# THE GENETICALLY MODIFIED ORGANISMS ACT 2004

Act No. 3 of 2004

Proclaimed by [Proclamation No. 47 of 2004]-Sections 1 to 5,6(1)(a) to (c) and 24 w. e. f. 01 January ,2005

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# AN ACT

To provide for measures to regulate the responsible planning, development, production, use, marketing and application of genetically modified organisms

Enacted by the Parliament of Mauritius, as follows -

#### 1. Short title

The Act may be cited as the Genetically Modified Organisms Act 2004.

# [Reprint No. 3 of 2004]

# 2. Interpretation

In this Act -

"accident" means an incident involving an unintended release of genetically modified organisms which could have an immediate or delayed adverse impact on the environment or human and animal health;

"applicant" means a person in control of a facility involving the genetic modification of organisms, or of activities involving genetically modified organisms, who applies for a GMO permit;

"authorised officer" means a public officer designated as such by the Permanent Secretary;

"Chairperson" means the Chairperson of the Committee;

"Committee" means the National Biosafety Committee set up under section 4'

"contained use" means any operation undertaken within a facility which involves genetically modified organisms that are controlled by specific measures to effectively limit their contact with, and their impact on, the external environment;

"environment" has the same meaning as in the Environment Protection Act 2002;

"facility" includes, but is not limited to, the following:

- (a) a building or part of a building;
- (b) a laboratory;
- (c) a green house;

- (d) a glasshouse;
- (e) an insectary;
- (f) an animal house;
- (g) a field;
- (h) any other place,

where activities involving genetically modified organisms are carried on.

"general release" means the introduction of genetically modified organisms into the environment by whatever means where the organisms are no longer contained by any system of barriers or under any person's control, so that the organisms are likely to survive and be disseminated;

"genetically modified organism (GMO)" -

- (a) means an organism, the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination, or both; and
- (b) includes any of its derivatives;

"GMO permit" means a permit issued by the Permanent Secretary under section 8;

"member" -

- (a) means a member of the Committee; and
- (b) includes the Chairperson;

"Minister" means the Minister to whom responsibility for agriculture is assigned;

"monitoring" means the maintaining of regular surveillance over, the checking of, the warning about, or the recording of, any activity involving genetically modified organisms;

"organism" -

- (a) means a cellular or non-cellular biological entity, capable of metabolism, replication, reproduction or of transferring genetic material; and
- (b) includes a microorganism;

"Permanent Secretary" means the Permanent Secretary of the Ministry;

"trial release" means the deliberate release of genetically modified organisms in confinement into the environment under conditions where the degree of dissemination of the genetically modified organisms is restricted by chemical, physical or built-in barriers which prevent the survival of such organisms outside the confined area;

"user" means a person responsible for the use of genetically modified organisms, and includes an end-user or a consumer.

# **3.** Application of Act

- (1) This Act shall apply to the genetic modification of organisms which occurs through
  - (a) recombinant nucleic acid techniques involving the formation of new combinations of genetic material;
  - (b) techniques involving the direct introduction into an organism of foreign nucleic acid molecules; or
  - (c) cell fusion, including protoplast fusion, beyond the same taxonomic family or hybridization techniques where live cells with new combination of genetic material are formed.
- (2) This Act shall not apply
  - (a) to techniques involving genetic manipulation of human cells; or
  - (b) in cases where recombinant nucleic acid molecules or genetically modified organisms are not employed.

#### 4. National Biosafety Committee

- There is established for the purpose of this act a National Biosafety Committee, which shall consist of –
  - (a) a Chairperson, with expertise in biotechnology and related fields, appointed by the Minister;
  - (b) a representative of the Ministry;
  - (c) a representative of the Ministry responsible for environment;
  - (d) a representative of the Ministry responsible for health;
  - (e) a representative of the Ministry responsible for international trade;
  - (f) a representative of the Mauritius Sugar Industry Research Institute;
  - (g) a representative of the University of Mauritius;
  - (h) a representative of the Food and Agricultural Research Council;
  - (i) a representative of the Mauritius Research Council;
  - (j) a law officer designated by the Attorney-General;
  - (k) a representative of consumer associations, appointed by the Minister.
- (2) (a) Every member, other than the ex-officio members, shall hold office for 2 years and shall be eligible for reappointment.
  - (b) The Minister may revoke the appointment of a member referred to in subsection 1(a) or 1(k) for any reason specified in section 37(3)(b) of the Interpretation and General Clauses Act or where he is of opinion that the person is no longer qualified to be a member.

