National Biotechnology Authority (Agricultural Biotechnology Products) Regulations, 2018

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

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PART II

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PART III

APPLICATION FOR REGISTRATION TO IMPORT, EXPORT, COMMERCIALIZE OR CARRY OUT A TRIAL RELEASE OF BIOFERTILIZER, BIOPESTICIDES AND BIOSTIMULANTS

PART IV

APPLICATION FOR BIOSAFETY IMPORT PERMIT

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PART I

PRELIMINARY

Title

1. These regulations may be cited as the National Biotechnology Authority (Agricultural Biotechnology Products) Regulations, 2018.

Interpretation

2. In these regulations—

"Agricultural Biotechnology Products (ABPs)" means any product which contains living organisms and/or components thereof which, when applied to seeds, plant surfaces, or soil; promotes growth by increasing the supply or availability of nutrients to the host plant, or controls plant diseases, insect pests and weeds;

"Authority" means the National Biotechnology Authority;

"biofertilizers" means a substance which contains living microorganisms which, when applied to seed, plant surfaces, or soil, colonizes the rhizosphere or the interior of the plant and promotes growth by increasing the supply or availability of nutrients to the host plant;

"biofungicide" means a substance which contains naturally occurring organisms and/or their by-products that can be employed for the control of pathogenic fungi;

"bioherbicides" means preparations made up of microorganisms such as bacteria, viruses, fungi and certain insects such as parasitic wasps, painted lady butterfly that can target specific weeds;

"bioinsecticides" means naturally occurring organisms, or their by-products' that can be employed for the control of insect pests;

"biopesticides" means biological preparations of predatory, parasitic organisms, or their pesticidal substances for pest(weeds, insects, diseases) control. Viruses, bacteria, protozoa, fungi, and mites and certain plants may be used as bio-pesticides;

"biosafety" means measures that need to be taken up for the prevention of large-scale loss of biological integrity, with a primary focus on both ecology and human health or the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release in the environment;

"Biosafety Clearing House (BCH)" means a mechanism set up by the Cartagena Protocol on Biosafety to the Convention on Biological Diversity to facilitate the exchange of information on Living Modified Organisms (LMOs) and assist the parties to better comply with their obligations under the Protocol;

"biostimulant' means any biological/biologically derived substance(s) whose function when applied to plants or the rhizosphere is to stimulate natural processes to

enhance nutrient uptake, nutrient efficiency, tolerance to abiotic stress and crop quality;

"biotechnology" means any technique that uses living organisms or parts of organisms to make or modify products, to improve plants or animals, or to develop micro-organisms for specific purposes;

"export" means to send agricultural biotechnology products out of Zimbabwe;

"genetically modified organism" (GMO) means an organism the genes or genetic material of which have been modified in a way that does not occur naturally through mating or natural recombination or both, and 'genetic modification' shall have a corresponding meaning;

"GMO declaration or certificate" means an official document stating the GMO status of a product;

"Institutional Biosafety Committee (IBC)" means a biosafety committee established in terms of section 30 of the National Biotechnology Authority Act [*Chapter 14:31*];

"import" means to bring agricultural biotechnology products into Zimbabwe;

"medical biologics" means a medical product which is produced from an organism e.g. animals, humans, microorganisms and mammalian cells and are used in the treatment, prevention or diagnosis of diseases and other medical conditions;

"microorganism" means bacteria, viruses, fungi, mycoplasma, cell lines, algae, protozoans and nematodes;

"nanobiotechnology" means any of several forms of biotechnology employing devices at nano scale;

"pest" means any organism or like agent whatsoever, including a virus, which is inimical to the growth or existence of living plants or injurious to plant products or capable of producing a disease of plants in whatever stage of development it may be;

"product" means agricultural biotechnology product;

"synthetic biology" (synbio) the design and construction of new biological parts, devices, and systems, or the re-design of existing, natural biological systems for useful purposes.

