the day of publication of a notice make notification to the competent authority in relation to the application.

(2) Notifications under sub-regulation 12(1) shall be –

(a) made in writing;

(b) addressed to the competent authority;

(c) forwarded so as to reach the competent authority within the period of 4 weeks beginning on the day of publication of the notice; and

(3) Any notifications that do not comply with the requirements of sub- regulation (2) shall be deemed invalid and the competent authority shall return such notification to the sender, if known, together with any accompanying fee.

(4) The competent authority upon receiving any notification in accordance with sub- regulation (1), shall –

(a) acknowledge the notification;

(b) consider the Notification in determining the application; and

(c) inform the person or body who made the notification, of its decision on the application.

13. Modifications

(1) 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 class, 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.

14. Accidents

(1) Every user shall before the commencement of a contained use activity, draw and put in place such measures or plans that may mitigate any adverse effects that may arise from an accident caused by the activity.

(2) In the event of an accident, the user shall:

(a) immediately inform the Competent Authority and provide :

(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;

(b) ensure that the relevant emergency services are informed of the accident;

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

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

(3) Where the 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) In the event of an accident, the competent authority may require the operator to defray or contribute towards any or all of the costs incurred by it arising from such accident.

15. Validity of authorization

(1) An authorization under this Part of the Regulations shall be for the period of the activity.

(2) An operator under this Part of the Regulations shall submit quarterly reports on the progress of the activity during the period of the implementation of activity.

16. Review of decision by Competent Authority

(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 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) As soon as may be, after it has completed a review under this regulation, the competent authority may:

(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.

17. Contingency plans

The Competent Authority shall ensure that before contained use commences:

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

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

18. Contravention of this Part

(1) An operator who contravenes any regulation of this Part commits an offence and shall be liable to a fine of not more than 100 000.00 Emalangeni or imprisonment not exceeding 2 years or both, plus any response measures which the court will determine to prevent adverse effects to the environment.

CHAPTER III

GMOs FOR FOOD, FEED AND PROCESSING

PART III

GMOs FOR FOOD

19. Scope

(1) This Part shall apply to:

(a) genetically modified organisms for food use;

(b) food containing or consisting of genetically modified organisms

(c) food produced from or containing ingredients produced from genetically modified organisms.

20. Requirements

(1) Food referred to in Regulation 19(1) shall not:

(a) Have adverse effects on human health, animal health or the environment;

(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.

(2) No person shall place on the market a genetically modified organism for food use or food referred to in Regulation 19(1) without an authorization granted by the Competent Authority.

(3) A person who contravenes this Regulation commits an offence and shall be liable, on conviction to a fine not exceeding 100 000.00 Emalangeni or imprisonment not exceeding 2 years or both.

(3) No genetically modified food for food use or food referred to in Regulation 19(1) shall be authorized unless the applicant for such authorization has adequately and sufficiently demonstrated that the food does not:

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

(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.

(4) Every authorization shall cover:

(a) a genetically modified organism and foods containing or consisting of that genetically modified organism as well as foods produced from or containing ingredients produced from that genetically modified organism; or

(b) food produced from a genetically modified organism as well as foods produced from or containing that food;

(c) an ingredient produced from a genetically modified organism as well as food containing that ingredient.

(5) 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.

21. Application for authorization

(1) An application for authorization shall be made to the Competent Authority and shall be accompanied by:

(a)the name and the address of the applicant;

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

(c) where applicable, the information set out in the First Schedule to these Regulations;

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

(e) 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 20(1);

(f) 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;

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

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

(i) 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 and/or in foods produced from it;

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

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

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

(2) In the case of an application relating to a genetically modified organism for food use, references to 'food' in paragraph 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) In the case of 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 a copy of the authorization decision;

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

22. Authorization

(1) The Competent Authority shall make a decision within two hundred and seventy 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.

(3) An authorization granted under this Part shall be valid for 10 years and shall be renewable.

(4) The authorized food shall be entered in the Register.

(5) Each entry in the Register shall mention the date of authorization and shall include the following particulars-

(a) the name and address of the applicant;

(b) the designation of the food, and its specification;

(c) where applicable, the information required under the First Schedule to these Regulations;

(d) the proposal for the labelling of the food and/or foods produced from it;

(e) where applicable, any conditions or restrictions which should be imposed on the placing on the market and specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment and conditions for the protection of particular ecosystems and geographical areas;

(f) the method for detection, including sampling, identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food and in foods produced from it; an indication of where appropriate reference material can be accessed;

(g) where appropriate a monitoring plan.

(6) The granting of authorization shall not lessen the general civil and criminal liability of any food operator in respect of the food concerned.

23. Status of existing products

(1) Products falling within the scope of this Part which have been lawfully placed on the market before the date of application of this Part of the Regulations may continue to be placed on the market, used and processed provided that the operators responsible for placing on the market the products concerned shall, within six months after the date of application of these Regulations, notify the Competent Authority that the products were placed on the market before the date of application of these Regulation.

(2) Within one 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.

24. Supervision

(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 placed on the market as food or feed.

(2) Where post-market monitoring or monitoring has been imposed on the operator, he shall ensure that it is carried out and shall submit reports to the Competent Authority in accordance with the terms of the authorization.

(3) The monitoring reports shall be made accessible to the public after deletion of any information identified as confidential.

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

(5) The operator shall forthwith inform the Competent Authority of any new scientific or technical information which might influence the evaluation of the safety in use of the food. 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.

25. Modification, suspension and revocation of authorizations

(1) On its own initiative or following a request from a member of the public the Competent Authority shall 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 and shall be liable on conviction to a fine not exceeding 100 000.00 Emalangeni or 2 years imprisonment.

26. Renewal of authorizations

(1) An operator may renew an authorization at the latest one year before the expiry date of the authorization.

(2) 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 authorization for placing the food on the market;

(b) a report on the results of the monitoring, if so specified in the authorization;

(c) 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;

(d) where appropriate, a proposal for amending or complementing the conditions of the original authorization, *inter alia* the conditions concerning future monitoring.

PART IV:

PROVISIONS RELATING TO LABELLING OF GENETICALLY MODIFIED FOODS

27. Scope of this Part

(1) This Part shall apply to foods which are to be delivered as such to the final consumer and which:

(a) contain or consist of genetically modified; or

(b) are produced from or contain ingredients produced from genetically modified organisms.

(2) This Part shall not apply to foods containing material which contains, consists of or is produced from genetically modified organisms in a proportion no higher than 0,9 per cent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.

(3) 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 material.

28. Labelling Requirements

(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 cm^2, the information required under this paragraph must 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 paragraph 28(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 paragraph 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.

PART V

PROVISIONS RELATING TO GENETICALLY MODIFIED FEED

29. Scope

(1) This Part shall apply to-

(a) genetically modified organisms for feed use;

(b) feed containing or consisting of genetically modified organisms;

(c) feed produced from genetically modified organisms

(2) Where necessary, it may be determined in accordance with the procedure referred to in Regulation 27(2) whether a type of feed falls within the scope of this regulation.

30. Requirements

(1) Feed referred to in Regulation 29(1) shall not:

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

(b) mislead the user;

(c) harm or mislead the consumer by impairing the distinctive features of the animal products;

(d) differ from feed which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for animals or humans.

(2) No person shall place on the market, use or process a feed product without an authorization granted by the Competent Authority.

(3) A person who contravenes regulation (2) commits an offence and shall be liable, on conviction to a fine not exceeding 100 000.00 Emalangeni or imprisonment not exceeding 2 years.

(4) An authorization under this Part may cover:

(a) a genetically modified organism and feed containing or consisting of that genetically modified organism as well as feed produced from that genetically modified organism; or

(b) feed produced from a genetically modified organism as well as feeds produced from or containing that feed.

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

(6) The applicant for an authorization and, after the authorization is granted, the operator or his representative, shall be established in Swaziland.

31. Application for authorization

(1)An application for authorization shall be accompanied by the following information-

(a) The name and the address of the applicant;

(b) The designation of the feed and its specification, including the transformation event(s) used;

(c) Where applicable, the information to be provided for the purpose of complying with the First Schedule to these Regulations;

(d) Where applicable, a detailed description of the method of production and manufacturing and intended uses of the feed;

(e) 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 feed complies with the requirements set out under this Part.

(f) Either an analysis, supported by appropriate information and data, showing that the characteristics of the feed 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 feed

(g) Either a reasoned statement that the feed does not give rise to ethical or religious concerns, or a proposal for labelling it;

(h) Where appropriate, the conditions for placing the feed on the market, including specific conditions for use and handling;

(i) 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 feed or in the feed produced from it;

(j) Samples of the feed and their control samples and information as to the place where the reference material can be accessed;

(k) Where appropriate, a proposal for post-market monitoring for the use of the feed for animal consumption;

(l) A summary of the dossier in a standardized form.

(2) In the case of an application relating to a genetically modified organism for feed use, references to 'feed' shall be interpreted as referring to feed containing, consisting of or produced from the genetically modified organism in respect of which an application is made.

(3) In the case of a genetically modified organism or feed containing or consisting of a genetically modified organism the application shall also be accompanied by-

(a) the complete technical dossier supplying the information and conclusions about the risk assessment or, where the placing on the market of the a genetically modified organism has been approved 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 authorization.

32. Authorization

(1) Within 270 days of receiving the application, the Competent Authority shall make a decision in respect of the application, taking into account the opinion of the public and other relevant regulatory agencies and shall communicate the decision to the applicant, in writing.