- (3) (a) The Committee shall meet as and when required by the Chairperson, or upon request of not less than 3 members, but not less than 4 times a year.
- (b) 6 members shall constitute a quorum.
  - (4) The Committee may, with the Minister's approval, co-opt any other person to attend its meetings for a specific purpose, or period of time, but without the right to vote.
  - (5) Where any matter is being or is to be, considered by the Committee and a member has a direct or indirect interest in it or there is likely to be a conflict of interest as a result of his participation in the debate, he shall forthwith declare his interest and abstain from participating in the debate.
  - (6) The Minister may, at the request of the Committee, appoint independent professionals or consultants to assist the Committee in the discharge of its functions under this Act.

# 5. Objects of the Committee

The objects of the Committee shall be to advise the Minister on -

- (a) all aspects concerning the importation, exportation, transit, development, research, production, use, application, marketing, sale and release of genetically modified organisms; or
- (b) any other matter concerning genetically modified organisms that may be referred to it.

# 6. Functions of the Committee

- (1) The Committee shall have such functions as are necessary to further most effectively the objects of the Committee, and in particular to
  - (a) publish guidelines and a code of practice, with the approval of the Minister, for all uses of genetically modified organisms;

- (b) encourage public participation in decision-making while maintaining confidentiality of information;
- (c) advise the Permanent Secretary, as and when required, on the appropriate strategy in cases of emergency;
- (d) examine any application made pursuant to section 7, and make its recommendations to the Permanent Secretary.
- (2) In examining an application under subsection 1(d), the Committee shall take account of the proposed activity of the GMO in respect of its likely
  - (a) direct or indirect effects on the environment and human and animal health; and
  - (b) social and economic effects on people and society.

#### 7. Application for GMO permit

- (1) Notwithstanding any other enactment, no person shall develop, use, market, produce, release into the environment, transit, import or export genetically modified organisms unless he holds a GMO permit issued under this Act.
- (2) An application shall be made to the Permanent Secretary in the form set out in the First Schedule and on payment of a prescribed application fee.
- (3) (a) The applicant shall submit a risk assessment report and a contingency plan in the form set out in the Second Schedule.
  - (b) A risk assessment for the purpose of paragraph (a) shall be carried out in a scientifically sound manner.
- (4) On receipt of an application under subsection (2),
  - (a) the Permanent Secretary shall –

- (i) cause a notice of any application for a GMO permit to be published in the Gazette and for 3 consecutive days, in not less than two daily newspapers;
- (ii) invite all interested persons, who so wish, to lodge with the Permanent Secretary such objections as they may have against the application.
- (b) the Minister shall make a statement in the National Assembly informing it of such application.
- (5) Any person who wishes to object to an application shall, not later than 21 days after the last date of the publication specified in subsection (4), lodge his objection in writing with the Permanent Secretary.
- (6) The Permanent Secretary -
  - (a) may, on receipt of an application, request the applicant to furnish such additional information as he may consider appropriate;
  - (b) may, if he deems necessary, seek the views of any public department, non-government organisation or any other person on the application; and
  - (c) shall refer the application, together with any additional information and views expressed thereon, to the Committee for its recommendations.
- (7) The Committee shall endeavour to identify and evaluate the possible adverse effects of the genetically modified organisms on the environment and on human and animal health.

#### 8. Grant or refusal of GMO permit

 The Permanent Secretary, after taking into consideration the recommendation of the Committee, may –

- Subject to subsection (3), grant a GMO permit and issue such permit on payment of the prescribed fees and on such terms and conditions as he may deem appropriate;
- (b) reject the application, giving his reasons for so doing, with a direction to communicate the decision together with the reasons to the applicant.
- (2) The reasons on which a decision under subsection (1)(b) is made shall be communicated, by registered post, to the applicant, within 7 days of the decision.
- (3) No GMO permit shall be issued under subsection (1) (a) except after the relevant particulars of the intended GMO permit holder shall have been specified in regulations made to that effect.
- (4) Any regulations made under subsection (3) may be subject to a motion for disallowance under section 20 of the Interpretation and General Clauses Act.

# 9. Suspension or revocation of GMO permit

- (1) Where
  - (a) a permit holder changes the type of activity allowed by his permit or otherwise breaches any of the terms and conditions of his permit;
  - (b) a permit holder moves his activity from a facility specified in his application form to a facility which, in the opinion of the Permanent Secretary, is not a fit and proper facility;
  - (c) the activity of the permit holder impacts adversely on the environment or on human and animal health, the Permanent Secretary may by notice in writing require the GMO permit holder to show cause, within 7 days from date of service of the notice, why his permit ought not to be suspended or revoked.
- (2) Where the Permanent Secretary is satisfied that, having regard to all the circumstances of the case, it is expedient to do so, he may suspend the permit for such period as is reasonable in the circumstances, or revoke the permit.

(3) The Permanent Secretary shall communicate, by registered post, any decision under subsection (2) to the GMO permit holder within 7 days of the decision.

