

## SUBSIDIARY LEGISLATION

### BIOSAFETY (MANAGEMENT OF GENETICALLY MODIFIED ORGANISMS) REGULATIONS

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G.N. 30/2007

BIOSAFETY (MANAGEMENT OF GENETICALLY MODIFIED ORGANISMS) REGULATIONS

under s. 41

PART I

PRELIMINARY

1. Citation

These Regulations may be cited as Biosafety (Management of Genetically Modified Organisms) Regulations.

2. Interpretation

In these Regulations, unless the context otherwise requires—

“applicant” means a person who submits an application for a licence or permit under the Act;

“Committee” means the National Biosafety Regulatory Committee established under regulation 3;

“Biosafety Registrar” means the officer appointed as such under regulation 8;

“operator” means any person who conducts activities under a licence or permit issued under the Act;

“register” means a register established under regulation 8 and containing particulars of Genetically Modified Organisms and activities that are licensed or permitted under the Act;

“risks to human health” means the potential adverse effects of biotechnology activities or their products on human health;

“reviewer” means a reviewer appointed under regulation 11.

## PART II

### INSTITUTIONAL FRAMEWORK

#### 3. National Biosafety Regulatory Committee

(1) There shall be a National Biosafety Regulatory Committee which shall consist of the following members, nominated by their institutions and appointed by the Minister—

- (a) the Secretary responsible for Agriculture and Food Security or his designated representative;
- (b) the Secretary responsible for Health or his designated representative;
- (c) the Secretary responsible for Industry and Trade or his designated representative;
- (d) the Director General of the Malawi Bureau of Standards or his designated representative;
- (e) Secretary responsible for Labour or his designated representative;
- (f) the Secretary responsible for Justice or his designated representative;
- (g) the Director of Forestry or his designated representative;
- (h) the Secretary responsible for Women and Child Welfare or his designated representative;
- (i) the Secretary responsible for Nutrition, HIV and Aids or his designated representative;
- (j) the Director of National Parks and Wildlife or his designated representative;
- (k) the Executive Director for the Council for Non-Governmental Organizations or his designated representative;
- (l) the Commissioner for Malawi Revenue Authority or his designated representative;
- (m) the Inspector General of the Malawi Police Service or his designated representative; and
- (n) the Executive Director for Consumers Association of Malawi or his designated representative.

(2) Members of the Committee shall be paid such an allowance as the Minister shall determine:

Provided that the Minister may make provision for reimbursement of any reasonable expense incurred by a member of the Committee in connexion with the business of the committee.

(3) The Minister shall appoint the Chairperson of the National Biosafety Regulatory Committee.

(4) The members of the Committee shall, at their first meeting, elect a Vice-Chairperson from amongst their number.

(5) In the absence of the Chairperson and Vice Chairperson the members of the Committee present shall elect a person from their number to preside over a meeting.

(6) The person presiding over a meeting shall exercise all the powers and perform all the duties of the Chairperson whenever the Chairperson is not present.

(7) A member of the Committee whose period of office has expired may be eligible for reappointment.

(8) Each institution shall designate a member and an alternate to serve on the Committee.

(9) The quorum for any meeting of the Committee shall be a simple majority of members.

(10) A decision on any matter before the Committee shall be by a simple majority of votes of the members present.

(11) In the case of an equality of votes, the person presiding over a meeting shall have a casting vote.

(12) The committee shall determine its own procedures for meetings.

(13) The Biosafety Registrar shall be the Secretary to the Committee.

#### 4. Immunity from suit

No action, suit or other proceedings shall be brought or instituted personally against any member of the Committee or public officer in respect of any act done in good faith in the course of carrying out the provisions of the Act or these Regulations.

#### 5. Tenure of office and vacancies

(1) The members of the Committee shall hold office for a period of three (3) years and may be eligible for reappointment.

(2) A member of the Committee shall cease to be a member of the Committee if—

(a) he resigns as a member of the committee;

(b) he ceases to be a member or employee of the institution that nominated him for appointment as member of the Committee;

(c) upon, conviction of any offence, he is sentenced to a term of imprisonment without the option of a fine;

(d) he is of unsound mind or an undischarged bankrupt;

(e) he is absent from three (3) consecutive meetings of the Committee, without a valid excuse, of which he has had notice;

(f) he dies; or

(g) the member is compromised to such an extent that his ability to impartially exercise the duties of his office is seriously in question.

#### 6. Functions of the Committee

The Committee shall—

(a) evaluate all applications concerning or related to genetically modified organisms and products thereof and make recommendations to the Minister in that regard;

(b) advise, on request or of its own accord, the Minister on matters concerning genetic modification of organisms, inter alia—

(i) on all aspects relating to the introduction of genetically modified organisms into the environment;

(ii) on all proposals for specific activities or projects concerning the genetic modification of organisms;

(iii) on all aspects concerning the contained use of genetically modified organisms;

(iv) on the exportation and importation of genetically modified organisms;

(v) on the amendment or withdrawal of a licence or permit issued under the Act;  
and

(vi) on proposed regulations and guidelines;

(c) liaise, through the relevant institutions, with international groups or organizations concerned with biosafety and biotechnology;

(d) invite knowledgeable persons to assist the Committee on any aspect related to genetically modified organisms and;

(e) carry out such other functions that are necessary for the effective implementation of these Regulations.