(2) The authorization document shall consist of:

(a) a summary of the application;

(b) the name and address of the applicant;

(c) the designation of the feed, and its specification;

(d) where applicable, the information set out in the First Schedule to these Regulations;

(e) the proposal for the labelling of the feed;

(f) where applicable, any conditions or restrictions which should be imposed on the placing on the market and specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment and, in the case of genetically modified organisms or feed containing or consisting of genetically modified organisms, conditions for the protection of particular ecosystems/environment and/or geographical areas;

(g) the method for detection, including sampling, identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the feed and/or in feed produced from it; an indication of where appropriate reference material can be accessed; and

(h) where appropriate, the monitoring plan

33. Status of existing products

(1) Products falling within the scope of this Part which have been lawfully placed on the market before the date of application of this Regulation may continue to be placed on the market, used and processed provided that within six months after the date of application of this Regulation, every operator shall notify the Competent Authority of the date on which they were first placed on the market in Swaziland and shall ensure that the requirements of these regulations are complied with.

(2) Within one year from the date of application of this Regulation and after verification that all the information required has been submitted and examined, the Competent Authority shall enter the particulars of the products concerned in the Register.

(3) Each entry in the Register shall include the particulars of the authorization as appropriate and, in the case of the products referred to in paragraph 1(a), shall mention the date on which the products concerned were first placed on the market.

(4) Within nine years from the date on which the products referred to in paragraph 33(1) were first placed on the market, but in no case earlier than three years after the date of

application of this Regulation, operators responsible for placing them on the market shall submit an application for renewal of the authorization.

(5) Where an operator fails to supply the required information within the period specified or the information supplied is found to be incorrect, or where an application is not submitted for renewal of an authorization within the period specified, the Competent Authority shall issue an order for the product concerned and any products derived from it to be withdrawn from the market.

(6) An order issued under this Regulation may provide for a limited period of time within which existing stocks of the product may be used up.

(7) In the case of an authorization not issued to a specific holder, the operator who imports, produces or manufactures the products referred to in this Regulation shall submit the information or the application to the Competent Authority.

34. Renewal of authorization

(1) An authorization granted under this Part shall be valid for a period of ten years and may be renewed on application to the Competent Authority by the operator at the latest one year before the expiry date of the authorization.

(2) The application shall be accompanied by the following particulars and documents:

(a) a copy of the authorization for placing the feed on the market;

(b) a report on the results of the monitoring, if so specified in the authorization;

(c)any other new information which has become available with regard to the evaluation of the safety in use of the feed and the risks of the feed to animals, humans or the environment;

(d) where appropriate, a proposal for amending or complementing the conditions of the original authorization, inter alia the conditions concerning future monitoring.

35. Supervision

(1) Every operator shall comply with any conditions or restrictions imposed in the authorization and shall in particular make sure that products not covered by the authorization are not placed on the market as food or feed.

(2) Where post-market monitoring or monitoring has been imposed on the operator, the operator shall ensure that it is carried out and shall submit reports to the Competent Authority in accordance with the terms of the authorization.

(3) The Competent Authority shall make the monitoring report accessible to the public after deletion of any information identified as confidential.

(4) If the operator proposes to modify the terms of the authorization, a new application to that effect must be submitted.

(5) The operator shall forthwith inform the Competent Authority of any new scientific or technical information which might influence the evaluation of the safety in use of the feed. In particular, the operator shall forthwith inform the Competent Authority of any prohibition or restriction imposed by any country in which the feed is placed on the market.

36. Modification, suspension and revocation of authorizations

(1) The Competent Authority may modify, suspend or revoke an authorization where the authorization holder is in contravention of the authorization or a condition issued under the authorization.

PART VI

PROVISIONS RELATING TO LABELLING OF GENETICALLY MODIFIED FEED

***37.* Scope**

(1)This Part shall apply to:
(a) genetically modified organisms for feed use;
(b) feed containing or consisting of genetically modified organisms;
(c) feed produced from genetically modified organisms

(2) This Part shall not apply to feed containing material which contains, consists of or is produced from genetically modified organisms in a proportion no higher than 0.9 per cent of the feed and of each feed of which it is composed, provided that this presence is adventitious or technically unavoidable.

(3) In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of such materials.

38. Labelling Requirements

(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 feeds referred to in Regulation 37(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 22 (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 15(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.

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

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

40. Public access

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.

41. Confidentiality

(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 food or feed and, 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 food or feed;

(d) Effects of the genetically modified food or feed on human and animal health and on the environment;

(e) Effects of the genetically modified food or feed 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 food or feed;

(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 must be made public if circumstances so require in order to protect human health, animal health 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.

42. Data protection

(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 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 this 10-year period, 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.

43. Emergency measures

(1) Where it is evident that food or feed imported into Swaziland is likely to constitute a serious risk to human health, animal 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 in question;

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

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

(d) any other appropriate interim measure.

(2) As soon as possible, and at most within 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.

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

(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.

45. Responsibilities of food business operators

(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-

(a) shall 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) shall 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.

46. Responsibilities for feed business operators

(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 and/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.

47. Transitional measures for adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation

(1) The presence in food or feed of material which contains, consists of or is produced from genetically modified organisms in a proportion no higher than 0,9 % shall not be considered to be in breach of these Regulations provided that:
(a) this presence is adventitious or technically unavoidable;
(b) the application for its authorization has not been rejected; and
(c) detection methods are publicly available.

(2) In order to establish that the presence of this material is adventitious or technically unavoidable, operators must be in a position to demonstrate to the Competent Authority that they have taken appropriate steps to avoid the presence of such materials.

48. Food/feed aid

(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 food aid into Swaziland shall be responsible for creating awareness among users/ consumers on the handling of such food products.

CHAPTER 3

PART VII

GMOS FOR RELEASE INTO THE ENVIRONMENT

49. Exemption

(1) This Part shall not apply to a medicinal substance or a compound for human use, which consists of, or contains, a genetically modified organism.

50. Prohibition

(1) No person shall release a genetically modified organism for purposes other than placing on the market unless 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 regulation 50 (1) commits an offence and shall be liable, on conviction to a fine not exceeding 200 000.00 Emalangeni or a term of imprisonment not exceeding 2 years or both.

51. Application to make an environmental release

(1) An application for environmental release shall be in the form set out in the First Schedule to these Regulations and shall be accompanied by-

(a) a technical dossier on the proposed environmental release containing the information specified in the Sixth Schedule;

(b) an environmental risk assessment and in accordance with the Sixth Schedule, and

(c) the conclusions arrived at by the applicant in accordance with Part D of the Sixth Schedule, together with any bibliographic references and details of the methods used; and

(d) 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 that 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) 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.

52. Advertisement of application to make an environmental release

(1) Every applicant of a proposed environmental release for purposes other than placing on the market shall, not more than 14 days after the date of receipt by the Competent Authority of the application, cause to be published in a newspaper circulating in the area 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) the fact that any person or body may, within the period of 28 days beginning on the day of publication of the notice, make Notifications in writing to the Competent Authority regarding the application; and shall send a copy of the notice to the Competent Authority within the said 28 days.

(2) The information on the location of the proposed environmental release shall be the same as the information on its location which is placed on the register maintained by the Competent Authority and for that purpose the applicant shall ascertain from the Competent Authority the information on the location which is to be or has been placed on the said register.

(3) The applicant shall, not more than 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.

53. Objections/Public Comments

(1) Upon request, the Competent Authority shall make available to any person portions of any application subject to recognition of confidential information as provided for in Section 14 of the Act for purposes of public analysis.

(2) Any person may, within the period of 21 days beginning from the date of the last publication, make written objections and/or comments to the Competent Authority in relation to the application.

(3) The Competent Authority shall, within 3 days from date of receipt, forward such objections and/or comments to the Applicant for appropriate attendance and response.

(4) The Applicant shall make the necessary responses and forward them to the Competent Authority within 5 days. The comments shall also be made available to the person who submitted the comments/objection.

54. Modification of application or new information before decision

(1) An applicant may modify an application before the Competent Authority makes a final decision:

(a) Where there is a modification of the proposed environmental release, or new information relevant to the proposed environmental release becomes available; and

(b) which could have consequences for the risks to human health or the environment.

(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 environmental release.

55. Procedure after receipt of application

(1) On receipt of an application the Competent Authority shall:

(a) acknowledge in writing, receipt of the application;

(b) examine it for compliance with these Regulations;

(c) forward to the National Biosafety Advisory Committee within 14 days of the receipt of the application, a copy of the application received;

(d) through the National Biosafety Advisory Committee, having regard to the Sixth Schedule, cause the undertaking of an environmental risk assessment at the cost of the applicant;

(e) consider any observations received from the Competent Authority and/or from the public with regard to the application;

(f) evaluate the risks posed by the proposed environmental release for human health or the environment, and

(g) record its conclusions in writing.

(2) The Competent Authority shall respond in writing to the applicant within 270 days of receipt of the application by indicating that authorization to the environmental release is either:

(a) granted, with or without, conditions, or

(b) refused and the reasons for the refusal

56. Power to request further information.

(1) The Competent Authority may request the applicant to provide further information on the proposed environmental release.

(2) Where the Competent Authority requests further information, it shall give its reasons in writing for so doing.