#### 10. Prohibition notice

- (1) Where he is of the opinion that a facility or the manner in which the facility is carrying on its activities involves a serious risk to environment or to human or animal health, the Permanent Secretary may serve, or cause to be served, a prohibition notice on the person owning, or managing, or in charge of, or in control of the facility.
- (2) A prohibition notice may be served whether or not -
  - (a) the facility, or the manner in which the activity is carried on, constitutes a contravention of this Act;
  - (b) there is in force in relation to the facility a GMO permit issued under this Act;
  - (c) there is before any Court of law or before a Judge sitting in Chambers any case involving the subject matter in relation to which a notice is being issued, unless the Court or Judge has issued an order preventing the Permanent Secretary from issuing the prohibition notice.
- (3) A prohibition notice shall
  - (a) state the Permanent Secretary's opinion;
  - (b) specify the risk involved, as well as the way in which the facility, or the manner in which the activity is carried on, is suspected to give rise to the risk;
  - (c) specify the measures that shall be taken to eliminate the risk and the period within which they shall be implemented;
  - (d) specify –

- (i) the facility, or any aspect of the facility, that is prohibited from operation or performance; or
- (ii) any conditions subject to which the activity may be resumed.
- (4) A prohibition notice shall not be a bar to a prosecution for any offence, even if there are consultations with the person served with the notice.
- (5) Any person who fails to comply with a prohibition notice, shall commit an offence.

# 11. Stop order

- (1) Where a person commences or carries on any development or activity without the relevant GMO permit issued under this Act, the Permanent Secretary may, where such development or activity contravenes this Act, serve, or cause to be served, on that person, or any person responsible for the giving of instructions for the carrying on of such development or activity, a stop order prohibiting the development or the activity.
- (2) Any person who fails to comply with a stop order issued under subsection (1) shall commit an offence.

# 12. Consultation on notices

- Before or at any time after issuing a notice, the Permanent Secretary shall as far as he deems practicable, consult –
  - (a) the person affected;
  - (b) the Committee.
- (2) The Permanent Secretary may consult a technical advisory committee set up by him, or any public department, on a notice.

# 13. Variation notice

- (1) Any person affected by a notice, may apply to the Permanent secretary for an amendment of the notice.
- (2) The Permanent Secretary, on his own initiative, or on application, may amend a notice by causing to be served on the person affected a variation notice.
- (3) A variation notice shall
  - (a) refer to the notice which is amended;
  - (b) specify the amendment to the notice;
  - (c) where necessary, vary the date specified in the notice.
  - (4) A variation notice shall supersede the notice to which it refers to the extent of the amendment.

#### 14. Service of notice

- (1) A notice issued under this Act shall be served
  - (a) personally on the person affected, or in the case of a body corporate, at its registered address; or
  - (b) by registered post sent to, or by leaving a copy at, the last known address of the person affected.
  - (2) Where service could not be effected by the means referred to in subsection (1), the service shall be effected by affixing a copy of the notice –
    - (a) at the facility which is the subject matter of the notice;
    - (b) where a contravention is being committed, or has been committed, or is suspected to have been committed.
  - (3) A certificate of an authorised officer or any other officer of the Ministry as to service under subsection (1) shall be prima facie evidence of effective service of the notice on the person affected.

#### 15. Revocation of notices

Where he is satisfied that -

- (a)(i) the measures required to be taken in a notice have been implemented; and
  - (ii) there exists no further risk to the environment or to human or animal health caused by the activity or the manner in which the activity is carried on; or
- (b) the notice is not, or will not be effectual,

the Permanent secretary may revoke a notice and shall inform the person affected in writing.

#### 16. Appeals

- (1) Any person who feels aggrieved by a decision taken by the Permanent Secretary may, within 21 days of the communication of the decision to him, and on payment of the prescribed fee, appeal against the decision to the Appeal Board appointed under subsection (2) by a written notice together with the grounds of appeal.
- (2) The Minister shall appoint on an ad hoc basis an Appeal Board comprising a Chairperson, who shall be a barrister with at least 5 years standing at the bar, and 2 members, being persons with expert knowledge in the field of biotechnology or related fields.
- (3) A person appointed under subsection (2) shall challenge himself if he has any direct or indirect interest in the subject matter of the appeal.
- (4) Any appeal lodged before the Appeal Board shall be dealt with as expeditiously as possible and the Appeal Board shall endeavour to dispose of the appeal within 6 months from the date the appeal was lodged.

- (5) The Appeal Board may, after giving the parties to the appeal an opportunity of being heard, pass such orders as it thinks fit, confirming, varying or setting aside the decision appeal against.
- (6) The Appeal Board shall send, by registered post, a copy of every order made by it to the parties to the appeal within 7 days.