"transit" means to transport agricultural biotechnology products via Zimbabwe;

"veterinary biologics" means viruses, serums, toxins, or analogous products of natural or synthetic origin which are intended for use in the management, diagnosis, prevention and treatment of animals.

Purpose

3. The purposes of these regulations pursuant to section 59 of the Act are to—

(a) regulate the import, export, transit, handling, use and application of biofertilizers biopesticides (bioinsecticides, biofungicides and bioherbicides) and biostimulants;

(b) monitor and manage the risks associated with the use of biofertilizers, biopesticides and biostimulants;

(c) provide mechanisms for enforcement of obligations arising out of the use of biofertilizers, biopesticides and biostimulants in a bid to protect the environment, animal and humans whilst enhancing food production with reduced chemical input usage.

Application

4. (1) These regulations shall apply to all biofertilizers, biopesticides and biostimulants for import, export, transit, trial and commercial release and any other purposes in Zimbabwe.

(2) These regulations shall not apply to food or feed or food and feed additives, veterinary biologics, synthetic biology products, nanobiotechnology products, medical biologics and biotechnology products used in the food industries.

PART II

Trial and Commercial Release of Biofertilizers, Biopesticides and Biostimulants

Technical committee

5. (1) The Authority shall establish an *ad hoc* technical committee which shall consist of at least three members appointed by the Authority.

(2) Selection of committee members shall be based on expertise required for a given application

(3) Appointed members can be part of more than one *ad hoc* technical committee.

(4) This committee shall be appointed for every specific application and it shall handle all matters relating to such application.

Function of committee

6. The general function of the committee shall be to advise the Authority on all aspects concerning the use of biofertilizers, biopesticides and biostimulants in agriculture and recommend commercialization or trial studies.

PART III

Application for Registration to Import, Export, Commercialize or Carry out Trial Release of Biofertilizers, Biopesticides and Biostimulants

Application for registration

7. (1) No person shall import, export, commercialize or carry out a trial release of biofertilizers, biopesticides and biostimulants without a registration certificate Form ABP 2 issued by the Authority.

(2) An application for registration shall be made to the Authority in Form ABP1 and shall be accompanied by all the necessary attachments as specified in the current guidelines and the appropriate fee prescribed in the First Schedule.

Grant or refusal for issuance

8. The Authority shall consider an application for registration within 72 hours and may —

(a) approve the application;

(b) contact the applicant requesting for further documents or information before granting the certificate;

(c) reject the application giving reasons for refusal in writing:

Provided that where an application is rejected or granted with conditions the Authority shall inform the applicant of his or her right of appeal under section 28.

Validity and renewal

9. (1) A registration certificate issued in terms of section 8 shall be valid for a period of one calendar year and may be renewed annually thereafter.

(2) A person shall apply for the renewal of the registration certificate issued in terms of section 8 at least one month before the expiry of the issued certificate.

(3) An application for the renewal of a certificate issued in terms of section 8 shall contain in addition to all the accompanying documents required for the initial registration—

(a) a copy of the expired certificate;

(b) a proposal for amending or complementing the conditions of the original approval (in case of new products);

(c) fee prescribed in the First Schedule;

(4) The Authority shall consider an application for renewal within two weeks of receiving the application and may—

(a) approve the application; or

(b) approve the application with conditions; or

(c) reject the application stating the reasons for rejection in writing; or

(d) notify the client if further documents are required.

Part IV

APPLICATION FOR BIOSAFETY IMPORT PERMIT

Application

10. (1) No person shall import biofertilizers, biopesticides or, biostimulants without an import permit Form ABP4 issued by the Authority.

(2) An application for an import permit shall be made to the Authority as in Form ABP3 and shall be accompanied by an application fee as prescribed in the First Schedule.

