Statutory Instrument 105 of 2026.

**[CAP. 14:31**

National Biotechnology Authority (Contained Use, Confined Field Trial and General Release of Genetically Modified Organisms) Regulations, 2026

ARRANGEMENT OF SECTIONS

PART I

PRELIMINARY

*Section*



PART II

CONTAINMENT MEASURES



PART III

APPLICATION FOR CONTAINED USE, CONFINED FIELD TRIAL AND GENERAL RELEASE OF GENETICALLY MODIFIED ORGANISMS

IT is hereby notified that the Minister of Higher and Tertiary Education, Innovation, Science and Technology Development has, in terms of section 59 of the National Biotechnology Authority Act [*Chapter 14:31*] and after consultation with the Research Council and the Authority made the following regulations:—

## PART I

## PRELIMINARY

### *Title*

1. These regulations may be cited as the National Biotechnology Authority (Contained use, Confined Field Trial and General Release of Genetically Modified Organisms) Regulations, 2026.

*Interpretation*

2. In these regulations—

"Act" means the National Biotechnology Authority Act [*Chapter 14:31*];

"biosafety level" means a specific combination of containment precautions (work practices, safety equipment and facilities) required to isolate biological agents in an enclosed facility and minimise the exposure of workers and the environment to infectious agents;

"biological diversity" means biological diversity as defined in the United Nations Convention on Biological Diversity adopted in 1992;

"confined field trial" means any activity undertaken within a field which involves genetically modified organisms that are controlled by specific measures to ensure safety for humans, animals and the environment;

"contained use premises" includes a laboratory, greenhouse, installation or other physical structure in which contained use is undertaken;

"facility" includes laboratory, greenhouse, animal house and confined field trial site;

"risk assessment" means the identification and evaluation of 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.

*Purpose*

3. (1) The purpose of these regulations is to ensure that potential adverse effects, arising from the research, manipulation, production, cultivation, movement, trade and use of genetically modified organisms are controlled to protect human health and biological diversity during contained use, confined field trial or general release.

(2) For the purposes of these regulations research refers to genetically modified organisms related activities carried out in the laboratory, greenhouses or field.

(3) These regulations will be used in conjunction with a number of guidelines subject to review from time to time in response to policy change, technological advancements and any other unanticipated incidents which may call for reviewing of these guidelines.

*Oversight bodies and agencies*

4. (1) The Authority shall—

(a) be the competent authority for all matters to do with genetically modified organisms, in accordance with the provisions of the Act.

(b) work closely with relevant regulatory agencies on decisions pertaining to contained use, confined field trials and general release of genetically modified organisms and their derivatives.

(2) Relevant regulatory agencies shall include, agencies under the Ministries responsible for Agriculture, Health and Environment.

## PART II

### Containment Measures

*Classification of containment levels*

5. (1) The Authority shall ensure that all appropriate measures are taken to avoid adverse effects on human health and biological diversity, which might arise from the contained use of a genetically modified organism.

(2) The Authority, in consultation with all relevant regulatory agencies, shall assess the suitability of a premise to conduct contained use activity involving genetically modified organism.

(3) Upon carrying out an assessment the Authority, in consultation with all relevant regulatory agencies, shall determine the

containment level required of a contained use premise in accordance with relevant guidelines provided by the Authority.

(4) The containment levels under these regulations shall apply to laboratory, animal house and greenhouse activities as well as transit of genetically modified organisms.

*Institutional Biosafety Committee*

6. Any institution undertaking contained use or confined field trial activities shall establish an Institutional Biosafety Committee (IBC) whose constitution and duties shall be in accordance with section 30 of the Act.

## PART III

## Application for Contained use, Confined Field Trial and General Release of Genetically Modified Organisms

*Application for permit*

7. (1) No person shall carry out contained use, confined field trial and general release for genetically modified organisms, without the approval of the Authority.

(2) An application for a permit to conduct activities referred to in subsection (1) shall be made in terms of section 25 of the Act in Form NBA (GMO) 1 as specified in the First Schedule and it shall be accompanied by a fee set out in the Second Schedule.

(3) On receipt of the application, the Authority shall confirm—

(a) its completeness;

(b) compliance of the application with the requirements of these regulations;

(c) the accuracy and comprehensiveness of submitted information;

(d) the risk assessment report submitted as part of the application.

(4) Upon receipt of the risk assessment report referred in subsection 3(d), the Authority may conduct a risk assessment and make recommendations for decision making.

(5) Where necessary, the Authority may request for more information from the applicant.