# 17. Confidentiality

- (1) No person shall disclose any information acquired by him through the exercise of his powers or the performance of his duties under this Act other than –
  - (a) the description of any genetically modified organism, the name and address of any applicant, the purpose of the contained use or release and the place of use;
  - (b) the methods and plans for the monitoring of genetically modified organisms in case of accident;
  - (c) the evaluation of any foreseeable disruptive impacts on human or animal health or on the environment; or
  - (d) any other information as may be approved by the Permanent Secretary.
- (2) Where an applicant withdraws an application, any person who has knowledge of the details of the application shall respect the confidentiality of the information supplied.
- (3) Nothing in the subsection (1) or (2) shall prevent the disclosure of information
  - (a) in so far as if is necessary for the proper application of this Act; or
  - (b) for the purpose of any legal proceedings under this Act.

# 18. Registration of facilities

(1) The Permanent Secretary shall keep a register of all facilities.

- (2) Every GMO permit holder responsible for the management of any facility shall register the facility with the Permanent Secretary.
- (3) The register shall contain the
  - (a) name and address of the GMO permit holder;
  - (b) details of the activities carried on; and
  - (c) location and description of the facility.

# **19.** Monitoring powers

- (1) Subject to subsection (2), where an authorised officer reasonably believes that a facility is being used for any activity involving genetically modified organisms, including contained use, trial release or general release, he may enter and inspect the facility for the purpose of inspecting and monitoring the activities carried on therein and to ensure compliance with this Act, any regulations made thereunder and any GMO permit issued under this Act.
- (2) Where the authorised officer reasonably believes that any activity specified in subsection (1) is being carried on in a dwelling house, he may enter and inspect either with the consent of the owner or occupier of the dwelling house, or in virtue of a warrant to that effect issued by a Magistrate.
- (3) The authorised officer may, in the course of an inspection
  - (a) secure copies of any relevant document kept in the facility;
  - (b) secure, on reasonable grounds, any material which he believes to be evidential material.

# 20. Accidents

(1) Every person who is informed or becomes aware of an accident shall immediately notify the Permanent Secretary.

- (2) Where a GMO permit holder notifies an accident, he shall supply to the Permanent Secretary
  - (a) all relevant information on the circumstances of the accident, the identity, quantity and quality of genetically modifies organisms released and any other information necessary to assess the impact of the accident on the environment and on human and animal health; and
  - (b) the details of any emergency measures taken to avoid or mitigate any adverse impact on the environment and human and animal health.
- (3) The Permanent Secretary shall appoint on an ad hoc basis a Special Committee comprising a Chairperson and 2 members, being persons having wide expertise in the field relating to the accident, to enquire into the circumstances of the accident and make a report with recommendations to the Permanent Secretary.
- (4) The Permanent Secretary may, after taking into consideration the report and recommendations of the Special Committee, and where he considers that the accident has had an adverse impact on the environment or on human or animal health, take a decision under section 9(2).
- (5) The Permanent Secretary shall inform as soon as reasonably practicable any other country of any accident which may have an impact on that country's environment or on human and animal health in that country.

# 21. Labelling and identification

- (1) Every GMO permit holder shall ensure that any genetically modified organisms is clearly identified and labelled, specifying the relevant traits and characteristics of the product.
- (2) The labelling of any genetically modified organisms shall comply with such requirements as may be prescribed.

# 22. Offences

(1) A person who –

- (a) fails to comply with any condition, permit, or prohibition under this Act;
- (b) obstructs or hinders an authorised officer in the exercise of his functions under this Act;
- (c) provides information under this Act which is false or misleading in any material particular;
- (d) otherwise contravenes this Act,

shall commit an offence and shall, on conviction, be liable -

- (i) on a first conviction to a fine not exceeding Rs 50,000 and to imprisonment for a term not exceeding 2 years;
- (ii) on a second or subsequent conviction, to a fine not exceeding Rs 100,000 and to imprisonment for a term not exceeding 4 years.
- (2) In addition to any penalty under subsection (1), the Court may order the forfeiture of any animal, plant, organism or any article used in, or connected in any way with, the commission of an offence.

# 23. Jurisdiction

- (1) An authorised officer may swear an information and conduct prosecution in respect of an offence under this Act before a Magistrate.
- (2) Notwithstanding section 114 of the Courts Act and section 72 of the District and Intermediate Courts (Criminal Jurisdiction) Act, a magistrate –
  - (a) shall have jurisdiction to try an offence under this Act; and
  - (b) may impose any penalty and forfeiture provided by this Act.

#### 24. Regulations

- The Minister may make such regulations as he thinks fit for the purposes of this Act.
- (2) Any regulations made under subsection (1) may
  - (a) provide for the levying of fees and charges;
  - (b) lay down requirements for laboratory development of genetically modified organisms;
  - (c) set out standards to which facilities for activities involving genetically modified organisms should conform;
  - (d) make provision for quarantine, transit, marketing, sale, transport, handling and packaging of genetically modified organisms;
  - (e) provide for liabilities of GMO permit holders in respect of prejudice caused by their activities to other persons;
  - (f) amend the Schedules.
- (3) Regulations made under this Act may provide that any person who contravenes them shall commit an offence and shall, on conviction, be liable to a fine not exceeding 50,000 rupees and to imprisonment for a term not exceeding 2 years.