7. Disclosure of Interest

A member of the Committee who has an interest, direct or indirect, in any matter before the Committee shall disclose such interest and shall not take part in the consideration or discussion of the matter.

8. Appointment of the Biosafety Registrar

(1) There shall be appointed, in the public service, a Biosafety Registrar and such other suitably qualified officers as may be required for the administration of these Regulations.

(2) The Biosafety Registrar shall exercise such powers and perform such duties as may be conferred upon him by the Minister, and the Committee.

9. Functions of the Biosafety Registrar

(1) The Biosafety Registrar shall—

(a) ensure that the provisions of the Act and these Regulations are known to the relevant authorities and the general public;

(b) maintain a register of all biotechnological activities in Malawi and all licences and permits issued under the Act;

(c) receive all documents relating to applications and appeals and transmit them to the Committee and the Minister;

(d) liaise with the Secretariat of the Convention on Biological Diversity;

(e) transmit information on biosafety to the Biosafety Clearing House Mechanism;

(f) facilitate and ensure the training of all inspectors in relevant aspects of biosafety and biotechnology;

(g) maintain a register of experts in biotechnology and biosafety; and

(h) perform any other functions as may be conferred upon him by the Minister or the Committee.

10. Inspectors

(1) Subject to the provisions of section 30 (2) and (3) of the Act, the institutions represented on the Committee shall nominate from their institutions suitably qualified public officers for appointment as inspectors by the Minister in accordance with the section 30 of the Act.

(2) Where the Committee has ascertained or suspects, on reasonable grounds, that genetically modified organisms are being imported or locally produced or used contrary to the provisions of the Act, these Regulations or the conditions of a licence or permit issued thereunder, the Committee shall instruct inspectors to—

(a) require the cessation of any genetic modification activity at the facilities where the provisions of the Act or the conditions of a licence or permit have not been or are not being complied with;

(b) ensure that appropriate measures are undertaken by all users at all times with a view to protect human health and the environment from hazards;

(c) serve notice upon any person by whom or on whose behalf genetically modified organisms are being imported into, produced or used in Malawi contrary to the Act or these Regulations, for the removal of such genetically modified organisms, to a place or facility and in a manner prescribed by the Committee; or

(d) destroy such genetically modified organisms or cause them to be destroyed, subject to procedures stipulated in the guidelines issued by the Minister.

#### 11. Reviewers

(1) The Committee may, before it considers any application for a licence or a permit, appoint one or more experts in any relevant field to review the application so as to provide the Committee with sufficient information to enable it make an informed decision.

(2) In the performance of the powers of appointment in accordance with subregulation (1) above, the Committee shall ensure that the composition of the reviewers reflects the expertise necessary to undertake a proper review of the subject in question and shall determine the size of each review team.

(3) The reviewers shall be responsible for reviewing risk assessment reports and auditing processes in order to establish the impact of the biotechnological activities on the environment and human health.

(4) The reviewers shall submit a report to the Committee, in respect of any assessment undertaken, giving, inter alia,—

(a) an opinion of the viability of the project under consideration;

(b) a description of any measures or actions that need to be taken to ensure the safe use of genetically modified organisms; and

(c) an outline of any gaps, deficiencies and the adverse human and environmental concerns.



(5) The reviewers shall, when compiling their report, have regard to the provisions of regulation 15.

### PART III

#### LICENCES AND PERMITS

12. Required information for applications for licences and permits for trial release and contained use

(1) Any person making an application for a licence or a permit for trial release and contained use under the Act shall provide to the Committee the information contained in the First Schedule hereto.

(2) Notwithstanding the provisions of subregulation (1) a permit referred to in the said subregulation shall not be required for organisms that are used under conditions of contained use in academic and research facilities.

(3) A licence or permit issued under the Act shall be in the format contained in the Second Schedule hereto and shall be valid for a period of one (1) year.

(4) Any person making an application for a licence or permit to export or import genetically modified organisms shall take into account the requirements of the Cartagena Protocol on Biosafety.

13. Fees

(1) Any person making an application or granted a licence or permit under these Regulations shall pay the fees set out in the Third Schedule hereto and the fees shall accompany each application or be paid before any licence or permit is granted, as the case may be.

(2) The Committee may recommend to the Minister to exempt indigenous Malawian researchers from paying fees under these Regulations.

(3) The Minister, on the recommendation of the Committee, shall determine the fees under these Regulations and may revise the fees from time to time.

14. Applications for licence for general release of genetically modified organisms

(1) A person who has been granted a licence or permit under the Act and proposes to release into the environment genetically modified organisms, shall make an application for a licence to the Minister in accordance with requirements contained in the Fifth Schedule hereto.

(2) The applicant shall publish the application for the proposed general release of genetically modified organisms in two (2) widely circulating newspapers.