(3) Notwithstanding any other provision of this Part, where the Competent Authority makes a request for further information, the applicant shall not make the environmental release unless following a response to the request from the applicant, the Competent Authority has granted an authorization in accordance with these Regulations and any conditions attached to the authorization have been complied with.

57. Modification of release after authorization

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

(2) Where the Competent Authority receives an amended application the Competent Authority shall deal with the amended application as if it were a new application in relation to the proposed modified environmental release.

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

If, after 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 consequences for the risks to human health or the environment, the person granted the authorization shall:

(1) immediately take the measures necessary to protect human health and the environment;
(2) inform the Competent Authority as soon as the unintended change is known or the new information becomes available; and
(3) 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.

59 Power to modify, suspend or terminate the Authorization

(1) If, after granting an authorization in writing to make an environmental release 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,

It may, following an evaluation of the matters concerned, require the person granted the authorization to modify the conditions of, suspend or terminate the environmental release.

(2) Once the Competent Authority has suspended an environmental release, a person granted an authorization shall ensure that the necessary conditions are complied with before the resumption of the release.

60 Communication of decision to suspend an authorization

(1) The Competent Authority shall, within 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

(2) The Competent Authority shall, within 14 days of the notice, suspend or terminate the environmental release and shall inform in writing:
(a) the person to whom the authorization had been granted;
(b) the public.

61 Post-release procedures

(1) A person granted an authorization under these Regulations shall at any subsequent intervals specified in the Authorization; submit a report to the Competent Authority on the results of the environmental release.

(2) The report shall be in such format as may be specified in the Authorization, and shall include:
(a) post-release evaluation of the risks to human health or the environment, and
(b) where appropriate, a statement on the results of the environmental release in relation to any product, or type of product, in respect of which an authorization for placing on the market may be sought.

PART VIII

PLACING ON THE MARKET OF PRODUCTS CONTAINING OR CONSISTING OF GENETICALLY MODIFIED ORGANISMS/INGREDIENTS

(62) Prohibition

(1) No person shall place on the market any product containing or consisting of a genetically modified organism/ingredients without a written authorization granted by the Competent Authority and the conditions attached to the authorization have been complied with.

(2) A person who contravenes Regulation 62(1) commits an offence and shall be liable on conviction to a fine not exceeding 200 000.00 Emalangeni or a term of imprisonment not exceeding 2 years or both.

(63) Mandatory requirements

Notwithstanding any other provision of this Part, an authorization under this Part shall specify at least:
(a) the scope of the authorization, including the identity of any genetically modified organism to which the authorization refers and the unique identifier of the genetically modified organism/ingredients concerned;
(b) the period of validity of the authorization;

(c) conditions under which the product may be placed on the market, including any specific condition of use, handling and packaging and conditions for the protection of ecosystems, environments or geographical areas;

(d) a requirement, on the applicant to make control samples available to the Competent Authority on request,

(e) labelling requirements, in accordance with these Regulations, clearly stating the presence of a genetically modified organism/ingredients and including, either on a label or in a document accompanying the product, the words, "This product contains genetically modified organisms/ingredients" and the name and address of the operator in Swaziland who is responsible for the placing on the market;

(f) monitoring requirements in accordance with these Regulations, including the time period of the monitoring plan, an obligation to report on the monitoring to the Competent Authority and, where appropriate, obligations on a person selling the product or any user of it, which may include an obligation to provide information at an appropriate level on the location at which the genetically modified organism/ingredients concerned is grown.

64. Power to restrict or prohibit use or placing on market

(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, the Competent Authority may by notice in writing to the person granted the authorization, restrict or prohibit the use, or placing on the market, of the genetically modified organism.

(2) 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.

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

65. Placing on the Market for the First Time

(1) A person wishing to place a product containing a genetically modified organism/ingredients on the market for the first time shall, apply for an authorization to the Competent Authority, in writing.

(2) An application to place a genetically modified organism in the market for the first time in the country shall be in the Form set out in the First Schedule where appropriate and Seventh Schedule and shall be accompanied by the prescribed fee.

(3) Every applicant shall, not more than 14 days after the date of receipt of the application by the Competent Authority, cause to be published in a newspaper of nationwide circulation, a notice of its proposal to place on the market a product containing or consisting of a genetically modified organism and shall send a copy of the notice to the Competent Authority within the said 14 days.

(4) A notice under sub-regulation (3) shall have the heading, "PROPOSED PLACING ON THE MARKET OF A PRODUCT CONTAINING OF A GENETICALLY MODIFIED ORGANISM" and shall contain the following information

(a) the name and address of the applicant;
(b) the description of the genetically modified organism concerned,
(c) the proof that an application has been submitted to the Competent Authority,
(d) the fact that further information on the proposed placing on the market may be obtained from the Competent Authority,
(e) the full title of the Competent Authority and the full postal address of its headquarters,
(f) the fact that any person or body may make Notifications in writing to the Competent Authority regarding the application within the period of 30 days.

66 Contents of an application

(1) An application to place on the market a genetically modified organism for the first time shall include either the following:

(a) the information specified in the First Schedule, insofar as that Schedule is appropriate to the particular placing on the market;
(b) the information specified in the Seventh Schedule;
(c) information on data and results obtained from any previous release of the organism or of organisms of the same description, which has been carried out by the applicant and such information from any previous application in connection with a release of the organism or of organisms of the same description, which the applicant has made to the Competent Authority in accordance with these Regulations;
(d) an environmental risk assessment in accordance with the Sixth Schedule;
(e) the conclusions arrived at by the applicant in accordance with Part D of the Sixth Schedule, together with any bibliographic references and details of the methods used;
(f) conditions for the placing on the market of the product, including specific conditions of use and handling;
(g) a proposed period of validity of the authorization not exceeding 10 years;

(h) a plan for monitoring in accordance with the First Schedule, including a proposal for a time-period for the monitoring plan (which may vary from the proposed period of validity of the authorization),
(i) a proposal for labelling in accordance with these Regulations, and
(j) a proposal for packaging in accordance with these Regulations.

(2) The applicant may, in making an application:

(a) 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;
(b) provide relevant information, additional to that required under these Regulations.

(3) The information provided by the applicant pursuant to these Regulations shall take into account the diversity of sites of use of the genetically modified organism concerned and shall include information obtained from research and development releases concerning the impact of the release on human health and the environment.

67. Modification of application prior to the decision

(1) If, after the receipt of an application but before the making of a decision to place on the market there is a modification of the proposed placing on the market, or new information relevant to the proposed placing on the market becomes available, which could have consequences for the risks to human health or the environment, the applicant 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 placing on the market.

68 Duty of the Competent Authority after receipt of Application

(1) On receipt of an application the Competent Authority shall:
(a) acknowledge in writing, to the applicant, the date of such receipt;
(b) immediately forward a copy of the application to the National Biosafety Advisory Committee for the purposes of the committee undertaking a risk assessment in accordance with these Regulations;
(c) without delay examine it for compliance with the other relevant provisions of these Regulations;

(d) having regard to the First Schedule, decide whether the environmental risk assessment carried out by the applicant pursuant to these Regulations is appropriate; and

(e) ask the applicant in writing for any further information, which the Competent Authority considers necessary, stating its reasons for so doing.

(2) Once it is satisfied that the requirements of the relevant provisions have been complied with, the Competent Authority shall:

(a) prepare, an assessment report, which shall indicate whether:

(i) the genetically modified organism concerned should be placed on the market and under which conditions (herein after referred to as a "favourable assessment"); or

(ii) the genetically modified organism concerned should not be placed on the market (herein after referred to as an "unfavourable assessment"), and

(iii) send a copy of the assessment report to the applicant.

69 Decision on the Application

(1) The Competent Authority shall grant an authorization to the applicant to place the product on the market where it has concluded a favourable assessment of the proposal within two hundred and seventy days.

(2) The Competent Authority shall, where it has concluded an unfavourable assessment, inform the applicant that authorization is denied and stating the reasons for such decision.

(3) Every decision shall be communicated by the Competent Authority in writing.

70 Limitation on authorization

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

71 Submission of renewal application

A person seeking to renew an authorization shall submit an application to the Competent Authority no later than 9 months before the expiry of the authorization that it is proposed to have renewed.

72 Information to be contained in a renewal application

A renewal application shall include:

(a) a copy of the authorization granted by the Competent Authority to the product being placed on the market and of any renewed authorization,

(b) a report on the monitoring carried out of the authorization or renewed authorization;

(c) any new information that has become available with regard to the risks of the product to human health or to the environment, and

(d) any proposals the applicant considers appropriate for the amendment of, or measures additional to, the conditions contained in the authorization, including conditions relating to future monitoring and time limitation of the authorization.

73 Limitation on renewal of authorization

The Competent Authority shall renew an authorization for a period not exceeding 10 years beginning on the date on which the renewal of the authorization is issued.

CHAPTER 4

PART IX

IMPORT, EXPORT AND TRANSIT OF GMOs

74 Application and authorization for import of GMOs

(1) Any person who intends to import a genetically modified organism or a product of a genetically modified organism shall ensure that the advance informed agreement is issued.

(2) The presentation of the advance informed agreement by the Competent Authority does not in any manner absolve the exporter from complying with any other provision of these Regulations regarding import, handling and intentional release and placing on the market of the genetically modified organism.

(3) No person shall import genetically modified organisms without an authorization by the Competent Authority.