(6) Upon being satisfied that the application meets the requirements stipulated in the Act and these regulations the Authority—

(a) shall review the risk assessment report and make recommendations for decision making;

(b) may approve the application and issue a permit subject to specified conditions; or

(c) may reject the application and give reasons.

(7) Any period during which the Authority is awaiting for additional information requested, from the applicant, shall be excluded from the timeline for decision making.

(8) No person shall conduct contained use or confined field trials other than in a facility registered by the Authority in terms of section 24 of the Act.

(9) Any person who contravenes subsection (1) and (8) shall be guilty of an offence and liable to a fine not exceeding level 12 or imprisonment for a period not exceeding five years or both such fine and such imprisonment.

(10) In the event of conduct of contained use or release of a genetically modified organism for which no approval was granted, the Authority shall—

(a) destroy the genetically modified organism and the product; and

(b) confiscate the facility.

*Issuance and validity of permit of contained use, confined field trial and general release*

8. (1) On approval of an application for contained use, confined field trial and general release the Authority shall—

(a) inform the applicant accordingly;

(b) issue to the applicant a permit for contained use, confined field trial or general release in Form NBA (GMO)2,

NBA(GMO)3 or NBA (GMO)4 as specified in the Third Schedule;

(c) make an appropriate entry in the Register of permits; and

(d) in the case of a general release, publish in the *Gazette*.

(2) The validity of a permit for—

(a) contained use and confined field trial shall be three years;

(b) general release shall be ten years.

(3) The Authority shall oversee the post release monitoring and evaluation of the product of a general release.

(4) An approval for the contained use, confined field trial or general release is not transferable.

(5) During the period of the approved contained use, confined field trial or general release, a holder of a permit shall submit a report on the progress of the activity.

*Cancellation of permit of contained use, confined field trial and general release*

9. (1) The Authority may at any time cancel any permit if the Authority has reasonable grounds for believing that—

(a) the permit was issued in error or through fraud or misrepresentation or non-disclosure of a material fact;

(b) the holder of a permit has contravened any provision of the Act or these regulations or any condition of its permit; or

(c) the holder of a permit has ceased the permitted activities.

(2) The Authority shall notify the holder of a permit in writing of its intention to cancel its permit and the reasons for doing so, and shall call upon the holder of a permit to show cause, within fourteen (14) days from the date of the notice, why the permit should not be cancelled:

Provided that if in the opinion of the Authority the continuous carrying out of activities by the holder of a permit may endanger public safety and biodiversity, the Authority may suspend for the purposes of concluding its investigations for a period not exceeding 30 days, the permit holder from conducting activities related to the permit.

(3) If, at the expiry of the period specified in the notice given in terms of subsection (2), and after considering any representations made by the holder of a permit—

(a) the Authority is satisfied that the permit must be cancelled, the Authority shall, by notice in writing to the holder of a permit, cancel the permit and take such other measures as it deems fit;

(b) the holder of a permit has satisfactorily justified why their permit must not be cancelled, the Authority shall withdraw the suspension and allow the permit holder to carry out the activities as before.

(4) If after the expiry of the period referred to in subsection (2) the holder of a permit does not submit any representation why their permit must not be cancelled, the Authority shall forthwith cancel the permit.

(5) Where the Authority suspends, lifts a suspension of any permit or cancel a permit it shall immediately make an appropriate entry in the register of permits.

*Handling of new information*

10. (1) Where a holder of a permit becomes aware of new information which could have significant consequences for the risks posed by the genetically modified organisms, the holder of a permit shall inform the Authority of such information immediately and in any case no later than 48 hours.

(2) Any person whose duty it is to provide information to the Authority but wilfully withholds any information which could reasonably be expected to change the evaluation of the risk posed by the activity shall be guilty of an offence and liable to a fine not exceeding level 5 or imprisonment for a period not exceeding one year or both such fine and such imprisonment.

(3) Where information subsequently becomes available to the Authority, which could have significant consequences for the risks posed by the genetically modified organisms, the Authority may modify the conditions of, or suspend or cancel the permit.

(4) A person who has been granted a permit, who wishes to modify the contained use or release, may make a written request to the Authority and the Authority shall within thirty days acknowledge receipt of the request.

(5) The Authority shall review the request and where it considers that—

(a) the modification does not require risk assessment the Authority shall communicate its decision within thirty days from the date of the receipt of the request; or

(b) the modification may have material effect on the outcome of the risk assessment upon which the decision was based, the Authority shall, if satisfied that a change is warranted, request for an updated risk assessment report from the applicant for review and make a decision within one hundred and twenty days from the date of the receipt of the request.