(3) The publication referred to in subregulation (2), shall contain the following details—

(a) full name and address of the applicant;

(b) a full description of the genetically modified organisms that the applicant proposes to release;

(c) a description of the proposed general release including the area and environment in which the release is to take place;

(d) a request that interested parties submit comments or objections in connexion with the intended release to the Biosafety Registrar within a period specified in the notice:

Provided that such period shall not be less than thirty (30) days after the date on which the notice appears in newspaper; and

(e) the address of the Biosafety Registrar, to which comments or objections may be submitted.

(4) The Biosafety Registrar shall refer any comments or objections received from interested parties to the Committee.

(5) The Committee shall, when reviewing an application for general release, consider all the comments and objections referred to the Committee in connexion with the said application.

#### 15. Risk assessment of activities

(1) No licence shall be issued unless a suitable and sufficient assessment of the risks that may be created thereby to the environment or human health is undertaken.

(2) The applicant shall conduct risk assessment in a scientifically sound manner, appropriate to the type of permit or licence being sought and in accordance with internationally recognized risk assessment techniques and shall, inter alia, take into account available information concerning any potential exposure to the genetically modified organisms.

(3) Risk assessments shall be based on the information included in the application and shall also cover the information set out in the Fourth Schedule hereto and any other available scientific evidence.

(4) Lack of scientific knowledge or lack of consensus on the safe use of genetically modified organisms shall not in itself be interpreted as indicating a particular level of risk, an acceptable risk or an absence of risk.

#### 16. Licensing of facilities and maintenance of records

(1) Subject to the provisions of subregulation (4), all facilities, for the purpose of carrying out genetic modification of organisms activities, shall be registered and licensed for such purposes.

(2) An application for the registration and licensing of a facility shall be made in a prescribed form and accompanied by a locality map that clearly indicates where the facility is situated and the construction materials to be used.

(3) Applications for licensing a facility that has already been active prior to the commencement of these Regulations, shall be made within six (6) months from the date of the commencement of these Regulations:

Provided that, where the Minister deems it necessary, upon the advice of the Committee, that a facility be registered prior to the expiration of the six (6) months period, the Minister may, by a written notice to the operator, require that a particular facility be licensed within a period specified in that notice.

(4) The Biosafety Registrar shall within three (3) weeks from the date of the issuance of facility licence, furnish the successful applicant a copy of the guidelines and conditions for the maintenance of the facility.

(5) The operator of a licensed facility shall, inter alia, keep and maintain the licence referred to in subregulation (4) and all records pertaining to risk assessments.

(6) The licence and records referred to in subregulation (5) shall, on request, be made available to the Biosafety Registrar or an inspector.

(7) The operator shall at all times, notify the Biosafety Registrar of any change to the information provided in terms of this regulation such as any extensions, improvements, modifications and damage to the facility.

(8) The operator shall not dispose of any list, register and record maintained in terms of this regulation except with the written permission of the Biosafety Registrar.

(9) Any person who contravenes the provisions of this regulation commits an offence and shall, upon conviction, be liable to a fine of two hundred thousand Kwacha (K200,000) and to imprisonment for three (3) years.

#### 17. Time within which to determine applications

(1) The Minister shall attend to applications for licences and permits within a reasonable time and in any event decisions relating to any application shall be made not later than three (3) months from the date the committee receives the application.

(2) Notwithstanding subregulation (1), where an applicant is required to furnish further information for the determination of his application, the number of days taken by the applicant to submit the required information shall not be included in the time set down for determining the application.

#### 18. Processing of applications

(1) All applications for licences and permits under the Act shall be made to the Biosafety Registrar.

(2) Upon receipt of an application, the Biosafety Registrar shall—

(a) acknowledge, in writing, receipt of such application within five (5) working days of such receipt; and

(b) determine whether the application conforms with the requirements of the Act, these Regulations and relevant international requirements, and if—

(i) the application does not conform to the relevant requirements in any respect, immediately refer the application back to the applicant and request the applicant to rectify the application; or

(ii) the application conforms to the relevant requirements submit the application to the Committee for consideration.

(3) The applicant or his authorized representative may appear in person before the Committee to answer any questions or provide any explanation pertaining to his application.

(4) The applicant shall publish in two (2) widely circulating newspapers a brief description of the application for a licence or permit under the Act and invite comments from members of the general public on such application.

(5) All public comments shall be made to the Biosafety Registrar within thirty (30) days of the publication of the application in accordance with subregulation (4).

(6) The Committee may—

(a) approve or reject the application depending on whether the proposed activity may pose significant risk to the conservation and sustainable use of biological diversity and human health and make the necessary recommendations to the Minister and shall give reasons for its decision; or

(b) refer the application back to the applicant for further and better particulars.

(7) When deciding an application for a general release licence, the Committee shall also consider the provisions of section 22 of the Act.

(8) In addition to the risk assessment report, the Committee shall consider the socio-economic impact of the general release of the genetically modified organism on a community living in the vicinity where the genetically modified organisms is proposed to be released.

(9) Where an applicant discovers any new information relating to the application that is being processed, he shall immediately notify the Biosafety Registrar of the new information.

(10) Upon receipt of the new information referred to in subregulation (9), the Biosafety Registrar shall refer the details thereof to the Committee which shall decide the effect of such information on the application.