# 25. Commencement

- Subject to subsection (2), this Act shall come into operation on a date to be fixed by Proclamation.
- (2) Different dates may be fixed for the coming into operation of different sections of this Act.

Proclaimed by [Proclamation No. 47 of 2004]-Sections 1 to 5,6(1)(a) to (c) and 24 w. e. f. 01 January ,2005

# FIRST SCHEDULE

# [section 7(2)]

# APPLICATION FOR GMO PERMIT

# PART I - GENERAL INFORMATION

# 1. INFORMATION ON APPLICANT

| Name of Applicant:                         |  |  |  |  |  |
|--|--|--|--|--|--|
| Official Registration Number of applicant: | Official Registration Number of applicant: |  |  |  |  |
| Address:                                   |  |  |  |  |  |
| Tel.:                                      | Fax. :                                     |  |  |  |  |
| Email address:                             |  |  |  |  |  |
| 2. NATURE OF REQUEST (Please tick          | as appropriate)                            |  |  |  |  |
| Permit Request                             |  |  |  |  |  |
| Category A                                 | Laboratory experimentation                 |  |  |  |  |
|  | Greenhouse trial                           |  |  |  |  |
| Si   | mall field testing                         |  |  |  |  |
|  | Large field trial                          |  |  |  |  |
|  | General release                            |  |  |  |  |
| Category B                                 | Food and feedstuffs                        |  |  |  |  |
| Category C                                 | Transit                                    |  |  |  |  |

| Category D | Importation            |
|------------|------------------------|
| Category E | Exportation            |
| Category F | Large scale production |

NB Applicants of category A should fill in Part A of Second Schedule

Applicants of category B should fill in Part B of Second Schedule

Applicants of categories C. D. E and F should fill in applicable parts of Part A & Part B of Second Schedule.

Have you applied for a similar permit before?

#### Yes

No

Give outcome of decision if Yes?

#### Approved

# Rejected

Applying for a GMO permit shall not entitle the applicant not to apply for any licence, permit or approval as required under any other enactment.

Give previous permit number:

Has your proposal been given the clearance by your Institutional Biosafety Committee?

.....

# **3.** NATURE OF GMO

Microorganism

Animal

Others, please specify.....

# 4. CONFIDENTIALITY

Can the decision be publicly released?

Yes

No

#### PART II - SPECIFIC INFORMATION

# 5. INFORMATION ON RESPONSIBLE PARTY/PRINCIPAL INVESTIGATOR OF PROPOSED PROJECT

Name of Responsible Person /Principal Investigator:

| Name of Institution/Laboratory/Firm:          |
|---|
| Address:                                      |
|   |
| Tel.:   |
| Email address                                 |
| Name of other persons involved in the project |

|    | (i)  |
|----|--|
|    |  |
|    |  |
|    | (ii)   |
|    |  |
|    | (iii)  |
|    |  |
|    | Background and experience of persons involved: |
|    |  |
|    | Title of project:                              |
|    | Title of project:                              |
| 6. | DESCRIPTION OF PROPOSED DEALING                |
|    |  |
|    |  |
|    |  |
|    |  |
|    |  |
| -  |  |
| 7. | DURATION OF PROPOSED DEALING                   |
|    | Expected date of commencement:                 |
|    |  |
|    | Expected date of completion:                   |
| 8. | PURPOSE AND AIMS OF PROPOSED DEALING           |
|    |  |
|    |  |
|    |  |
|    |  |
|    | ·····  |

6.

7.

8.

.....

# 9. JUSTIFICATIONS AND BENEFITS OF THE PROPOSED DEALING

| ••••••••••••••••••••••••••••••••••••••• | • | •••••• | • |
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# **10. SCALE OF PROJECT**

Volume or area to occupy:....

Will the material be destroyed after the experiment?

Yes

#### No

If yes, give details of proposed method to eliminate or remove the GMO from the test site upon completion of the experiment:

.....

.....

.....

If no, give details of future plans:

# 11. DESCRIPTION OF INFRASTRUCTURE INVOLVED IN EXECUTION OF PROPOSED DEALING

# **26**.

# 27. Details on laboratory, greenhouse, storage and any other facilities involved

Location of site (provide map of trial site):.....

Facility type (laboratory, greenhouse, insectary, etc.):.....

Physical containment level: .....

Date of registration of facility:

Registration number:....

Date of recent inspection:

# 12. DESCRIPTION OF PACKING CONDITIONS

Proposed method of packaging (if applicable):....

Description of labelling (attach label if available):.....