*Contingency plans for contained use and confined field trial*

11. (1) The Authority shall ensure that before activities commence, the applicant draws up short-term and long-term contingency plans for contained use and confined field trial as provided in Form NBA (GMO) 5 as specified in the Fourth Schedule to mitigate risks to human health and biodiversity within or outside the premises.

(2) In the event of an accident, the holder of a permit shall notify the Authority as stipulated in section 27 of the Act.

*Risk Management Plan*

12. (1) The Authority shall ensure that any holder of a permit of general release provides a comprehensive risk management plan prior to commencement of any activity.

(2) The Risk Management Plan referred to in subsection (1) shall, at a minimum, delineate the specific short-term and long-term risk management strategies and control measures to be employed during the general release.

(3) The holder of a permit shall at all times maintain the Risk Management Plan in a state of operational readiness.

(4) In the event that an audit, monitoring activity, or simulation reveals a deficiency in the Risk Management Plan, or where new scientific evidence becomes available regarding potential risks to human health or biodiversity, the holder shall forthwith revise the plan and submit the amendments to the Authority for written approval prior to implementation.

*Amendment and replacement of permit*

13. (1) The Authority may at any time amend a permit or any terms or conditions thereof—

(a) to correct any error in the permit; or

(b) if the holder of a permit requests the amendment; or

(c) in the public interest.

(2) The Authority shall notify the permit holder in writing of its intention to amend a permit on a ground referred to in subsection (1)(a), (b) or (c).

(3) Where a permit holder requests an amendment to a permit, the holder of a permit shall make an application to the Authority therefore in Form NBA (GMO)6 as specified in the Fifth Schedule, together with a fee specified in the Second Schedule.

(4) Where it is established by the Authority that the amendment sought by the applicant changes the original permit in material respect, the Authority shall advise the holder of a permit to make an application in terms of section 7.

(5) Where a permit is lost or destroyed, the holder of a permit may apply to the Authority in Form NBA (GMO)6 for a replacement permit together with the fee specified in the Second Schedule:

Provided that if the holder of a permit finds the permit, he or she shall forthwith surrender it to the Authority.

(6) Any person who contravenes the proviso to subsection (5) shall be guilty of an offence and liable to a fine not exceeding level 5 or imprisonment for a period not exceeding one year or to both such fine and such imprisonment.

*Register of genetically modified organisms permits*

14. (1) The Authority shall establish and maintain a register for the purpose of registering all activities involving genetically modified organisms as stipulated in section 23 of the Act.

(2) The Authority shall keep and maintain the register in both material and electronic form.

## PART IV

### Facilities

*Subletting of facilities*

15. (1) No owner of a facility shall sublet the facility without approval of the Authority.

(2) In case the owner of a facility wishes to sublet the facility to a third party they must enter into an agreement which shall be approved by the Authority.

(3) Any owner of a facility who contravenes subsection (1) and (2) shall be guilty of an offence and liable to a fine not exceeding level 12 or to imprisonment not exceeding five years or to both such fine and such imprisonment.

*Public awareness and participation*

16. (1) The Authority shall promote awareness and participation of the general public on genetically modified organisms issues.

(2) The Authority shall—

(a) by notice in the *Gazette*;

(b) in at least two newspapers of wide circulation; and

(c) on its website;

make available to the public information on applications for general release of genetically modified organisms.

(3) Any person may submit written comments on any application for general release of a genetically modified organism within twenty-eight (28) days from the date of the notice.

*Decision to application*

17. The Authority's decision on an application shall be recorded on the Biosafety Clearing House and by notice in the *Gazette*.

*Monitoring*

18. (1) A holder of a permit shall continuously conduct monitoring exercises for every contained use, confined field trial and general release and report to the Authority from time to time.

(2) Notwithstanding subsection (1), the Authority may from time to time conduct inspections in terms of section 33 of the Act.

FIRST SCHEDULE (*Section 7*)

Application for Contained Use, Confined Field Trial or General Release of GMOs under the National Biotechnology Authority [*Chapter 14:31*].