(3) In considering an application for a biosafety import permit, the Authority shall require the applicant's letter to—

(a) have company logo, physical and postal addresses and telephone numbers;

(b) have original author's signature, be dated and bear company's official stamp;

(c) specify type and quantity of product to be imported;

(d) specify country of origin and port through which the consignment is to enter Zimbabwe;

(e) include a GMO declaration/GMO Certificate which shall meet the following—

(i) be on original letterhead, bear physical and postal addresses and telephone numbers of the testing laboratory;

(ii) be issued by a testing laboratory accredited to a competent authority in the country in which the testing facilities are located;

(iii) have original signature of the person in charge of the testing facilities, dated and officially stamped;

(iv) bear a certificate number;

(v) state name and address of the importing organisation;

(vi) state the type, variety/brand and quantity sampled;

(vii) state place of sampling, sampling method and quantity of source material;

(viii) date of testing of not more than three months and the random sampling procedure;

(ix) provide clear specifications of the PCR analysis including : sample number, PCR Cycles, Limit of Detection (which should be not more than 0.02%).

(4) The Authority may prescribe a pre-shipment inspection prior to importation in order to gather more information on the exact nature of the product including production, GM status, quality and storage of the product and raw materials; this will be done as prescribed in Form ABP5.

Grant or refusal for issuance

11. The Authority shall consider an application for a permit within 72 hours and may—

(a) approve the application with no special conditions; or

(b) approve the application with conditions for example, a post-shipment inspection as in Form ABP6; or

(c) contact the applicant requesting further documents or information before granting the permit:

Provided that where an application is rejected or granted with conditions the Authority shall inform the applicant of his or her right of appeal under section 28.

Validity and renewal

12. (1) A permit granted in terms of section 11 shall be valid for a period of three months from the date of its issue and may be renewed if it expires before all the stated quantities have been imported.

(2) If a product fails to reach the country within the designated date on the permit, an application for renewal of the permit shall be submitted two weeks before the expiry date.

(3) An application for renewal of a permit in terms of subsection (2) shall be done only once and shall—

(a) contain all the documents required for the initial application;

(b) copy of the expired permit;

(c) provide official evidence from the customs authority with received and outstanding quantities of the product for which a renewal of the permit is being sought.

(4) The Authority shall consider an application for renewal within 72 hours of receiving the application and may—

(a) approve the application; or

(b) approve the application with conditions; or

(c) reject the application stating the reasons for rejection in writing.

PART V

GMO Declarations and GMO Certificates for Exports

Application

13. (1) No person shall export biofertilizers, biopesticides, biostimulants without complying with exportation rules as provided for in this section.

(2) An application to export shall be submitted to the Authority as in Form ABP7 and shall be accompanied by an application fee prescribed in the First Schedule and shall meet the following—

(a) have a company logo, physical and postal addresses and telephone numbers;

(b) have original author's signature, be dated and bear company's official stamp;

(c) specify type and quantity of product to be exported;

(d) state the method by which the product was produced;

(e) state mode of transport and containment measures to be taken during transportation;

(f) state the country the consignment is to be received and port through which consignment is to leave Zimbabwe.

Grant or refusal for issuance

14. The Authority shall consider an application for a GMO declaration and/ or GMO certificate within 72 hours and may—

(a) issue a GMO declaration Form ABP8 or GMO certificate Form ABP9 or both as the case maybe; or

(b) refuse to grant a GMO certificate or declaration; or

(c) contact the applicant requesting further documents or information before making a decision on granting the GMO certificate or declaration.

(d) notify the applicant if the test to be employed requires more time:

Provided that where an application is rejected or granted with conditions the Authority shall inform the applicant of his or her right of appeal under section 28.

Validity and renewal

15. (1) A GMO declaration or certificate granted under these regulations, shall be valid for a period of three months from the date of its issue and may be renewed if it expires before the stated quantities have been exported.

(2) At least two weeks before the expiry of the permit, a person can apply for the renewal of the GMO declaration or certificate.

(3) An application for renewal of a GMO declaration or certificate issued under these regulations shall—

(a) contain all the documents required for the initial application;

(b) contain a copy of the expired GMO declaration or certificate;

(c) provide official evidence from the customs authority with received and outstanding quantities of the product for which a renewal of the permit is being sought.