(4) An application to import a genetically modified organism shall be in the form set out in the Eight Schedule to these Regulations and shall be accompanied by:
(a) a cover letter; and
(b) an application fee of prescribed in the 8th Schedule.

(5) An application under Regulation 4 shall specify-
(a) the species or identity and amount of the genetically modified organism proposed to be imported; and
(b) the proposed boarder post of entry into Swaziland;
(c) the intended purpose for the genetically modified organism; and
(d)a risk assessment report.

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

A person who contravenes this Regulation commits an offence and shall be liable, on conviction to a fine not exceeding 100 000.00 or a term of imprisonment not less than 2 years.

75. Unauthorized importation.

(1) In the event of an import of a genetically modified organism for which no authorization has been granted, the Competent Authority:

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

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

76. Transportation of GMOs for, export

(1) Any 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) An exporter shall not be authorized for the re-export of a genetically modified organism or 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 a 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 a product of a genetically modified organism.

77. No export of banned GMOs or their product

(1) The Competent Authority shall not authorize the import or export of GMOs or their products that are banned by the laws of the exporting or as the case may be, importing country.

78. Transporting GMO

(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) No cage or container shall be used for transportation of genetically modified organisms unless it is approved by the Competent Authority.

79. Measures to be taken during transportation

A person transporting GMOs shall, during the transportation take the measures to ensure that no damage and/or dispersal of the contents including ensuring that;

(a) the GMOs are put in an unbreakable locking 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;

(d) accounting procedure is set up to ensure that the number of containers exported are the same upon delivery.

80. Transportation within institutions

(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.

81. Transportation of micro-organism

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.

82. Procedure regarding GMOs in transit

(1) The transit operations of GMOs and their products through the national territory, destined to other countries in the Region, shall observe the following requirements:

(a) to submit to the Competent Authority the request for transit authorization ;

(b) to produce the import authorization issued by the country of destination with the expected dates for the trans-boundary movements of GMOs and their products;

(c) to produce the term of responsibility for reception issued by the country of destination or the country through which the products will move across.

(2) Following the evaluation and authorization of the documents referred to in the paragraph 1 of this regulation, the Competent Authority shall issue a transit permit for transit through the national territory prior to the departure of the consignment from the country of origin and within a maximum time limit of forty-five days, starting from the date of the submission of the request.

(3) All shipments containing GMOs and their products should be properly sealed and packed.

(4) The applicant shall present the transit certificate, whenever it is requested.

83. Conditions for transit.

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

(2) An approval to transit shall include:

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

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

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

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

84. Unauthorized transit.

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

(a) confiscate the genetically modified organism;

(b) destroy the genetically modified organism; or

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

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

(2) A person who contravenes this Regulation commits an offence and shall be liable, on conviction to a fine not exceeding 100 000.00 or a term of imprisonment not less than 2 years.

85. ***Unintentional release while on transit.***

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

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

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

(i) the circumstances of the accident;

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

(iii) the type of accident; and

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

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

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

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

CHAPTER 4

PART VI

LIABILITY AND REDRESS ON DAMAGE CAUSED BY ACTIVITIES OF GMO

86. Strict liability

(1) An operator shall be strictly liable for any harm, injury or loss caused directly or indirectly by such GMO or products thereof or any activity in relation to them.

(2) The harm, injury or loss includes personal injury, damage to property, financial loss and damage to the environment or to biological diversity as well as taking into account socio-economic, cultural and ethical concern.

(3) In case of harm to the environment or biological diversity compensation shall include the costs of reinstatement, rehabilitation or clean-up measures which actually are being incurred and, where applicable, the costs of preventive measures.

87. Extent of liability of environmental damage

In the case of harm to the environment or to biological diversity, redress shall include the costs of re-instatement, rehabilitation or clean-up measures actually incurred or to be incurred and, where applicable, the costs of preventative measures and any loss or damage caused by the taking of preventative measures;

a. provided that the operator shall be required to carry out the reinstatement or
b. rehabilitation at its own cost and to the satisfaction of the competent authority.

88. Liability for socio-economic damage

Liability shall also extend to harm or damage caused directly or indirectly by the GMOs or products thereof to the economy, social or cultural practices, livelihoods, indigenous knowledge systems or indigenous technologies. Such harm shall include *inter alia*: disruption or damage to production systems, agricultural systems, reduction in yields and damage to the economy of any area or community.

90. Gain payable as damages

The court may also summarily enquire into and assess the monetary value of any advantage gained or likely to be gained by such person in consequence of that offence, and, in addition to any other punishment imposed in respect of that offence, the court may order the award of damages, compensation or a fine equal to the amount so assessed.

91. Insurance

(1) An applicant for a permit or authorization under these regulations shall satisfy the Competent Authority that he has subscribed to an insurance policy covering the risks that may arise out of the activity for which the permit or licence is required.

(2) An applicant shall, upon written instructions by the Competent Authority, subscribe to an insurance policy to cover risks caused by that GMO or GMO products thereof.

92. Time based limits

The right to bring any action to redress the harm caused by the GMOs or products thereof shall lapse only after a reasonable period from date on which the affected person or community could reasonably be expected to have learned of the harm, taking due account of:

(a) The time the harm may take to manifest itself; and

(b) The time that it may reasonably take to co-relate the harm with the GMOs or products thereof, having regard to the situation or circumstance of the person or community affected.

93. Defences

(a) It shall not be a defence to any claim for compensation or damage that the activity had been consented to by the competent authority.

(b) An operator who alleges and proves that damage was resultant from an act of God or *force majeure* may be exempt from liability for damage caused by GMOs or products thereof, provided his insurance shall be used for any response measures to avert any damage or potential damage to the environment and human health.

94. *Costs*

After convicting an operator(s), the court may, upon application by the Director of Public Prosecutions or any other state organ, order such operator(s) to pay the reasonable costs incurred concerning the investigation and prosecution of the offence.

Chapter 5

Part X

Response Measures

95. Duty of operator to report damage

(1) 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.

(2) 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.

(3) 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.

(4) 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.

(5) 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.

(6) 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.

(7) 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.

(8) 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.

CHAPTER 6

PART XI

ENFORCEMENT

96. Enforceability of judgements

(1) Orders and decisions of the Competent Authority shall have the same force and effect and be executable in the same manner as if they had been given in the High Court.

(2) Whenever any person is convicted of an offence under these Regulations and it appears that such person has by that offence caused loss or damage, including the cost incurred or likely to be incurred by any organ of state in rehabilitating the environment or preventing damage to the environment, the court may in the same proceedings at the written request of the Minister or other organ of state and in the presence of the convicted person, ascertain the amount of the loss or damage so caused.

(3) the court may also summarily enquire into and assess the monetary value of any advantage gained or likely to be gained by such person in consequence of that offence, and, in addition to any other punishment imposed in respect of that offence, the court may order the award of damages, compensation or a fine equal to the amount so assessed.

(4) The court may, upon application by any person who is interested on the subject matter of the case order such person to pay the reasonable costs incurred by the director of public prosecutions and the organ of state concerned in the investigation and prosecution of the offence.

98. Revocation, cancellation of permits

The Competent Authority may revoke, cancel or withdraw a permit where it has a reason to believe that the authorized activity is likely to cause adverse effect to human health or the environment or that the conditions of issue has been violated.

99. ***Interdicts***

The High Court may, on the application of the Competent Authority, by order, prohibit or restrict any activity involving an environmental release or placing on the market where the Court is satisfied that the commencement or continuation of the activity would:

(a) constitute a contravention of these Regulations; or

(b) pose a real and substantial danger to human health or the environment.

100. Orders in terms of Environment Management Act, 2002

(1) Where any matter is not adequately addressed or at the discretion of the Competent Authority are necessary to be employed for purposes of effecting compliance with these Regulations, the Competent Authority may exercise any of the administrative orders as provided for by the Environment Management Act, 2002.

(2) Such orders shall have the effect as orders of the High Court.

PART XII

MISCELLANEOUS

101. Co-existence

(1) A person who cultivates any genetically modified crop shall prevent any contamination or commingling of the genetically modified crop with any non-genetically modified crop.

(2) A person who keeps or owns genetically modified livestock shall prevent any cross - breeding between genetically modified and non-genetically modified livestock.

(3) Any person who contravenes subsections 101 (1) or 101 (2) commits an offence and is liable upon conviction to a fine not exceeding 200 000.00 Emalangeni or to imprisonment for a term not exceeding 2 years, or to both.

(4) In addition to any penalty that may be imposed under subsection 100(3), any person(s) responsible for the contamination or commingling of genetically modified crop with any non-genetically modified crop or cross-breeding between genetically modified livestock with non-genetically modified livestock shall compensate the person(s) whose crop has been contaminated or livestock crossbred as the case may be.

(5) The Minister may, by statutory instrument, provide for—

(a) the management measures to ensure non-contamination of non-genetically modified crops by genetically modified crops;

(b) the measures to be taken during cultivation, harvesting, transportation, storage and processing of any genetically modified crop;

(c) the prevention and management of any accidental mixing of any genetically modified crop with non-genetically modified crop;

(d) the prevention of cross pollination and commingling between any genetically modified crop and non-genetically modified crop;

(e) appropriate segregation, certification, identification and labelling practices and measures;

(f) the restriction of cultivation of a certain type of crop in any area;

(g) the skill and qualifications of persons involved in the cultivation, storage, handling, harvesting, transportation and processing of any genetically modified crop; and

(h) generally, the co-existence of any farming practices and systems.