19. Review of decisions

(1) Any applicant may apply to the Minister to review his decision with respect to an activity conducted or proposed to be conducted by the applicant where the applicant considers that—

(a) change of circumstances has since occurred that may have had a material effect on the decision or the outcome of the risk assessment upon which the decision was based; or

(b) additional scientific or technical information has become available that may have a material effect on the decision including any conditions, limitations or requirements imposed under a licence or permit.

(2) If the Minister, upon consultation with the Committee, is satisfied that a change is warranted, he may revise the decision and any conditions in the licence or permit in a manner that is consistent with the new information.

PART IV

MISCELLANEOUS PROVISIONS

20. Accidents

(1) In the event of an accident involving genetically modified organisms, it shall be the responsibility of the operator to ensure that—

(a) the Biosafety Registrar is notified immediately both verbally and in writing of such accident regarding—

(i) the circumstances of the accident;

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

(iii) any information that is necessary to assess the impact of the accident on the environment and human health;

(iv) the emergency measures taken to avoid or mitigate any adverse impact of such accident on the environment and human health; and

(v) the capacity to deal with the situation occasioned by the accident; and

(b) all appropriate short term, medium term and long term measures are taken to avoid or mitigate any adverse impact of such accident on the environment and human health.

21. Caution and determination of liability

(1) Operators shall take appropriate measures to avoid any adverse impact on the environment and human health, which may arise from any trial release or contained use involving genetically modified organisms.

(2) The liability for damage caused to the environment and biodiversity by the use or release of a genetically modified organism shall be borne by the operator.

22. Public access to information and confidentiality

(1) Subject to subregulation (2), every person shall have access to information submitted to the Biosafety Registrar under these Regulations.

(2) No person shall disclose any information acquired by him through the exercise of his powers or the performance of his duties in terms of these Regulations, except—

- (a) in so far as it is necessary for the proper application of the provisions of the Act;
- (b) for the purposes of any legal proceedings under the Act;
- (c) when ordered to do so by any competent court; or
- (d) if he is authorized to do so by the Committee or Minister.

(3) The Biosafety Registrar shall, after consultation with the applicant, recommend to the Committee which information should be kept confidential and shall inform the applicant of his decision provided that the following information shall not be kept confidential—

(a) the description of the genetically modified organisms, the name and address of the applicant, and the purpose of the contained use, confined field trial or general release;

(b) the methods and plans for the monitoring of the genetically modified organisms and for emergency measures in the case of an accident; and

(c) the evaluation of foreseeable impacts, in particular any pathogenic or ecologically disruptive impacts.

(4) Notwithstanding the provisions of subregulation (2), the Biosafety Registrar may, after being satisfied on the grounds of information furnished by the applicant that certain information should be withheld in order to protect the intellectual property of the applicant, withhold such information for the period needed to protect such rights.

(5) If, for whatever reasons, the applicant withdraws an application, any party who has knowledge of the details of the application shall keep confidential the information supplied.

(6) Any person who contravenes subregulation (5), commits an offence and shall, upon conviction, be liable to the penalty prescribed under section 33 of the Act.

23. Requirements for effective management of waste

(1) An operator who possesses or controls waste arising from biotechnology activities shall manage and dispose of the waste in such a manner that the waste shall not negatively impact on the environment and human health.

(2) An operator shall comply with all relevant national and local authority legislation in force in the management and disposal of waste arising from biotechnology activities.

(3) Any person who contravenes subregulations (1) and (2) commits an offence and shall, upon conviction, be liable to a fine of two hundred thousand Kwacha (K200,000) and to two (2) years imprisonment:

Provided that if the person commits a further offence he shall be liable to a fine of twenty thousand Kwacha (K20,000) during each day the offence continues.

#### 24. Advertisements

(1) No person shall advertise genetically modified organisms in a manner which misleads the general public or makes false claims regarding the use of genetically modified organisms.

(2) The Biosafety Registrar shall, after consultation with the Committee, instruct an inspector to confiscate genetically modified organisms which contravene subregulation (1).

(3) Any person who contravenes subregulation (1) commits an offence and shall, upon conviction, be liable to a fine of two hundred thousand Kwacha (K200,000) or to an amount equivalent to the financial gain generated by the offence.

#### 25. Guidelines

In addition to the information required for all applications under these Regulations, the Minister shall issue guidelines to be followed by applicants in the conduct of biotechnology activities.

#### 26. Appeals

(1) An appeal under the Act shall—

(a) be lodged in writing within thirty (30) days from the date on which the applicant was notified in writing of the decision or action concerned and shall state:

(i) the reference number and the date of the document by means of which such applicant was notified of that decision or action; and

(ii) the grounds on which the appeal is based; and

(b) be accompanied by the fees set out in the Third Schedule contained hereto.

(2) The applicant shall lodge the appeal with the office of the Biosafety Registrar.

(3) The applicant shall be notified in writing by the Biosafety Registrar not less than fourteen (14) days in advance of the date, time and place at which he is to appear before the appeals committee.

(4) The applicant shall be entitled to legal representation during any appearance before the appeals committee.

(5) An appeals committee shall provide the Minister with a decision on the appeal within thirty (30) days after the hearing of the appeal.