(4) The Authority shall consider an application for renewal within 72 hours of receiving the application and may—

(a) issue a GMO declaration or certificate;

(b) refuse to grant a GMO declaration or certificate; or

(c) contact the applicant requesting further documents or information before making a decision on granting the permit.

PART VI

BIOSAFETY TRANSIT PERMIT

Application

16. (1) No person shall transit agricultural biotechnology products across Zimbabwe without a biosafety transit permit, Form ABP12 issued by the Authority.

(2) An application for a biosafety transit permit shall be made in Form ABP11 as highlighted in Form ABP10 and should be accompanied by appropriate transit application fee prescribed in the First Schedule, a copy of the import permit issued by the receiving country indicating quantity and GMO status of the product.

(3) Consignments passing through Zimbabwe will be inspected at ports of entry and exit.

(4) Transportation of agricultural biotechnology products within Zimbabwean borders requires that the products be appropriately packaged and transported in accordance with applicable International standards e.g. IATA PI 602, IATA IP 650 depending on the nature of the consignment

Authorisation of GM products

17. In the event of transit of GMOs or GMO products the Authority—

(a) shall restrict accesses to the consignment until set protocols are observed; and

(b) shall set conditions for such transit; and

(c) require the owner of the consignment to meet any cost incurred during assessment and supervised transit as set on the biosafety transit permit.

Transiting GM products

18. (1) A person transiting GMOs or GMO products shall at the exiting port, provide a copy of the approval granted by the Authority.

(2) An approval to transit shall include—

(a) conditions issued by Authority as per the consignment;

(b) a statement that the shipment meets transit conditions under these regulations.

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

PART VII

TRIAL RELEASE

Application for a trial release permit

19. (1) No person shall carry out potentially harmful research or undertake the contained use or trial release of biofertilizers, biopesticides, and biostimulants without a valid permit issued by the Authority.

(2) An application for contained use or trial release of biofertilizers, biopesticides or biostimulants shall be made to the Authority in Form ABP14 and shall be accompanied by all the necessary attachments including Form ABP15 and as provided for in Form ABP13 and the application fee prescribed in the First Schedule.

(3) The Authority may issue an alternative version of Form AB15 depending on the nature of the agricultural biotechnology product.

Review of application

20. (1) Upon receiving an application, the Authority shall—

(a) screen the application for completeness;

(b) assess all attachments;

(c) carry out safety assessments;

(d) carry out confirmatory tests or validate methods proposed by the applicant;

(e) request for further documents or information if necessary;

(2) An applicant may—

(a) refer to data or results from previously published articles;

(b) submit additional information that the applicant considers relevant.

Approval

21. (1) The Authority shall communicate its final decision within 90 days of receipt of the application which could lead to—

(a) granting of a permit, Form ABP16; or

(b) refusal; or

(c) granting of a permit with special conditions.

(2) Where the Authority, after a risk assessment, considers that it is necessary for the proposed product to be subjected to contained, isolated or quarantined use, the Authority shall communicate its decision to the applicant in writing and relevant provisions shall apply.

(3)The Authority may opt not to supervise trial release where it feels sufficient experience or information exists to conclude that the environmental release of a proposed product does not pose significant harm to the environment.

(4)Where information is available that an approved activity poses risk to human health, animals or the environment, the Authority may amend or revoke the approval.

Monitoring

22. (1) A person issued with a permit under these regulations together with the relevant IBC shall carry out periodic monitoring of the trial release and submit reports to the Authority.

(2) The Authority shall ensure that all appropriate measures are taken to avoid adverse effects on the health of humans, animal and the environment, which might arise from the release of any agricultural biotechnology product.

(3) In the event of a release of any agricultural biotechnology product for which no approval was granted, the Authority shall ensure that—

(a) necessary measures are taken to terminate the trial release of such products;

(b) remedial action is taken, if necessary; in case of unintentional release;

(c) the public is informed and appropriately advised of such release.