(6) The regulations made under subsection 101 (4) and 101 (5) may make provision for measures specific to different types of crop, taking into account any local or national factors.

(7) Subsections 101(4) and 101(5) apply with necessary modifications to livestock.

102. Insurance

(1) An applicant for a permit or licence under regulations shall satisfy the Competent Authority that he has subscribed to an insurance policy covering the risks likely to arise out of the activity for which the permit or licence is required.

(2) An applicant shall, upon written instructions by the Competent Authority, subscribe to an insurance policy to cover risks caused by that GMO or GMO products thereof.

103. Unintentional release and emergency measures

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.

104. Notification of accident

(1) The operator shall inform the Registrar of any accident immediately and provide the following information:

(a) the circumstances of the accident;

(b) the identity and quantity of the GMOs or products thereof released;

(c) any measures necessary to assess the effects of the accident on the environment, biological diversity and human and animal health as well as taking into account socio-economic, cultural and ethical concern; and

(d) the emergency measures taken or intended to be taken.

105. Guidelines and manuals

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.

106. Amendment of schedules

The Schedules to these regulations may be amended by the Minister as may be necessary through a Government Gazette.

PART XIII

FEES AND PENALTIES

107. Fees

(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 Ninth Schedule

(2) The amounts paid by the applicant shall not be reimbursable 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.

108. Breaches and fines

(1) Under the present Regulation and without prejudice to what is stipulated in specific legislation, the following acts constitute breaches:

(a) the import and placing on the marketing of GMOs and their products destined for food, feed or processing without an authorization from the Competent Authority;

(b) the handling, manipulation, production and possession of GMOs and their products without authorization from the Competent Authority;

(c) the execution of field experiments with GMOs and its products without an authorisation from the Competent Authority;

(d) to provide false declarations or biased information;

(e) the obstruction of the work of the inspectors

(f) the lack of labelling and correct identification of products containing GMOs;

(g) the failure to report to the competent authority about any accident involving GMOs that have occurred;

(h) The utilisation of GMOs for purposes different from what was indicated in the import authorization;

(i) The introduction of GMOs and their products in the country through an entry point different from what was stipulated in the import authorization.

(2) Any infringement under the paragraph 107(1) of present regulation shall be punished through a fine as determined in the Tenth Schedule and it shall imply the refusal of entry and subsequent returning of the imported products to the country of origin, or its seizure and subsequent destruction by the State.

(3) The violator shall be liable for meeting the financial costs resulting from the measures taken to redress the infringement.

(4) The fines charged under the present Regulation shall be calculated according to the table contained in the Tenth Schedule.

(5) Where a person violated these Regulations, fines can be payable on demand by the Competent Authority within a specified period (not exceeding 21 working days). Failure to pay despite demand shall lead to subsequent court process.

SCHEDULES

FIRST SCHEDULE

I. INFORMATION REQUIRED FOR THE APPLICATION

A. General information

1. Name and address of the applicant include contact details

Postal and physical address

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.

C. Insurance Information

II. INFORMATION RELATING TO THE GENETICALLY MODIFIED ORGANISM(S) OR PRODUCTS THERE OF

A. Characteristics of the donor/ the recipient; or parental organism(s) (where appropriate);

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 seasonability 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;

(d) Presence of genes, which confer resistance.

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 down stream 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 down stream 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) allergenecity;

(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 INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GENETICALLY MODIFIED ORGANISM(S) OR PRODUCTS THERE-OF 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.

3. Genetic transfer capability:

(a) post-release transfer of genetic material from genetically modified organism (s) or products thereof into organisms in affected ecosystems;

(b) post-release transfer of genetic material from indigenous organisms to the genetically modified organism (s) or products thereof;

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.

V. 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 and disposal

1. Type of waste generated;

2. Expected amount of waste;

3. Possible risks;

4. Description of treatment envisaged.

5. Waste disposal

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.

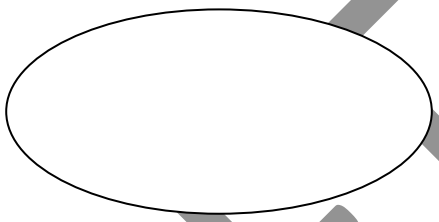
5. Plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

SECOND SCHEDULE

CHECK LIST NOTIFICATION FORM FOR AUTHORIZATION FOR CONTAINED 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 genetically modified organism in the State of export.	
4. Intended date or dates of the transboundary movement, if k	
5. Taxonomic status, common name, point of collection or acqui organisms related to biosafety.	
6. Centres of origin and centres of genetic diversity, if known, of th of the habitats where the organisms may persist or proliferate.	
7. Taxonomic status, common name, point of collection or acquisition 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 produc modified organism origin, containing detectable novel combina modern biotechnology.	
10. Quantity or volume of the genetically modified organism to be	
11. Is there previous and existing risk assessment report conduc whether you have annexed and marked it as such.	
12. Proposed methods for the safe handling, storage, transport and contingency procedures, where appropriate.	
13. Regulatory status of the genetically modified organism within banned or restricted and the reasons for its decision.	

14. Result and purpose of any notification by the exporter to o transferred.	
15. Have you annexed a declaration that the above-mentioned info	
16. Have you indicated on written annex herein information that you co	
Additional comments which should be considered by NBAC:	
Applicant's Signature	**Date of submission**



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Registrar's Stamp on date of receipt of notification Signature

THIRD SCHEDULE

PRINCIPLES TO BE FOLLOWED FOR THE RISK ASSESSMENT REFERRED TO IN REGULATION 8

This Schedule describes in general terms the elements to be considered and the procedure to be followed in carrying out the risk assessment referred to in Regulation 8.

A. ELEMENTS OF THE ASSESSMENT

1. The following shall be considered as potentially harmful effects:

    (a) disease to humans, including allergenic or toxic effects;

    (b) disease to animals or plants;

    (c) deleterious effects due to the impossibility of treating a disease or providing an effective prophylaxis;

    (d) deleterious effects due to establishment or dissemination of the micro- organism in the environment;

    (e) deleterious effects due to the natural transfer of inserted genetic material to other organisms.

2. The risk assessment shall be based on the following:

    (a) The identification of any potentially harmful effects, in particular those associated with:

        (i) the recipient organism,

        (ii) the genetic material inserted (originating from the donor organism),

        (iii) the vector,

        (iv) the donor micro-organism (where the donor micro-organism is used during the activity),

        (iv) the resulting genetically modified organism,

    (b) The characteristics of the activity,

    (c) The severity of the potentially harmful effects, and

    (d) The likelihood of the potentially harmful effects being realised.

B PROCEDURE

3. The assessment shall involve:

(a) identification of any harmful properties of the recipient and, where appropriate, the donor micro-organism;

(b) identification of any harmful properties associated with the vector or inserted material, including any alteration in the recipient's existing properties;

(c) identification of the level of risk associated with the genetically modified micro-organism;

(d) identification of the appropriate containment measures from those specified in the applicable Table in Part B of the Fourth Schedule, on the basis of the level of risk identified and taking into consideration:

(i) the characteristics of the environment likely to be exposed (e.g. whether, in the environment likely to be exposed to the genetically modified micro-organism, there are known biota which could be adversely affected by the micro-organism),

(ii) the characteristics of the activity (e.g. its scale, nature),

(iii) any non-standard operations (e.g. the inoculation of animals with genetically modified micro-organisms, use of equipment likely to generate aerosols),

(e) in the light of the outcome of the procedures specified in paragraph (d), review and, where necessary, adjustment of the level of risk identified

(f) classification of the contained use into one of the classes specified under these Regulations;

(g) review and confirmation of the classification in the light of the completed assessment.

FOURTH SCHEDULE

Regulation 10

A. GENERAL PRINCIPLES OF GOOD PRACTICE AND GOOD OCCUPATIONAL SAFETY AND HYGIENE

For the purposes of these Regulations, principles of good practice and good occupational safety and hygiene practice shall include-

(i) keeping the workplace and environmental exposure to any genetically modified micro-organism to the lowest practicable level;

(ii) exercising engineering control measures at source and, where necessary, supplementing these with appropriate personal protective clothing and equipment;

(iii) testing and maintaining control measures and equipment;

(iv) testing, where necessary, for the presence of viable process organisms outside the primary physical containment;

(v) providing appropriate training of personnel;

(vi) establishing biological safety committees or subcommittees, where required;

(vii) formulating and implementing local codes of practice for the safety of personnel, where required;

(viii) where appropriate, displaying biohazard signs;

(ix) providing washing and decontamination facilities for personnel;

(x) keeping adequate records, prohibiting eating, drinking, smoking, applying cosmetics or the storing of food for human consumption in the work area,

(xii) prohibiting mouth-pipetting;

(xiii) where appropriate, providing written standard operating procedures to ensure safety;

(xiv) having effective disinfectants and specified disinfection procedures available in case of spillage of genetically modified micro-organisms; and

(xv) where appropriate, providing safe storage for contaminated laboratory equipment and materials.

B. 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 measures are laid down.

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

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

CONTAINMENT MEASURES AND LEVELS

The following tables specify the minimum requirements and measures for each level of containment.