FIRST SCHEDULE regs. 12 and 14

## REQUIRED INFORMATION FOR APPLICATIONS OF LICENCES AND PERMITS

### SECTION ONE

#### PART I

##### GENERAL INFORMATION

1. The name and address of the applicant, and the name, qualifications and experience of the scientists and of every other person responsible for planning and carrying out the release of the organisms, and for the supervision, monitoring and safety of the release.

2. The name and address of the collaborating institution or institutions, and of the name, qualifications and experience of the scientists and of every other person responsible for planning and carrying out the release of the organisms, and for the supervision, monitoring and safety of the release.

3. The curriculum vitae of all the scientists and other persons involved in paragraphs 1 and 2 above.

4. The title of the project.

#### PART II

##### INFORMATION RELATING TO THE PARENTAL OR RECIPIENT PLANT

5. The full name of the plant—

- (a) family name;
- (b) genus;
- (c) species;
- (d) subspecies;
- (e) cultivar/breeding line; and
- (f) common name.



6. Information concerning—

- (a) the reproduction of the plant—
  - (i) the mode or modes of reproduction;
  - (ii) any specific factors affecting reproduction; and
  - (iii) generation time, and
- (b) the sexual compatibility of the plant with other cultivated or wild plant species, including the distribution in Malawi of the compatible species.

7. Information concerning the survivability of the plant—

- (a) its ability to form structures for survival or dormancy; and
- (b) any specific factors affecting survivability of the plant.

8. Information concerning the dissemination of the plant—

- (a) the means and extent (such as an estimation of how viable pollen and/or seeds decline with distance, where applicable) of dissemination; and
- (b) any specific factors affecting dissemination.

9. The geographical distribution of the plant.

10. Where the application relates to a plant species which is not normally grown in Malawi, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

11. Any other potential interactions, relevant to the genetically modified organism, of the plant with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

PART III

INFORMATION RELATING TO THE GENETIC MODIFICATION

12. A description of the methods used for the genetic modification.

13. The nature and source of the vector used.

14. The size, intended function and name of the donor organism or organisms of each constituent fragment of the region intended for insertion.

PART IV

## INFORMATION RELATING TO THE GENETICALLY MODIFIED PLANT

15. A description of the trait or traits and characteristics of the genetically modified plant which have been introduced or modified.

- The information on the sequences actually inserted.
- The information on the expression of the insert such as the parts of the plant where the insert is expressed, such as roots, stem or pollen.

16. Information on how the genetically modified plant differs from the parental recipient plant in the following respects—

- (a) mode or modes and/or the rate of reproduction;
- (b) dissemination, and
- (c) survivability.

17. The genetic stability of the insert and phenotypic stability of the genetically modified plant.

18. Any change to the ability of the genetically modified plant to transfer genetic material to other organisms.

19. Information on any toxic, allergenic or other harmful effects on human health arising from the genetic modification.

20. Information on the safety of the genetically modified plant to animal health, particularly regarding any toxic, allergenic or other harmful effects arising from the genetic modification, where the genetically modified plant is intended to be used in animal feeding stuffs.

21. The mechanism of interaction between the genetically modified plant and target organisms, if applicable.

22. The potential changes in the interactions of the genetically modified plant with non-target organisms resulting from the genetic modification.

23. The potential interactions with the abiotic environment.

24. A description of detection and identification techniques for the genetically modified plant.

25. Information about previous releases of the genetically modified plant, if applicable.

## PART V

### INFORMATION RELATING TO THE SITE OF RELEASE

(Applications for Licences or Permits for release only)

26. The location and size of the release site or sites.

27. Details of any sexually compatible wild relatives or cultivated plant species present at the release sites.

28. The proximity of the release sites to officially recognized biotopes or protected areas which may be affected.

## PART VI

### INFORMATION RELATING TO THE RELEASE

(Applications for Licences or Permits for Trial release only)

29. The purpose of the release of the genetically modified plant, including its initial use and any intention to use it as or in a product in the future.

30. The foreseen date or dates and duration of the release.

31. The method by which the genetically modified plants will be released.

32. The method for preparing and managing the release site, prior to, during and after the release, including cultivation practices and harvesting methods.

33. The approximate number of genetically modified plants (or plants per square meter) to be released.

## PART VII

### INFORMATION ON CONTROL, MONITORING, POST-RELEASE AND WASTE TREATMENT PLANS

(Applications for Licences or Permits to release only)

34. A description of any precautions to—

(a) maintain the genetically modified plant at a distance from sexually compatible plant species, both wild relatives and crops; and

(b) any measures to minimize or prevent dissemination of any reproductive organ of the genetically modified plant (such as pollen, seeds, tuber).

35. A description of the methods for post-release treatment of the site or sites.

36. A description of the post-release treatment methods for the genetically modified plant material, including wastes.

37. A description of monitoring plans and techniques.

38. A description of any emergency plans.

39. Methods and procedures to protect the site.

## PART VIII

### INFORMATION ON METHODOLOGY

40. A description of the methods used or a reference to standardized or internationally recognized methods used to compile the information required by this Schedule, and the name of the body or bodies responsible for carrying out the studies.