PART VIII

COMMERCIAL RELEASE

Application

23. (1) No person shall place on the market; biofertilizers, biopesticides or biostimulants without a valid Product registration certificate Form ABP17 issued by the Authority.

(2) An application for a product registration certificate for biofertilizers, biopesticides or biostimulants shall be made to the Authority in Form ABP14 and shall be accompanied by all the necessary attachments including Form ABP15 as provided for in Form ABP13 and the application fee prescribed in the First Schedule.

(3) The Authority may issue an alternative version of Form ABP15 depending on the nature of the agricultural biotechnology product.

Review of application

24. Upon receiving an application, the Authority shall—

(a) screen the application for completeness;

(b) assess all attachments;

(c) carry out safety assessments;

(d) carry out confirmatory tests or validate methods proposed by the applicant;

(e) request for further documents or information.

Approval

25. The Authority shall communicate its final decision within 120 days of receipt of the application which could lead to—

(a) granting of a permit; or

(b) refusal to grant a permit; or

(c) granting with special monitoring conditions required.

Monitoring

26. If information becomes available that an approved product poses risk to human health, animals or the environment, the Authority may amend or revoke the approval and call for immediate withdrawal of the product from the market.

PART IX

MISCELLANEOUS

Monitoring for compliance and keeping of register of compliance

27. (1) The Authority shall liaise with other relevant Government regulatory agencies to monitor any imported/exported/transited agricultural biotechnology products for compliance with the regulations.

(2) The Authority shall maintain a register, which shall contain all applications made to, and decisions made by, the Authority under these regulations.

Appeals

28. (1) Any person who is aggrieved by a decision of the Authority may appeal to the Board with the prescribed fee within 14 working days from the date he or she is notified of the decision.

(2) Subject to subsection (3), the period between the lodging of the appeal in terms of subsection (1) and its determination shall not exceed 30 days, and if the appeal has not been determined after that period it shall be deemed (except in the case of an appeal against the rejection of an application for a permit or conditional granting or suspension or cancellation of a permit) to have been determined in favour of the appellant.

(3) The Board may before deciding an appeal request the appellant to make such further written submissions or supply such further information as he or she considers will be of assistance in determining the appeal, in which event the thirty day period referred to in subsection (2) shall be extended by a further period so that the appeal may be determined on a date no later than 60 days from the date when the appeal was lodged.

(4) On an appeal under this section, the Board may confirm, vary or set aside the decision or action appealed against.

(5) Upon making its determination, the Board shall notify the appellant and the Authority stating its reasons for the determination.

(6) If the determination is favourable to the appellant the Authority shall within seven working days from the date of such notification, grant to the appellant the permit in question.

(7) For the avoidance of doubt it is declared that where—

(a) an appellant whose application for a permit has been rejected or whose permit is granted conditionally or whose permit has been suspended or cancelled; and

(b) the appeal has not been determined timeously in accordance with subsection (2);

such appellant has a right under the Administrative Justice Act [*Chapter 10:28*] to apply to the High Court to compel the appellate authority

to furnish reasons why the determination of his or her appeal has not been made timeously and for such other relief that the High Court may grant under that Act.

Review of decisions

29. Where the Authority or a person granted an approval under these regulations considers that—

(a) a change in circumstances has occurred that may influence the approval or the conditions issued under the approval; or

(b) additional relevant scientific or technical information has become available, the Authority may on its own volition or on the request of the person granted the approval, review its decision.

Registration of decisions with the Biosafety Clearing House (BCH)

30. The Authority shall register all decisions pertaining to GMOs or GM products made under these regulations on the BCH.

Confidential information

31. (1) An applicant may indicate the information in the application which should be treated as confidential and shall give verifiable justification for such indication.

(2) The Authority shall make a decision on the application made in terms of subsection (1) after consultation with the applicant and the Authority shall communicate its decision in writing to the applicant.

(3) The Authority shall not disclose to a third party any information considered to be confidential and shall respect the intellectual property rights related to the information received.