# PART III - INFORMATION ON PROPOSED DEALING

# 13. ORIGIN OF GMO

| Port of Entry:                 |   |
|--------------------------------|---|
| Means of                       | Air   |
| shipment                       | Sea   |
| Proposed mode of tra           | ansport inland:   |
| Final Destination (if          | transit):   |
| Information on Exporter:       | Name of Company:  |
|                                | Address:  |
|                                | Contact Person:   |
|                                | Tel.:   |
|                                | Fax:  |
|                                | Email address:  |
| Please attach evidence to cert | tify that the Exporter is an authorised dealer of GMOs. |
| Information on Importer:       | Name:   |
|                                | Address:  |
|                                | Contact Person:   |
|                                | Tel.:   |
| Fax:                           |   |
|                                | Email address:  |
| 14. FULL DESCRIPTIO            | ON OF THE GMO   |
| PLANT                          | Family name :   |

|                | Genus:   |
|----------------|--|
|                | Species:   |
|                | Sub-species:   |
|                | Cultivar/breeding line:                                |
|                | Common name:   |
|                | Give information on the mode(s) of reproduction of the |
|                | plant:   |
| MICROORGANISM: |  |
|                | Bacterium  |
|                | Fungus   |
|                | Virus  |
|                | Mycoplasma   |
|                | Name:  |
|                | Genus:   |
|                | Species:   |
|                | Sub species:   |
|                | Strain:  |
| ANIMAL         |  |
|                | Family name:   |
|                | Genus:   |

|     |                | Spe               | cies:        |            |                                 |     |            |
|-----|----------------|-------------------|--------------|------------|---------------------------------|-----|------------|
|     |                | Bree              | eding line:  |            |                                 |     |            |
|     | OTHERS (Ple    | ease specify)     |              |            |                                 |     |            |
|     |                |                   |              |            |                                 |     |            |
|     |                |                   |              |            |                                 |     |            |
| 15. | AMOUNT OI      | F GMO             |              |            |                                 |     |            |
|     | Units, weight, | volume:           |              |            |                                 |     |            |
| 16. | DETAILS OF     | <b>PRODUCT</b>    |              |            |                                 |     |            |
|     | Description of | f product:        |              |            |                                 |     |            |
|     | What are the b | penefits of the   | proposed GN  | IO?        |                                 |     |            |
|     | Description of | f the gene intro  | duced:       |            |                                 |     |            |
|     | Method used i  | in introducing    | the gene:    |            |                                 |     |            |
|     | Has the produ  | ct been tested/   | commercializ | zed elsewh | ere?                            |     |            |
|     | What are the r | results of the te | ests?        |            |                                 |     |            |
|     |                | nce of the resu   |              |            |                                 |     |            |
|     |                |                   |              |            |                                 |     |            |
|     |                |                   |              |            |                                 |     |            |
|     | How do         | o you             | verify       | for        | the                             | GMO | concerned? |
|     |                |                   |              |            | • • • • • • • • • • • • • • • • | •   |            |

What potential hazardous or deleterious effects resulting from the trial release of the GMO can be anticipated?

.....

# 17. RELEVANT PUBLICATIONS ON THE GMO (Provide a list)

\_\_\_\_\_

# 18. GENERAL INFORMATION ON GMO OR DERIVATIVES TO BE INTRODUCED

|                   | Parent Organism | Recipient |
|-------------------|-----------------|-----------|
| Scientific name   |                 |           |
| Common name       |                 |           |
| Commercial name   |                 |           |
| Other designation |                 |           |

.....

Signature of Applicant

Date

For official use only

Date received: Application No: Approved or Rejected: If rejected, give reasons why ..... ······

.....

.....

Chairman, National Biosafety Committee Date

SECOND SCHEDULE

[section 7(3)]

# 1. PART A

# INFORMATION ON RISK ASSESSMENT OF GENETICALLY MODIFIED ORGANISMS FOR CONTAINED, CONFINED AND GENERAL RELEASE

# 1. **IDENTITY OF GMO**

.....

# 2. **BENEFITS**

Describe the benefits to be gained through the GMO, e.g, agronomic gains, improvement of nutritional quality or pest resistance, etc:

.....

# 3. NATURE OF ORGANISM AND NOVEL GENETIC MATERIAL

3.1 Identity of organism: Scientific name of parent organism: Common name of parent organism: Modified trait: 3.2 Is it known whether the unmodified form(s) have any adverse effect on: i. Humans, animals or plants? ii. Agricultural production? Any other aspect of the environment? iii. ..... 3.3 Give a description of the genetic and resultant phenotypic modification of the GMO. Provide information on (i) the source of inserted DNA, (ii) the outline of the DNA construct, (iii) the nature and source of the vector and procedure used to introduce the gene and (iv) the extent to which it has been characterised: .....

.....