| | |
|---|---|
| 1. Applicant:<br>(a) Name: | |
| (b) Address: | |
| (c) Telephone Number: | |
| (d) Email Address: | |
| 2. Details of Contact Person:<br>(a) Name: | |
| (b) Designation: | |
| (c) Address: | |
| (d) Telephone Number: | |
| (e) Email address: | |

| | |
|---|---|
| 3. In accordance with the National Biotechnology Authority Act I hereby apply for: | Contained Use ☐<br>Confined Field Trial ☐<br>General Release ☐<br>Amendments ☐<br>**tick applicable* ☐ |
| 4. GMO Type: | Plant ☐<br>Animal ☐<br>Microorganism ☐<br>Vaccine ☐<br>Other ☐<br>**tick applicable* |
| 5. Information on the Unmodified Organism | |
| 6. (a) Information on the GMO and Genetic Modification | |

| **Taxonomic Details** | **GMO Trade Name** | **Unique identifier of the genetically modified organism** | **Introduced/modified trait and genes** |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

| | |
|---|---|
| (b) Is the GMO registered in the country of origin? | **YES** ☐<br>**NO** ☐<br>**NB:** If yes please attach Registration Certificate |
| (c) Intellectual property ownership of the novel trait, if any | |
| (d) Description of Modification | |
| 7. Information on the Donor Organism | |
| 8. Information on Intended Use and Receiving Environment | |

9. Application Components
   (a) I have attached the following to this application form (Highlight using a tick):

(i) Completed Questionnaire.
(ii) Reports of analysis of product from accredited/approved laboratories.
(iii) Detailed Trial Report.
(iv) Product Certificate from Country of origin.
(v) Expired Certificate/The one to be amended.
(vi) Amendment letter (clearly stating and justifying reasons for amendment).
(vii) Post Registration Monitoring Plan.
(viii) Declaration of intellectual property or patents or 'commercial-in-confidence' information.

(b) Name of Applicant: _____

Position within the applying organisation: _____

Date of Submission: _____

Signature: _____

Official Stamp of applying Organisation should be placed here

**FOR OFFICIAL USE OF REGISTERING AUTHORITY ONLY**

..... .....

Name of Officer Designation

.....

Signature Date and Stamp

1. Receipt No.: .....

2. Recommendation of registering authority (fill in where appropriate):

(a) Approval without conditions recommended: .....
.....

(b) Approval recommended subject to the following conditions:
.....

(c) Rejection recommended for the following reasons: .....
.....

**NOTIFICATION PARTICULARS**

The decision on this application was notified to the applicant:

ON..... SIGNED.....

SECOND SCHEDULE (*Sections 7 and 13*)

FEES

| Section | Description | US$ or ZWG equivalent |
|---|---|---|
| (7) | Permit for contained use<br><br>Permit for confined field trial | Fee specified in the National Biotechnology Authority (Biotechnology Facility Registration) Regulations<br><br>2 000 |
| (7) | Permit for General Release | 5 000 |
| (12) | Amendment of Permit | 300 |
| (12) | Replacement of Permit | 50 |

*Inspection Fees*

| Item | US$ or ZWG equivalent |
|---|---|
| 1. Contained Use<br>2. Confined Field Trial | Inspection: Human expertise fee per inspector per day – 50<br><br>Inspection fees exclude accommodation and meals. In the case that the inspectors may need to sleep over for any number of days, the cost will be borne by the client.<br><br>Transport: Clients will meet transport costs and these will be charged using the prevailing Automobile Association of Zimbabwe rates. |

THIRD SCHEDULE (*Section 8*)

PERMIT FOR CONTAINED USE, CONFINED FIELD TRIAL AND GENERAL RELEASE OF GMOS

NBA (GMO) 2

NATIONAL BIOTECHNOLOGY AUTHORITY

21 Princess Drive Newlands, Harare
Tel: +263 242 782856/ 782167/ 782155
E-mail: nba@nba.ac.zw

Permit of Contained Use of Genetically Modified Organisms

*National Biotechnology Authority Act (Chap:14:31) of 2006*

This permit approves

**XXXX XXX** to conduct contained use activities for the project titled: ABC

NAME OF GENETICALLY MODIFIED ORGANISM: XYZ

In accordance with the NBA Act [*Chap. 14:31*] of 2006 Section 33; the NBA may at fixed intervals agreed with the registered user of the GMO or at any time without giving prior notice enter upon and inspect progress to ensure adherence to permit conditions.

.....

*CEO & Registrar, National Biotechnology Authority*

*Permit Number*.....
*Permit Issue Date*.....
*Permit Expiry Date*.....

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www.nba.ac.zw

NBA (GMO) 3

NATIONAL BIOTECHNOLOGY AUTHORITY

21 Princess Drive Newlands, Harare
Tel: +263 242 782856/ 782167/ 782155
Email: nba@nba.ac.zw

## Permit of Confined Field Trial of Genetically Modified Organisms

*National Biotechnology Authority Act (Chap :14:31) of 2006*

This permit approves

**XXXX** to conduct a confined field trial of

Product name:

In accordance with the NBA Act [*Chap. 14:31*] of 2006 Section 33; the NBA may at fixed intervals agreed with the registered user of the GMO or at any time without giving prior notice enter upon and inspect progress to ensure adherence to permit conditions (see attached conditions).