The title of each table is indicative:

- table IA specifies minimum requirements for a contained use carried out in a laboratory;

- table IB specifies additions to, and modifications of, table IA for the purpose of a contained use carried out in a plant growth facility;

- table IC specifies additions to, and modifications of, table IA for the purpose of a contained use involving animals and carried out in an animal unit, and

- table 1D specifies minimum requirements for a contained use in a facility other than a facility covered by tables IA, IB or IC.

For the purposes of the tables, “optional” means that the Directorate may, in the case of any individual contained use, on foot of a application or otherwise at the request of the user, having regard to the risk assessment carried out and the class of the contained use identified, decide whether the relevant containment measures specified for the said class in the appropriate table or tables, as the case may be, shall be applied.

Where necessary, a combination of measures from table IA and table II, of the same level, shall be applied.

At the request of the user, the Directorate may, having regard to the assessment carried out in accordance with article 13, in relation to the individual contained use –

(a) accept that the application of a particular measure specified under a particular level of containment is not necessary, or
(b) accept the application of measures from different 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 environment	Not required	Not required	Required	Required
6	Extract and input air from the laboratory should be HEPA–filtered	Not required	Not required	Required	Required for input
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	Suitable protective	Suitable protective	Complete change of clothing and

		clothing	clothing; footwear optional	clothing and footwear	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 modified organisms in contaminated material and waste	Optional	Required	Required	Required
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

For the purposes of this Table:

(1) In measure 1, “isolation” means that the laboratory is separated from other areas in the same building or is in a separate building.

(2) In measure 4, “airlock” means that entry must be made through a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities, or by interlocking doors.

(3) In measure 5, “negative pressure relative to the pressure of the immediate environment” is only required for a class 3 contained use where airborne transmission can occur.

(4) “HEPA” means high efficiency particulate air.

(5) In measure 6, where viruses which are not capable of being retained by HEPA filters are used in a class 4 contained use, extra requirements shall be provided for extract air.

(6) In measure 8, “en suite” means that where the autoclave is located outside the laboratory in which the contained use is being carried out but within the laboratory suite, validated procedures shall be in place to ensure the safe transfer of material into the autoclave and to provide a level of protection equivalent to that which would be achieved if the autoclave were in the laboratory.

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 control	Required to minimise dissemination	Required to minimise dissemination	Required to prevent dissemination	Required to prevent dissemination

	dissemination of genetically modified micro-organisms				

For the purposes of this Table:

(1) In measure 1, a permanent structure means a fixed structure with walls, a roof and a floor, designed and used principally for growing plants in a controlled and protected environment. Where the permanent structure is a greenhouse, it shall also have a continuous waterproofed covering and self-closing lockable outer doors, and be located on a site graded to prevent entry of surface-water run-off.

(2) In measure 3, control of contaminated run-off water is only required for containment level 2 where transmission can occur through the ground.

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

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

For the purposes of this Table:

(1) In measure 1, an "animal unit" means a building or separate area within a building, containing an animal facility and other areas such as changing rooms, showers, autoclaves and food storage areas.

(2) In measures 2 and 3, an "animal facility" means a facility normally used to house stock, breeding or experimental animals, or one which is used for the performance of minor surgical procedures.

(3) In measure 3, "designed to facilitate decontamination" includes the use of waterproof and easily washable material.

(4) In measure 5, the keeping of animals in "appropriate containment facilities" includes cages, pens and tanks.

(5) In measure 6, "isolators" means transparent boxes where small animals are contained within or outside a cage.

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 s closed system	Optional	Required	Required	Required
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	Optional	Required, by va	Required, by va	Required, by va
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 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

For the purposes of this Table:

(1) In measure 8, “airlock” has the same meaning at that provided for the purposes of measure 4 in Table 1A.

CHECKLIST FOR CONTAINMENT INSPECTION MEASURES IN DIFFERENT LEVELS (L1,L2;L3,L4): – 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	Floor to wall, wall to ceiling and wall to wall junctions should be rounded for easy cleaning	yes	yes	yes	yes
6	All joints between door frames and wall should be sealed	yes	yes	yes	yes
7	Animal facilities have to be cleaned regularly. Sinks have to be disinfected regularly.	no	yes	yes	yes
8	Surfaces have to be disinfected after work	no	yes	yes	yes
9	Used cages have to be decontaminated	yes	yes	yes	yes
10	Material to be sterilised or incinerated as well as used cages have to be transported so that the environment is not contaminated	yes	yes	yes	yes
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	yes	yes	yes	yes

	through the walls or floor should prevent the ingress of rodents and insects				
19	Accidents, bites and scratches caused by animals have to be reported to the project leader who makes a written report	yes	yes	yes	yes
20	Personnel has to be trained in the handling of the animals	yes	yes	yes	yes
21	There have to be written records about the transfer of foreign 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 can	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	yes	yes	yes	yes

	material and waste should be inactivated				
35	If genetically modified organisms can be transmitted, working tools and equipment have to be sterilised	no	yes	yes	yes
36	Waste contaminated with genetically modified organisms must only be transported in suitable containers	no	yes	yes	yes
37	Genetically modified organisms must only be transported in 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 should be given to the means of removing or extracting the fumigant	no	yes	yes	yes
39	Hygiene plan	no	yes	yes	yes
40	The animal facility has to be entered via a lock equipped with two self closing doors, hand washing basin, disinfection dispenser and shower	no	no	yes	yes
41	Acceptability of windows that open	yes	yes	no	no
42	Emergency power supply for safety relevant equipment such as ventilation system	no	no	yes	yes
43	Where mechanical ventilation 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	no	no	yes	yes

	HEPA* filtration to the exterior. Alternatively, animals shall be housed in cages within ventilation units with ventilation exhausts placed behind cages.				
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, leakproofed and disinfected containers	no	no	yes	yes
49	Waste water has to be sterilised	no	no	yes	yes

*High-efficiency particle arresting

CHECKLIST FOR CONTAINMENT INSPECTION MEASURES IN DIFFERENT LEVELS (L1,L2;L3,L4): – 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	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 Dissemination	Minimise dissemination	Prevent dissemination	Prevent Dissemina-tion
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	No	Yes	N/A	N/A

	treatments should be made periodically to eliminate, or render inactive, any organisms potentially entrapped by the gravel				
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	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 available	Yes	Yes
33	The glasshouse has to be surrounded by a security fence or equal protection system	No	No	Yes	Yes

CHECKLIST FOR CONTAINMENT INSPECTION MEASURES IN DIFFERENT LEVELS (L1,L2;L3,L4): – 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	Wash hand basin or sink that can be used for hand washing with: - dispenser containing soap - dispenser containing hand disinfectant - paper towels	yes	yes	yes	yes
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					

FIFTH SCHEDULE

Regulation 10 (2)

INFORMATION REQUIRED IN THE NOTIFICATION OF A FIRST TIME USE OF PREMISES OR OF A CONTAINED USE.

PART A

Information required for applications under regulation 10:

(a) name of user, including those responsible for supervision and safety;
(b) information on the training and qualifications of the persons responsible for the activity;
(c) supervision and safety;
(d) details of any biological committees or subcommittees;
(e) address and general description of the premises;
(f) a description of the nature of the work which will be undertaken;
(g) the class of the contained use;
(h) in the case of a class 1 contained use, a summary of the Risk assessment and information on waste management.

PART B

Information required for the notification referred to in Regulation 10:
(a) date of submission of the application;
(b) the names of the persons responsible for supervision and safety and information on their training and qualifications;
(c) the recipient, donor and/or parental micro-organism(s) used and, where applicable;
(d) the host-vector system(s) used;
(e) the source(s) and the intended function(s) of the genetic material(s) involved in the modification(s);
(f) identity and characteristics of the genetically modified micro-organism;
(g) the purpose of the contained use including the expected results;
(h) approximate culture volumes to be used;
(i) 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;
(j) a summary of the risk assessment;
(k) the information necessary for the Directorate to evaluate any emergency response plans if required.

PART C

(a) Information required for application referred to in regulation 16:
(b) the date of submission of the application;
(c) the names of the persons responsible for supervision and safety and information on their training and qualifications;
(d) the recipient or parental micro-organism to be used;
(e) the host-vector system to be used (where applicable);

(f) the source and intended function of the genetic material involved in the modification,
(g) identity and characteristics of the genetically modified micro-organism;
(h) the culture volumes to be used;
(i) 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;
(j) the purpose of the contained use including the expected results;
(k) description of the parts of the premises;
(l) information about accident prevention and emergency response plans, if any;
(m) any specific hazards arising from the location of the premises;
(n) the preventive measures applied such as safety equipment, alarm systems and
(o) containment methods;
(p) procedures and plans for verifying the continuing effectiveness of the containment measures,
(q) a description of information provided to workers;
(r) the information necessary for the competent authority to evaluate any emergency
(s) response plans if requires; and
(t) a copy of the risk assessment

PART D

APPLICATION FORM FOR CONFINED FIELD TRIAL (PLANTS)

This application form must be completed for each individual genetically modified plant. The application may include more than one submission of a genetic modification of that particular species, Trial site Location and/or Trial Protocol. Complete section 2 for each submission, section 3 for each trial site and section 4 for each trial protocol included in the application. All sections must be completed. Additional pages can be attached if the space provided is not sufficient.

Applications for new and renewal of previously authorized confined research field trials should be submitted separately.