..... ..... ..... Is the gene inserted a pathogenic determinant capable of causing disease in human beings, 3.4 animals or plants? ..... ..... ..... ..... 3.5 Is the gene introduced stable? ..... ..... ..... What is the frequency of reversion, that is, loss of genetic modification? 3.6 .....

.....

3.7 How do you verify for the presence of the gene?

.....

.....

3.8 Have similar tests/releases of similar GMOs been made before, either within or outside this country?

.....

3.9 What data are available to suggest that the introduced genetic trait has no deleterious effect in the long term upon the species into which it has been introduced or allied species or any other organisms or the environment in general?

.....

3.10 Does the GMO differ from the parental or recipient organism (e.g mode of reproduction, dissemination, survivability)?

.....

.....

If so, please give details: ..... ..... What experimental results/information are available to show the probable consequences 3.11 of of (positive negative) the release the GMO? or ..... •• ..... 3.12 Does the GMO have any impact on i. Human, animal, plant health? ..... ii. Agricultural production? ..... Target and non-target organisms? iii. ..... . . . . . . . . . . . . . . . . . . .

iv. The general ecology, biodiversity?

. . . . . . . . . . . . . . . . . . . Has a trial release been carried out in the country of origin of the GMO? 3.13 ..... 3.14 Can the genetic trait be transmitted by means other than by normal reproduction? ..... ..... 3.15 Has the introduced gene been shown to be toxic to animals and humans? ..... ..... ..... 

3.16 Is there a risk of harm to the environment associated with the dispersal of the organism or the gene concerned?

| 41   | Give the location size of field trial(s) or release site(s) (provide map of site) as well as |
|------|--|
| 4.   | DETAILS OF FIELD TRIALS AND GENERAL RELEASE  |
|      |  |
|      |  |
|      |  |
|      |  |
|      |  |
|      |  |
|      | ·····  |
|      |  |
|      |  |
|      | from containment/confinement:  |
| 3.17 | List details of action proposed to be taken in case of an accidental release of the GMO      |
|      |  |
|      |  |
|      |  |
|      |  |
|      |  |
|      |  |
|      |  |
|      |  |
|      |  |

4.1 Give the location, size of field trial(s) or release site(s) (provide map of site) as well as isolation distances from other trials:

-----

······

4.2 Describe the ecosystem including slope, climate, flora and fauna, presence of endangered species, including information on natural predators and parasites surrounding the field trial or release site:

.....

4.3 List any sexually compatible wild relatives or cultivated plant species present around the trial or release site:

.....

4.4 Describe the barriers planned in order to segregate the experiment/trial release from the surrounding environment:

.....

.....

4.5 How will the supervision and monitoring be carried out during and after the trial release?

.....

4.6 Provide details of how the plant materials including wastes will be eliminated after the trial (herbicidal treatment, incineration, etc):

.....

4.7 Provide contingency plans to deal with unforeseen circumstances such as cyclone, flood etc. during the course of the trial:

| 4.8 | Give | the | duration | of | the | trial | or | release: |
|-----|------|-----|----------|----|-----|-------|----|----------|
|     |      |     |          |    |     |       |    |          |
|     |      |     |          |    |     |       |    |          |
|     |      |     |          |    |     | ••••• |    | •••••    |
|     |      |     |          |    |     |       |    |          |

## 5. ADDITIONAL INFORMATION FOR GENTICALLY MODIFIED PLANT

You must also fill in this part if you are proposing to deal with a GMO that is a plant.

## 5.1 Information about the use of the parent plant

State whether the parent plant has an extended history of cultivation and safe use:

.....

·····

## 5.2 Information about any unintended pleiotropic effects

Give details of any undesirable effects on the parent plant that- may result from expression of the transgene, or an associated insertion-related mutation, in the GMO (for example, reduced fertility, increased disease prevalence, production loss, grain shredding), including the likelihood of any such events:

## 5.3 Information about pollen and cross-pollination

5.3.1 Describe the mechanism of pollen spread (by insect vectors or by any other means) in the plant population:

5.3.2 Give details of pollen viability for the parent plant and the GMO:

5.3.3 Provide details of any potential pollinators for the parent plant and the GMO, and their range and distribution in Mauritius:

······

.....

.....

5.3.4 Are quantitative data available on successful cross-pollination between the parent plant, the GMO and its wild relatives?

······

5.3.5 List only sexually compatible plants near the site of the proposed release and provide details of the quantity and the chances for cross-pollination with the GMO:

.....

.....

5.3.6 If cross-pollination with the GMO were to occur, provide details of the likely resulting plants and an assessment of whether they would survive and compete well with unaffected plants:.....

## 5.4 Information about weeds

5.4.1 List members of the family of unmodified parent plants that are known to be weeds in any environment:

······

5.4.2 Give details of cross-pollination between the species to which the GMO belongs and relatives known to be weeds, including a copy of any peer-reviewed reports that support the information:

.....