SECOND SCHEDULE regs. 12 and 14

### LICENCE/PERMIT

#### FORM C

This Licence/Permit is hereby granted to: .....

.....

.....

..... (Name, Contact Address and description of applicant) in accordance with the Biosafety Act.

.....

.....

.....

..... (description of the genetically modified organism, products, trials and release) located at: .....

.....

.....

.....

..... (geographical description of the location of the site of the facility).

This Licence/Permit is issued subject to the Regulations under which it is issued and the conditions attached hereto. It may be withdrawn should the holder breach any provisions of the Act, Regulations or the attached conditions.

..... (Name of applicant) being the holder, including his/her agents, undertakes to abide by the conditions of this Licence/Permit and to promptly report any matter

that may prejudice the interests of Malawi and other conditions attached to the grant of this Licence/permit.

This Licence/Permit is not transferable.

Signed: .....

Dated: .....

Minister

### THIRD SCHEDULE reg. 13

#### FEES

1. Every application shall be accompanied by a non-refundable scrutiny fee of K300,000.
2. Fees payable on the application of a permit or licence—

Matter	Fee Payable on Grant of Licence	Application for—K t
(a)	development of genetically modified organisms	500,000000
(b)	contained use of genetically modified organisms	1,000,000000
(c)	confined field trial of genetically modified organisms	3,000,000000
(d)	general release and marketing of genetically modified organisms	3,000,000000
(e)	importation of genetically modified organisms for commercial use	3,000,000000
(f)	exportation of genetically modified organisms	10,000000
(g)	appeal	50,000000

### FOURTH SCHEDULE reg. 15

#### PART I

#### INFORMATION TO BE INCLUDED IN A ASSESSMENT REPORT

1. An identification of the characteristics of the recipient organism which are relevant to the assessment of the relevant genetically modified organisms.
2. A description of the way in which the characteristics of the organisms have been affected by genetic modification.
3. An identification of any known risks of damage to the environment resulting from the release into the environment of the recipient non-modified organism.
4. An assessment of whether the genetic modification has been characterized sufficiently for the purpose of evaluating any risks of damage to the environment.
5. An identification of any new risks of damage to the environment that may arise from the release of the relevant genetically modified organisms as compared to the release of the corresponding non-modified organism, based on the environmental risk assessment.
6. A conclusion which addresses the proposed use of the product, risk management and the proposed monitoring plan, and states whether the relevant genetically modified organisms should be marketed and under which conditions, or should not be marketed, including reasons for that conclusion.

## PART II

### RISK ASSESSMENT PROCEDURES

#### Objective of Risk Assessment

1. The objective of risk assessment under these Regulations is to identify and evaluate the potential adverse effects of genetically modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

#### Use of Risk Assessment

2. Risk assessment is, inter alia, used by competent authorities to make informed decisions regarding genetically modified organisms.

#### General Principles

3. Risk assessment shall be carried out in a scientifically sound and transparent manner, and take into account expert advice of, and guidelines developed by, relevant international organizations.

4. Lack of scientific knowledge or scientific consensus shall not necessarily be interpreted as indicating a particular level of risk, an absence of risk or an acceptable risk.

5. Risks associated with genetically modified organisms or products thereof, namely, processed materials that are of genetically modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, shall be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

6. Risk assessment shall be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living genetically modified organism concerned, its intended use and the likely potential receiving environment.

#### Methodology

7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand, information on other subjects may not be relevant in some instances.

8. Risk assessment entails, as appropriate, the following steps:

(a) an identification of any novel genotypic and phenotypic characteristics associated with the genetically modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;

(b) an evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the genetically modified organism;

(c) an evaluation of the consequences should these adverse effects be realized;

(d) an estimation of the overall risk posed by the genetically modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;

(e) recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and

(f) where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the genetically modified organism in the receiving environment.

#### Points to Consider

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects—

(a) recipient organism or parental organisms: the biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

(b) donor organism or organisms: taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;

(c) vector: characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

(d) insert or inserts and/or characteristics of modification: genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

(e) genetically modified organisms: identity of the genetically modified organism, and the differences between the biological characteristics of the genetically modified organism and those of the recipient organism or parental organisms;

(f) detection and identification of the genetically modified organism: suggested detection and identification methods and their specificity, sensitivity and reliability;

(g) information relating to the intended use: information relating to the intended use of the genetically modified organism, including new or changed use compared to the recipient organism or parental organisms; and

(h) receiving environment: information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.

#### FIFTH SCHEDULE reg. 4

#### SECTION ONE

#### INFORMATION TO BE INCLUDED IN APPLICATIONS FOR GENERAL RELEASE OR MARKETING OF GENETICALLY MODIFIED ORGANISMS

##### PART I

##### GENERAL INFORMATION

1. The name and address of the applicant, and the name, qualifications and experience of the scientist and of every other person who will be responsible for planning and carrying out the release of the organisms, and for the supervision, monitoring and safety of the release.