(4) The Authority shall not treat or consider the following information as confidential—

(a) the name of the applicant's organisation;

(b) address of the applicant's organisation;

(c) name of contact person;

(d) e-mail address, telephone and fax number of contact person;

(e) name of the agricultural biotechnology product to be released;

(f) location and size of planned introduction;

(g) purpose of planned introduction;

(5) Where the applicant withdraws an application made in terms of this section, the Authority shall respect the confidentiality of the information declared.

Offences and penalties

32. Any person who violates the provisions of sections 7(1), 10(1), 13(1), 16(1), 19(1), 23(1) commits an offence and is liable to a fine not exceeding level 12 or to imprisonment not exceeding five years or to both such fine and such imprisonment.

FIRST SCHEDULE (*Sections 7,9,10,13, 16, 19 and 23*)

FEES

Section	*Description*	*Form*	*Fees* $US
7(2)	Application for registration	ABP1	500
10(2)	Application for a biosafety import permit:	ABP3	
	1 000 MT/m3 or Less		30
	1001 MT/m3 - 5 000 MT/m3		40
	5 001 MT/m3 - 10 000 MT/m3		50
	10 001 MT/m3 - 15 000 MT/m3		60
	Above 15 000 MT/m3		80
	Additional cost for emergency permits		20
	Permit renewal		Fee for new permit
	Amendment of permit		10

Section	*Description*	*Form*	*Fees* $US
	Inspection fee per truck		20
13(1)	Application for biosafety export permit: GMO declaration certificate	ABP7	100
13(2)	GMO Testing fee per sample		250
16(2)	Application for biosafety transit permit	ABP11	20
	Inspection: Human Expertise fee per inspector per day		50
	Transport: Clients will meet transport costs and these will be charged using the prevailing Automobile Association of Zimbabwe rates		

Key

1m3 = 1000 litres

1MT = 1000kg

Assumptions

1kg = 1 litre

1MT = 1M3 =1 000kg =1000litres

(a) Sample collection fees exclude accommodation and meals. In the case that the inspectors may need to sleep for any number of days, the cost will be borne by the client.

(b) The number of inspections will be agreed depending on duration of trial release and the nature of the product.

SECOND SCHEDULE

FORMS **ABP1**

ZIMBABWE

21, Princess Drive, Newlands
P. O. Box CY379, Harare.
Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

TITLE: Application for certificate of registration of institutions involved in biotechnology research and applications regulated under the NBA Act [*CHAPTER 14:31*] of 2006.

NOTE: *This registration form is applicable to those institutions and individuals who wish import, export, carry out trial release, commercialize, and use Biofertilizers, Biopestides and Biostimulants.*

TO: **The Chief Executive Officer and Registrar**

National Biotechnology Authority

Address .....

.....

.....

.....

I hereby apply to be recognised as a registered organisation in accordance with the National Biotechnology Authority Act:

1.—

(a) Name of organisation:.....

(b) Organisation's registration No.

.....

(Please enclose certified copies of your certificate of incorporation, CR14, tax clearance certificate and company profile)

ABP1

ZIMBABWE

21, Princess Drive, Newlands
P. O. Box CY379, Harare.
Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

(c) Physical address:.....

.....

.....

(d) Postal address:.....

.....

.....

(e) Telephone Number:.....

(f) Fax Number: .....

(g) E-mail address: .....

(h) If is desired for only a part of the organisation to be registered, clear identification, including physical location, of that part is:.....

.....

.....

2.—

(a) If the applying is par t of a group or subsidiary of a holding company, the name of that group of company:.....

.....

ABP1

ZIMBABWE

21, Princess Drive, Newlands
P. O. Box CY379, Harare.
Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

(b) If the applying organisation is controlled by or associated with a foreign company, the name and address of that group of holding company.

.....

.....

3.—

(a) Number of employees: .....

(b) Working hours from:..... to:.....

(c) Indicate shifts where applicable:.....

4.—

(a) Name and title of the head of organisation: .....

.....

(b) Name and title of the organisation representative: .....

.....