# 5.5 Information about the possible result of the imparted characteristics being integrated into other species

- 5.5.1 State whether the novel characteristics of the GMO could be integrated into other species and if so, provide details of its potential to affect:
  - 1. the distribution and abundance of populations of the affected species; and
  - 2. factors that normally control populations of the affected species in the environment (for example, pathogens, herbivory and physiological stress)

5.5.2 List any other possible adverse consequences:

-----

5.5.3 Give details of proposed measures to minimise the risk (for example, by imparting male sterility or other means of reproductive isolation):

.....

.....

# PART B

INFORMATION ON RISK ASSESSMENT OF FOOD AND FEEDSTUFFS DERIVED FROM GENETICALLY MODIFIED ORGANISMS

# 1. DESCRIPTION OF THE GMO

1.1 Name of GMO from which the Food and Feedstuffs is derived:

.....

.....

1.2 Give a description of the genetic and resultant phenotypic modification of the GMO:

.....

.....

.....

1.3 Describe (i) the source of the inserted DNA, (ii) the outline of the DNA construct, (iii) the vector and procedure used to introduce the gene and (iv) the extent to which it has been characterised:

| 1.4 | Which of the following characteristics have been introduced in the GMO? |                                 |  |  |  |  |  |  |
|-----|---|---------------------------------|--|--|--|--|--|--|
|     | i.  | Pesticidal properties           |  |  |  |  |  |  |
|     |   |                                 |  |  |  |  |  |  |
|     | ii.   | Resistance to Plant Pathogen    |  |  |  |  |  |  |
|     | <br>iii.  | Insect resistance               |  |  |  |  |  |  |
|     | iv.   | Herbicide resistance            |  |  |  |  |  |  |
|     |   |                                 |  |  |  |  |  |  |
|     | v.  | Antibiotic resistance           |  |  |  |  |  |  |
|     |   |                                 |  |  |  |  |  |  |
|     | vi.   | Environmental stress resistance |  |  |  |  |  |  |

..... vii. Nutritional improvement (e.g protein modification, carbohydrates, fatty acid) ..... viii. Others, please specify ..... 1.5 Is the GMO commercialised? If so, list the countries where it is marketed: ..... ..... Provide name and address of the supplier: ..... ..... ..... 

..... ..... 1.6 Does the GMO has any impact on: i. Human, animal, plant health? ..... Agricultural production? ii. ..... Target and non-target organism? iii. ..... The general ecology, diversity? iv. ..... 2. **FOOD AND FEEDSTUFFS** Describe the product derived from the GMO: 2.1 ..... .....

2.2 What is the proportion of the GMO in the food/feedstuffs?

2.3 What method can be used to verify that you have the desired GMO?

.....

2.4 What methods are to be used to test for batch to batch consistency?

.....

2.5 How does the food/feedstuff ingredient from the genetically modified plant differ from the same food/feedstuff ingredient derived from the unmodified host?

······

2.6 Has the food/feedstuff derived from the GMO been shown to be substantially equivalent to an existing food or food component?

······

## 3. HUMAN AND ANIMAL HEALTH

3.1 Has any adverse effect on health been demonstrated upon consumption of the food/feedstuffs derived from the GMO in humans and animals? Provide results of any trials carried out:

| 3.2 | Provide information of any toxic or allergenic effects observed from the consumption of the food/feedstuffs derived from the GMO: |
|-----|---|
|     |   |
|     |   |
|     |   |
|     |   |
|     |   |
| 3.3 | Could any toxic products concentrate in natural and human food chain?   |
|     |   |
|     |   |
|     |   |
|     |   |
|     |   |
|     |   |

# 4. ENVIRONMENTAL SAFETY

4.1 Has any adverse effect of the release of the GMO food/feed on environment been demonstrated?

-----

.....

4.2 What are the precautionary measures forecast to prevent accidental propagation of the GMO (e.g GM maize seed, germination and growing)?

.....

## 5. LABELLING

5.1 Give the proposed commercial name of the product:

.....

5.2 Describe the labelling details on packaging:

.....

## 6. ADDITIONAL RELEVANT INFORMATION

6.1 What are the measures to be taken in the event of the escape of the organisms in the product or misuse of the product:

.....

······

6.2 Give details of specific instructions or recommendations for storage and handling of the product including transportation inland:

|                     |                 |       | <br>      | <br> | <br> | <br> | <br> |
|---------------------|-----------------|-------|-----------|------|------|------|------|
|                     |                 |       | <br>      |      |      |      |      |
|                     |                 |       | <br>      | <br> | <br> | <br> | <br> |
|                     |                 |       | <br>      |      |      |      |      |
|                     |                 |       |           |      |      |      |      |
|                     |                 |       | <br>      | <br> | <br> | <br> | <br> |
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