Section 1.0 General Information

<table>
<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></td><td>(Indicate if perennials, annuals, trees etc.)</td></tr>
</table>

1.3 Feed Section

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

Yes □

No □

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

1.6 Summary of trial

1.6.1 Brief Description of Proposed Trial

1.6.2 Objective

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

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

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

1.6.6 Summary of the risk assessment
1.7 Description of unmodified plant species
1.7.1 Describe mechanisms and frequency of intra-and inter-specific out-crossing.
1.7.2 Describe the mechanism of infertility
1.8 Phenotypic Characteristics Provide information on plant mechanisms responsible for:
1.8.1 Tendency to weediness
1.8.2 Allelopathy
1.8.3 Dormancy
1.8.4 Pollen dispersal
1.8.5 Seed dispersal
1.8.6 Vegetative dispersal
1.8.7 Other dispersal
1.8.8 Other Characteristics
1.9 Toxins
1.9.1 List any known toxins from this species, including natural defence compounds.

1.9.2 Indicate the levels at which these compounds induce toxicity.
1.9.3 Indicate the species affected by these toxins.
1.10 Allergens
1.10.1 List any known allergens for this species, including natural defence compounds.
1.11 Describe any pathological, ecological and physiological traits that relate to the genetically modified organism but not to the unmodified plant.

Section 2: Submission
Fill out section 2 for each individual submission (genetic modification of that particular species)

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 transl 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 Allergenicity of the Transformed Trait(s)			
2.10.1 To what extent are transformed gene products toxic when ingested by native fauna populations, including mammals, birds, reptiles, and insects?			
2.10.1.1 How has this been determined?			
2.10.2 To what extent are transformed gene products allergens?			
2.10.2.1 How has this been determined			
2.11 Altered Plant Characteristics *Please indicate any changes with respect to the following:*			
2.11.1 Persistence and invasiveness			
2.11.2 Allelopathy			
2.11.3 Dormancy			
2.11.4 Pollen Dispersal			
2.11.5 Seed Dispersal			
2.11.6 Vegetative Dispersal			

2.11.7 Any other Dispersal Mechanism
2.11.8 Any other altered characteristic (s) Are any of the likely gains directly linked to losses in other characteristics of the species?
2.11.9 Please describe if any toxins and allergens are produced by the GMO that were not produced by the unmodified plant.
2.11.10 What is the frequency of reversion, i.e., loss of genetic modification?
2.11.11 How do you verify that you have the desired GMO?
2.11.12 What methods are to be used to test for batch-to-batch consistency?
2.12 Trial Site Locations and Trial Protocols

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

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

Section 3: Confined Field Trial Site

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

3.1 Town/City *(Nearest city)*	**3.2 Region**	**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	3.8.3 If yes, list

or near the site? Yes □ No □	
*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 Person(s) having control over the site during the post-harvest/trial land use period, including the isolation area	
3.9. 1.1 Name	3.9.1.2 Address
3.9.1.3 Telephone	3.9.1.4 Facsimile
3.9.2 Describe how the site boundaries will be marked to facilitate subsequent inspection.	
3.10 Submissions and Trial Protocols Please list all submissions and trial protocols used at this site.	
3.10.1 Submission *(genetically modified organism designation – List of possible designations/unique identifier)*	**3.10.2 Trial Protocol(s)**

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

Section 4: Confined Field Trial Protocol

Please fill out Section 4 for each Trial Protocol included in the application.

<table>
<tr><td>4.1 Trial Protocol (Study) Title:</td><td colspan="2"></td></tr>
<tr><td colspan="3">4.2 Protocol</td></tr>
<tr><td colspan="3">4.2.1 Fully describe the following</td></tr>
<tr><td colspan="3">4.2.2 Purpose of the field trial</td></tr>
<tr><td colspan="3">4.2.3 Experimental design</td></tr>
<tr><td colspan="3">4.2.4 Nature and type of data to be collected</td></tr>
<tr><td colspan="3">4.2.5 Arrangements for transporting the GMO to the trial site</td></tr>
<tr><td colspan="3">4.2.6 Proposed, if any, herbicide/pesticide use</td></tr>
<tr><td colspan="3">4.3 Provide work schedule (post approval) to include:</td></tr>
<tr><td colspan="2">4.3.1 Planting (anticipated)</td><td>4.3.2 Harvest/Sampling (anticipated)</td></tr>
<tr><td colspan="3">4.4 Isolation
State the isolation measures being implemented for this trial and give details.
.</td></tr>
<tr><td colspan="3">4.4.1 If using bags or nets, please provide the mesh size of the material being used and justify the effectiveness</td></tr>
<tr><td rowspan="2">4.5 Seeding
4.5.1 Material will be planted by:

4.5.1.1 Hand □

Or

4.5.1.2Mechanically □</td><td colspan="2">4.5.2 Will any unmodified plants of the same or a related species be planted at the trial site location?</td></tr>
<tr><td colspan="2">4.5.3 If yes, state reason</td></tr>
</table>

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 legislation*

4.7 Harvesting

4.7.1 Will plants be allowed to set seed 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	4.7.4 Material retention If yes

Yes □ No □	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 tria
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 E

APPROVAL 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*

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 consequences
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

Dated ……....……, 20....

_____

SIXTH SCHEDULE

PRINCIPLES FOR ENVIRONMENTAL RISK ASSESSMENT

This schedule describes in general terms the objective to be achieved, the elements to be considered and the general principles and methodology to be followed to perform an environmental risk assessment required by these Regulations.

With a view to contributing to a common understanding of the terms "direct, indirect, immediate and delayed" when implementing this schedule, without prejudice to further guidance in this respect and in particular as regards the extent to which indirect effects can and should be taken into account, these terms are described as follows:

'Direct effects' refers to primary effects on human health or the environment, which are a result of the genetically modified organism (hereinafter referred to as "GMO" itself and which do not occur through a causal chain of events:

'Indirect effects' refers to effects on human health or the environment occurring through a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management. Observations of indirect effects are likely to be delayed:

'Immediate effects' refers to effects on human health or the environment, which are observed during the period of the release of the GMO. Immediate effects may be direct or indirect;

'Delayed effects' refers to effects on human health or the environment, which may not be observed during the period of the release of the GMO, but become apparent as a direct or indirect effect either at a later stage or after termination of the release.

A general principle for environmental risk assessment is also that an analysis of the 'cumulative long-term effects' relevant to the release and the placing on the market is to be carried out. 'Cumulative long-term effects' refers to the accumulated effects of approvals on human health and the environment including inter alia, flora and fauna, soil fertility, soil degradation of organic material, the feed/food chain, biological diversity, animal health and resistance problems in relation to antibiotics.

A. Objective

The objective of an environmental risk assessment is, on a case by case basis, to identify and evaluate potential adverse effects of the genetically modified organisms, either direct and indirect, immediate or delayed, on human health or the environment which the environmental release or the placing on the market of genetically modified organisms may have. The environmental risk assessment should be conducted with a view to identifying if there is a need for risk management and, if so, the most appropriate methods to be used.

B. General Principles

In accordance with the precautionary principle, the following general principles should be followed when performing the environmental risk assessment;

- Identified characteristics of the GMO and its use which have the potential to cause adverse effects should be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations;
- The environmental risk assessment should be carried out in a scientifically sound and transparent manner based on available scientific and technical data;
- The environmental risk assessment should be carried out on a case by case basis meaning that the required information may vary depending on the type of the genetically modified organisms concerned, their intended use and the potential receiving environment, taking into account inter alia, genetically modified organisms already in the environment;
- If new information on the genetically modified organism and its effects on human health or the environment become available, the environmental risk assessment may need to be re-addressed in order to:
- Determine whether the risk has changed;
- Determine whether there is a need for amending the risk management accordingly.

C. Methodology

C.1. Characteristics of genetically modified organisms and releases

Depending on the case, the environmental risk assessment has to take into account the relevant technical and scientific details regarding characteristics of:

- The recipient or parental organism(s);
- The genetic modification(s), be it inclusion or deletion of genetic material, and relevant information on the vector and the donor;
- The GMO;
- The intended release or use including its scale;
- The potential receiving environment; and
- The interaction between these.

Information from releases of similar organisms with similar traits and their interaction with similar environments can assist the environmental risk assessment.

C.2. Steps in the environmental risk assessment

In drawing conclusions for the environmental risk assessment, the following points should be addressed:

1. Identification of characteristics, which may cause adverse effects:

Any characteristics of the genetically modified organisms linked to the genetic modification that may result in adverse effects on human health or the environment shall be identified. A comparison of the characteristics of the GMO(s) with those of the non-modified organism under corresponding conditions of the release or use will assist in identifying the particular potential adverse effects arising from the genetic modification.

It is important not to discount any potential adverse effect on the basis that is unlikely to occur.

Potential adverse effects of genetically modified organisms will vary from case to case and may include:

- Disease to humans including allergenic or toxic effects (see for example items II.A.11. and II.C.2 (i) in Part I of the Third Schedule, and B.7. in Part II of that Schedule);

- Disease to animals and plants including toxic, and where appropriate, allergenic effects (see for example items II.A.11. and II.C.2. (i) In Part I of the Third Schedule, and B.7. and D.8. in Part II of that Schedule);

Effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations (see for example items IV.B.8. 9 and 12 in Part I of the Third Schedule);

- Altered susceptibility to pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors;

- Compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine (see for example items II.A. 11.(e) and II.C.2.(i)(IV) in Part I of the Third Schedule);

- effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material (see for example items II.A.11.(f) and IV.B.I 5 in Part I of the Third Schedule and D.11 in Part II of that Schedule).