*Permit Number*.....
*Permit Issue Date*.....
*Permit Expiry Date*.....

.....

***CEO & Registrar, National Biotechnology Authority***

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*www.nba.ac.zw*

NBA (GMO) 4

NATIONAL BIOTECHNOLOGY AUTHORITY

21 Princess Drive Newlands, Harare
Tel: +263 242 782856/ 782167/ 782155
E-mail: nba@nba.ac.zw

## Permit of General Release of Genetically Modified Organisms

*National Biotechnology Authority Act (Chap :14:31) of 2006*

PERSUANT TO THE PROVISIONS OF THE NATIONAL BIOTECHNOLOGY AUTHORITY ACT [*CHAP 14:31*] OF 2006, THE PRODUCT DESCRIBED HEREUNDER HAS BEEN FOUND TO CONFORM TO THE REQUIREMENTS AND STANDARDS FOR THE GENERAL RELEASE OF GENETICALLY MODIFIED ORGANISMS:

This permit approves XXXXX to release a Genetically Modified Organism into the environment.

**PRODUCT NAME:**

**MANUFACTURER:**

**CONDITIONS:** see attached.

.....

***CEO & Registrar, National Biotechnology Authority***

*Permit Number.....*
*Permit Issue Date.....*
*Permit Expiry Date.....*

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FOURTH SCHEDULE (*Section 11*)

TITLE: Contingency Plan for Contained Use or Confined Field Trial of GMOS under the National Biotechnology Authority Act [*Chapter 14:31*] of 2006.

TO: The Chief Executive Officer and Registrar
National Biotechnology Authority

| | |
|---|---|
| 1. Name of Applicant | 2. Address of Workplace |
| 3. Accurate identification of contained use premisesor confined field trial site where the genetically modified organism will be used and the exact location of where these premises sites or facilities are situated | |
| 4. Describe your contingency plan in the case of accidental release of GMO material (e.g. spills), or the breakdown of isolation. | |
| 5. Describe your contingency plans if after accidental release there is unexpected spread of the GMO material. | |
| 6. Provide a plan of the workplace, clearly identifying places that are important for the reduction of accident consequences, places of storage of GMOs and the protective measures of the contained/confined space | |
| 7. Provide a description of an accident that can possibly occur in space or place where the GMO will be used | |
| 8. Provide a review on how these potential accidents can have impacts on human, animal health and the environment, including the methods for detection of such impacts and effective protection measures from these impacts | |
| 9. What validated procedures are available for the detection of the presence of the GMO you will be working with? | |
| 10. What validated methods and procedures are available for the inactivation of the GMOs that will be used and for decontamination of an affected space? | |
| 11. What methods of isolation of spaces and facilities affected by accidents are in place? Include methods of control of isolation effectiveness | |
| 12. What are the methods of disposal or remediation of the plants and animals that were in the affected area at the time of the accident? | |
| 13. What procedures are to be carried out for the protection of human health and the environment in case of undesirable effects of an accident? | |
| 14. Provide a description of the procedure of subsequent monitoring of sites and premises after the termination of the remedial action. | |
| 15. What mode of communication will be used to alert the NBA and other relevant regulatory agencies of an accident? Include the manner of warning the inhabitants on its possible consequence. | |

Name of Applicant: .....

Position within the applying organisation: .....

Date of Submission: .....

Signature: .....

FIFTH SCHEDULE (*Section 13*)

Application for Amendment or Replacement of a Permit for Contained use, Confined field trial and General Release of Genetically Modified Organisms

| | |
|---|---|
| **Name and Address of Applicant:** | |
| **Contact Details** (*Phone and Email address*)**:** | |
| **NBA Permit No.:** | |
| **Date of issue:** | |
| **Application for :** | ☐ Amendment<br>☐ Replacement |
| **Reason for Amendment or Replacement:** | |
| **Contact Person** (*Name and Designation*)**:** | *Signature: ….…..* |
| **Contact Details** (*Phone and Email address*)**:** | |

**FOR OFFICIAL USE OF REGISTERING AUTHORITY ONLY**

..... .....

Name of Officer Designation

.....

Signature Date and Stamp

1. Receipt No.: .....

2. Recommendation of registering authority (fill in where appropriate):

(a) Approval without conditions recommended: .....

.....

(b) Approval recommended subject to the following conditions: .....
.....

(c) Rejection recommended for the following reasons: .....
.....

**NOTIFICATION PARTICULARS**

The decision on this application was notified to the applicant:

ON ..... SIGNED.....