2. The title of the project.

##### PART II

##### INFORMATION RELATING TO THE ORGANISMS

##### Characteristics of Donor, Parental and Recipient Organisms

3. Scientific name and taxonomy.

4. Usual strain, cultivator or other name.

5. Phenotypic and genetic markers.

6. The degree of relatedness between donor and recipient or between parental organisms.

7. The sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques.

8. The description of the geographic distribution and of the natural habitat of the organisms including information on natural predators, prey, parasites and competitors, symbionts and hosts.

9. The organisms with which transfer of genetic material is known to occur under natural conditions.

10. Verification of the genetic stability of the organisms and factors affecting that stability.

11. The following pathological, ecological and physiological traits—



- (a) the classification of hazard according to existing legislation concerning the protection of human health and the environment; and
- (b) the generation time in natural ecosystems and the sexual and asexual reproductive cycle.
- (c) information on survivability, including seasonability and the ability to form survival structures, including seeds, spores and sclerotia;
- (d) pathogenicity, including infectivity, toxigenicity, virulence, allergenicity, ability to act as a carrier (vector) of pathogen, possible vectors, host range including non-target organisms and possible activation of latent viruses (pro-viruses) and ability to colonise other organisms;
- (e) antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy; and
- (f) involvement in environmental processes, including primary production, nutrient turnover, decomposition of organic matter and respiration.

12. The sequence, frequency of mobilization and specificity of indigenous vectors, and the presence in those vectors of genes which confer resistance to environmental stresses.

13. The history of previous genetic modifications.

#### Characteristics of the Vector

14. The nature and source of the vector.

15. The sequence of transposons, vectors and other non-coding genetic segments used to construct the genetically modified organisms and to make the introduced vector and insert functions in those organisms.

16. The frequency of mobilization, genetic transfer capabilities and/or methods of determination of the inserted vector.

17. The degree to which the vector is limited to the DNA required to perform the intended function.

#### Characteristics of the Modified Organisms

18. The methods used for the modification.

19. The methods used—

- (a) to construct the insert or inserts and to introduce it or them into the recipient organism, and
- (b) to delete a sequence.

20. The description of any insert and/or vector construction.

21. The 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.

22. The methods and criteria used for selection.

23. The sequence, functional identity and location of the altered, inserted or deleted nucleic acid segment or segments in question, and in particular any known harmful sequence.

#### Characteristics of the Genetically Modified Organisms in their Final Form

24. The description of genetic trait or traits or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed.

25. The structure and amount of any vector or donor nucleic acid remaining in the final construction of the modified organisms.

26. The stability of the organisms in terms of genetic traits.

27. The rate and level of expression of the new genetic material in the organisms, and the method and sensitivity of measurement of that rate and level.

28. The activity of the gene product.

29. The description of identification and detection techniques, including techniques for the identification and detection of the inserted sequence and vector.

30. The sensitivity, reliability (in quantitative terms), and specificity of detection and identification techniques.

31. The history of previous releases or uses of the organisms.

32. In relation to human health, animal health and plant health—

- (a) the toxic or allergenic effects of the organisms and/or their metabolic products;
- (b) the comparison of the organisms to the donor, recipient or (where appropriate) parental organisms regarding pathogenicity;
- (c) the capacity of the organisms for colonization; and
- (d) if the organisms are pathogenic to humans who are immunocompetent—
  - (i) diseases caused and mechanism of pathogenicity including invasiveness and virulence;
  - (ii) communicability;

- (iii) infective dose;
  - (iv) host range and possibility of alteration;
  - (v) possibility of survival outside of human host;
  - (vi) presence of vectors or means of dissemination;
  - (vii) biological stability;
  - (viii) antibiotic resistance patterns;
  - (ix) allergenicity;
  - (x) availability of appropriate therapies; and
- (e) the other product hazards.

### PART III

#### INFORMATION RELATING TO THE CONDITIONS OF RELEASE

##### The Release

33. The description of the proposed deliberate release, including the initial purpose or purposes of the release and any intention to use the genetically modified organism as or in a product in the future.

34. The intended dates of the release and time planning of the experiment including frequency and duration of releases.

35. The preparation of the site before the release.

36. The size of the site.

37. The method or methods to be used for the release.

38. The quantity of organisms to be released.

39. The disturbance on the site, including the type and method of cultivation, and mining, irrigation or other activities.

40. The worker protection measures taken during the release.

41. The post-release treatment of the site.

42. The techniques foreseen for elimination or inactivation of the organisms at the end of the experiment or other purpose of the release.

43. Information on, and the results of, previous releases of the organisms, and in particular, releases on a different scale or into different ecosystems.

The environment (both on the site and in the wider environment)

44. The geographical location and national grid reference of the site or sites on to which the release will be made, or the foreseen areas of use of the product.

45. The physical or biological proximity of the site of the organisms to humans and other significant biota.

46. The proximity to significant biotopes, protected areas or drinking water supplies.

47. The climatic characteristics of the region or regions likely to be affected.

48. The geographical, geological and pedological characteristics.

49. The flora and fauna, including crops, livestock and migratory species.

50. The description of the target and non-target ecosystems likely to be affected.

51. The comparison of the natural habitat of the recipient organisms with the proposed site or sites of release.

52. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

#### PART IV

#### INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE ORGANISMS AND THE ENVIRONMENT

##### Characteristics Affecting Survival, Multiplication and Dissemination

53. The biological features which affect survival, multiplication and dissemination.

54. The known or predicted environmental conditions which may affect survival, multiplication and dissemination, including wind, water, soil, temperature and pH.