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

- the spread of the genetically modified organism(s) in the environment;

- the transfer of the inserted genetic material to other organisms, or the same organism whether genetically modified or not;

- phenotypic and genetic instability;

- interactions with other organisms;

- changes in management, including, where applicable, in agricultural practices.

2. Evaluation of the potential consequences of each adverse effect, if it occurs:

The magnitude of the consequences of each potential adverse effect should be evaluated.

This evaluation should assume that such an adverse effect will occur. The magnitude of the consequences is likely to be influenced by the environment into which the genetically modified organism(s) is (are) intended to be released and the manner of the release.

3. Evaluation of the likelihood of the occurrence of each identified potential adverse effect:

A major factor in evaluating the likelihood or probability of adverse effects occurring is the characteristics of the environment into which the genetically modified organism(s) is (are intended to be released, and the manner of the release.

4. Estimation of the risk posed by each identified characteristic of the genetically modified organism(s):

An estimation of the risk to human health or the environment posed by each identified characteristic of the genetically modified organism which has the potential to cause adverse effects should be made as far as possible, given the state of the art, by combining the likelihood of the adverse effect occurring and the magnitude of the consequences, if it occurs.

5. Application of management strategies for risks from the environmental release or marketing of genetically modified organism(s):

The risk assessment may identify risks that require management and how best to manage them, and a risk management strategy should be defined.

6. Determination of the overall risk of the genetically modified organism(s):

An evaluation of the overall risk of the GMO(s) should be made taking into account any risk management strategies which are proposed.

D. Conclusions on the potential environmental impact from the release or the placing on the market of genetically modified organisms

On the basis of an environmental risk assessment carried out in accordance with the principles and methodology outlined in parts B and C of this schedule, information on the points listed in parts D1 or D2 of this schedule should be included, as appropriate, in applications with a view to assisting in drawing conclusions on the potential environmental impact from the release or the placing on the market of genetically modified organisms.

D.1.In the case of genetically modified organisms other than higher plants:

1. Likelihood of the genetically modified organism to become persistent and invasive in natural habitats under the conditions of the proposed release(s).

2. Any selective advantage or disadvantage conferred to the genetically modified organism and the likelihood of this becoming realised under the conditions of the proposed release(s).

3. Potential for gene transfer to other species under conditions of the proposed release of the genetically modified organism and any selective advantage or disadvantage conferred to those species.

4. Potential immediate and/or delayed environmental impact of the direct and indirect interactions between the genetically modified organism and target organisms (if applicable).

5. Potential immediate and/or delayed environmental impact of the direct and indirect interactions between the genetically modified organism with non-target organisms including impact on population levels of competitors, prey, hosts, symbionts predators, parasites and pathogens.

6. Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the genetically modified organism and persons working with, coming into contact with or in the vicinity of the genetically modified organism release(s).

7. Possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the genetically modified organism and any product derived from it, if it is intended to be used as animal feed.

8. Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the genetically modified organism and target and non-target organisms in the vicinity of the genetically modified organism release(s).

9. Possible immediate and/or delayed, direct, and indirect environmental impacts of the specified techniques used for the management of the genetically modified organism where these are different from those used for non-genetically modified organisms.

D.2. In the case of genetically modified higher plants (hereinafter referred to as “GMHP”):

1. Likelihood of the GMHP becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats.

2. Any selective advantage or disadvantage conferred to the GMHP.

3. Potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GMHP and any selective advantage or disadvantage conferred to those plant species.

4. Potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the GMHP and target organisms, such as predators, parasitoids and pathogens (if applicable).

5. Possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens.

6. Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMHP and persons working with, coming into contact with or in the vicinity of the GMHP release(s).

7. Possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any products derived from it, if it is intended to be used as animal feed.

8. Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s).

9. Possible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs.

SEVENTH SCHEDULE

ADDITIONAL INFORMATION REQUIRED IN THE CASE OF APPLICATION FOR PLACING ON THE MARKET OF PRODUCTS CONTAINING OR CONSISTING OF GENETICALLY MODIFIED ORGANISMS

PART 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, in addition to that required pursuant to the First Schedule:

1. proposed commercial name(s) of the product and name(s) of genetically modified organisms contained therein, and any specific identification, name or code used by the applicant to identify the genetically modified organism. After any approval, any new commercial name(s) should be provided to the Competent Authority by the applicant,

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

PART B

The following information shall be provided in the application, in accordance with Regulation 30, 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.

EIGHTH SCHEDULE

Part A

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

<table>
<tr><td rowspan="2">1. Name, address (including physical address)

and contact details of the importer/exporter</td><td>Type of application (Tick as appropriate)</td></tr>
<tr><td>□Import
□ Export
□Transit</td></tr>
<tr><td>2. Contact details of the competent authority as applicable</td><td>2.1 Importing /Destination country</td></tr>
<tr><td rowspan="2"></td><td>2.1 Exporting country</td></tr>
<tr><td></td></tr>
<tr><td>3. Name, address and contact details of the supplier.</td><td>4. Country of origin</td></tr>
<tr><td></td><td>5.Expected date of import/export/ transit organism.</td></tr>
<tr><td>6. Common name, scientific name, commercial name or unique identifier code of the genetically modified organism</td><td>7. Port:
7.1 Boarder Post for Entry into Swaziland</td></tr>
<tr><td></td><td>7.2 Boarder Post for Exit from Swaziland</td></tr>
<tr><td>8. Evidence of approval of the genetically modified organism from the exporting country (Attach)</td><td>9. Consent for import from the destination country (in case of export or transit).</td></tr>
<tr><td>10. The intended use of the genetically Modified organism in Swaziland and what it was used for in the exporting country</td><td>11. The quantity of the genetically modified organism to be imported into Swaziland</td></tr>
<tr><td colspan="2">12. A summary of the risk assessment report</td></tr>
<tr><td colspan="2">13. Methods and plans for safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures.</td></tr>
<tr><td colspan="2">14. Describe the emergency response plan in Swaziland in the event of an accident with the genetically modified

organisms</td></tr>
</table>

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

Part B

APPROVAL TO IMPORT, EXPORT AND TRANSIT GENETICALLY MODIFIED ORGANISMS

<table>
<tr><td>APPROVAL NUMBER _____</td><td>DATE OF ISSUE _____
VALID UP TO _____ _____</td></tr>
<tr><td colspan="2">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.</td></tr>
<tr><td rowspan="4">1.0 Name of the Applicant</td><td>2.0 To import/export/transit from/to</td></tr>
<tr><td>2.1 Name and address of supplier:</td></tr>
<tr><td>2.2 Country of supplier:</td></tr>
<tr><td>2.3 Country of destination:</td></tr>
<tr><td>3.0 Identity of the genetically modified organism</td><td></td></tr>
<tr><td>4.0 Specification of the genetic modification</td><td></td></tr>
<tr><td>5.0 Quantity approved</td><td></td></tr>
<tr><td>6.0 Purpose</td><td></td></tr>
<tr><td colspan="2">This approval is granted subject to the following conditions-
1._____
2._____
3._____
4. _____</td></tr>
<tr><td colspan="2">7.0 The applicant should meet the following requirements for conveyor shipment
1._____
2._____
3._____
4._____</td></tr>
<tr><td rowspan="2">Name:

Signature:_____
The Executive Director
Swaziland Environment Authority</td><td>Place:</td></tr>
<tr><td>Date</td></tr>
</table>

Note:

- the applicant shall make samples available to the Authority on request
- This approval is not transferrable
- ensure that any other relevant legal requirements have been met

*** -** Please delete as appropriate

NINTH SCHEDULE

Part A

Schedule of Fees

	Service Fee	**(SZL)**
1.	Handling of general application form for importation of Genetically Modified Organisms and their products	**1200. 00**
2.	Renewal of import and exportation permit	**200.00**
3.	Handling of risk assessment form of genetically modified organisms and their products intended for direct use as for food, feed or processing	**3000. 00**
4.	Handling of risk assessment form for genetically modified organisms and their products destined for research conducted in laboratories and green houses	**3000. 00**
5.	Handling of risk assessment form for genetically modified organisms and their products destined for field trials	**3000. 00**
6.	Handling of risk assessment form for genetically modified organisms and their products destined for the deliberate release into environment	**5000. 00**
7.	Issuing of certificate of transit	**1000. 00**
8.	Permit for field trials	**1000. 00**
9.	Request for inspection at the entry points and storage and/or re-packaging sites of genetically modified organisms and their products within the country	**1000. 00**
10.	Request for authorisation of re-packaging of genetically modified organisms within country.	**1000. 00**

Part B

Schedule of Fines

	Breach	**Fine (SZL)**
1.	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 to 200 000**
2.	The handling, manipulation, production and possession of GMOs and their products without authorization from the Competent Authority	**100 000 to 200 000**
3.	The execution of field experiments with GMOs and its products without an authorisation from the Competent Authority	**25 000 to 200 000**
4.	To provide false declarations or biased information	**10 000**
5.	The obstruction of the work of the inspectors	**5000**
6.	Destruction of GMOs	**5000 to 50 000**
7.	The lack of labelling and correct identification of products containing GMOs	**5 000**
8.	The failure to report to the competent authority about any accident involving GMOs that have occurred	**50 000 to 200 000**
9.	The utilisation of GMOs for purposes different from what was indicated in the import authorization	**20 000**
10.	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**