55. The sensitivity to specific agents.

##### Interactions with the Environment

56. The predicted habitat of the organisms.

57. The studies on the behaviour and characteristics of the organisms and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms and greenhouses.

58. The capability of post-release transfer of genetic material—

- (a) from the genetically modified organisms into organisms in affected ecosystems; and
- (b) from indigenous organisms to the genetically modified organisms.

59. The likelihood of post-release selection leading to the expression of unexpected or undesirable traits in the genetically modified organisms.

60. The measures employed to ensure and to verify genetic stability, the description of genetic traits which may prevent or minimize dissemination of genetic material, and methods to verify genetic stability.

61. The routes of biological dissemination, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact and burrowing.

62. The description of ecosystems to which the organisms could be disseminated.

63. The potential for excessive population increase of the organisms in the environment.

64. The competitive advantage of the organisms in relation to the unmodified recipient or parental organism or organisms.

65. The identification and description of the target organisms if applicable.

66. The anticipated mechanism and result of interaction between the released organisms and the target organisms if applicable.

67. The identification and description of non-target organisms which may be adversely affected by the release of the genetically modified organisms, and the anticipated mechanisms of any identified adverse interaction.

68. The likelihood of post-release shifts in biological interactions or in the host range.

69. The known or predicted interactions with non-target organisms in the environment, including competitors, preys, hosts, symbionts, predators, parasites and pathogens.

70. The known or predicted involvement of the organisms in biogeochemical processes.

71. Any other potential interactions of the organisms with the environment.

## PART V

### INFORMATION ON MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS

#### Monitoring Techniques

72. Methods for tracing the organisms and for monitoring their effects.

73. Specificity (to identify the organisms, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques.

74. Techniques for detecting transfer of the donated genetic material to other organisms.

75. Duration and frequency of the monitoring.

#### Control of the Release

76. Methods and procedures to avoid and/or minimize the spread of the organisms beyond the site of release or the designated area for use.

77. Methods and procedures to protect the site from intrusion by unauthorized individuals.

78. Methods and procedures to prevent other organisms from entering the site.

#### Waste Treatment

79. Type of waste generated.

80. Expected amount of waste.

81. Description of treatment envisaged.

#### Emergency Response Plans

82. Methods and procedures for controlling the organisms in case of unexpected spread.

83. Methods, such as eradication of the organisms, for decontamination of the areas affected.

84. Methods for disposal or sanitation of plants, animals, soils, and any other thing exposed during or after the spread.

85. Methods for the isolation of the areas affected by the spread.

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

#### PART VI

##### INFORMATION ON METHODOLOGY

87. A description of the methods used or a reference to standardized or internationally recognized methods used to compile the information required by this Schedule, and the name of the body or bodies responsible for carrying out the studies.

#### SECTION TWO

## INFORMATION TO BE INCLUDED IN APPLICATIONS FOR LICENCE TO MARKET GENETICALLY MODIFIED ORGANISMS

### PART I

#### GENERAL INFORMATION

1. The proposed commercial name of the product and names of the genetically modified organisms in the product, and any specific identification, name or code used by the applicant to identify the genetically modified organism.

2. The name and address in Malawi of the person who is responsible for the marketing, whether it be the manufacturer, importer or distributor.

3. The name and address of the supplier or suppliers of control samples.

4. A description of how the product and the genetically modified organism are intended to be used, highlighting any differences in use or management of the genetically modified organism compared to similar non-genetically modified products.

5. A description of the geographical area or areas and types of environment where the product is intended to be used within Malawi, including, where possible, an estimate of the scale of use in each area.

6. A description of the intended categories of users of the product, such as industry, agriculture or consumer use by the public.

7. Information on the genetic modification for the purposes of placing on one or several registers modifications in organisms, which can be used for the detection and identification of particular products to facilitate post-marketing control and inspection. This information should include where appropriate the lodging of samples of the genetically modified organism or its genetic material with the Minister, and details of nucleotide sequences or other type of information which is necessary to identify the product and its progeny, for example, the methodology for detecting and identifying the product, including experimental data demonstrating the specificity of the methodology. Information that cannot be placed, for confidentiality reasons, in the publicly accessible part of the register should be identified.

8. The proposed labelling, which must include, in a label or an accompanying document, at least in summarized 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 name and address of the person established in Malawi who is responsible for marketing the product, and how to access the information in the publicly accessible part of the register.

### PART II

#### ADDITIONAL RELEVANT INFORMATION

9. The measures to be taken in the event of the escape of the organisms in the product or misuse of the product.

10. Specific instructions or recommendations for storage and handling of the product.

11. Specific instructions for carrying out monitoring and reporting to the applicant stipulated in the Guidelines issued by the Minister.

12. The proposed restrictions in the approved use of the genetically modified organism, such as where the product may be used and for what purposes.

13. The proposed packaging.

14. The estimated production in and/or imports to Malawi.