(c) What are the intended biotechnology researches and/ applications?

.....

.....

(d) Are they small or large – scale operations?

.....

ABP1

ZIMBABWE

21, Princess Drive, Newlands
P. O. Box CY379, Harare.
Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

6. Should the National Biotechnology Authority have any queries in connection with this application, the person to contact is.

Signed: .....

Position within the applying organisation:.....

Date: .....

Verified by the CEO:.....

Signature: .....

Date: .....

ABP2

National Biotechnology Authority

21 Princess Drive, Newlands, Harare
Tel: +263 4 782167, +263 4 782155, +263 4 782856/9
Email: nba@nba.ac.zw

Government of Zimbabwe

Certificate of Registration

NO: 000000000

National Biotechnology Authority Act (Chap: 14:31)

CERTIFICATE NUMBER: - NBA-RA/00/00/00

THE NATIONAL BIOTECHNOLOGY AUTHORITY HEREBY GRANTS TO:-

COMPANY XYZ

COMPANY ADDRESS

(HEREAFTER CALLED THE REGISTERED INSTITUTION) THE RIGHT TO CARRY OUT WORK INVOLVING BIOTECHNOLOGY RESEARCH AND APPLICATIONS IN ACCORDANCE WITH THE PROVISIONS OF THE NATIONAL BIOTECHNOLOGY AUTHORITY ACT *[CHAP 14:31]* OF 2006. PRODUCTS PRODUCED SHALL BE DEVELOPED, USED OR APPLIED BY THE REGISTERED INSTITUTION, AND THE SERVICES SHALL BE OFFERED AT OR FROM ONLY THE ADDRESS SHOWN ABOVE.

SIGNED_____

CHIEF EXECUTIVE OFFICER AND REGISTRAR, NBA

ISSUE DATE 00/00/00
EXPIRY DATE 00/00/00

A hub for Biotechnolgy, Biosafety, Research & Development

www.nba.ac.zw

ABP3

ZIMBABWE

21, Princess Drive, Newlands
P. O. Box CY379, Harare.
Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

National Biotechnology Authority

ATTENTION TO ALL IMPORTERS OF AGRICULTURAL BIOTECHNOLOGY PRODUCTS

SECTION A

RE: SPECIFICATIONS FOR APPLICATION FOR AN IMPORT PERMIT FROM THE NATIONAL BIOTECHNOLOGY AUTHORITY

The National Biotechnology Authority would like to highlight the following procedures to be adhered to by importers when submitting applications for authority to import agricultural biotechnology products.

Any organisation seeking authority from the NBA to import agricultural biotechnology products into Zimbabwe should meet the following requirements:

1. First, the organisation must be registered with NBA and its certificate of registration should be valid. To register the organisation must provide the following documents:
   - Completed Company Registration Form
   - CR14
   - Certificate of incorporation
   - Company profile
   - ZIMRA tax clearance
   - Registration fee
2. Complete and submit **Section B**.
3. On submission of the application it must be accompanied with the following:
   - A GM certificate or declaration from a competent authority (e.g. NBA in Zimbabwe) in the country of origin.

ABP3

ZIMBABWE

21, Princess Drive, Newlands
P. O. Box CY379, Harare.
Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

4. The GMO certificate must meet the following requirements:
   - Be on **original letterhead** of the laboratory conducting the test. The letterhead should have the logo, physical and postal addresses and telephone numbers.
   - The testing laboratory should be accredited to a competent authority in the country in which the testing facilities are located.
   - Have the original signature of the person responsible for the testing facilities.
   - Bear the official stamp of the testing institute.
   - **The date of testing must not be more than three months old.**
   - State the date of **testing** of the product and date of issue of the certificate.
   - Bear the certificate number.
   - State the name and address of the importing organization.
   - Provide clear description of the sample i.e. type, variety, quantity.
   - State the place of sampling, sampling method and quantity of source material.

     Please note that sampling must be done by the testing laboratory and this should be indicated on the GMO certificate.
   - Provide clear specifications of the PCR analysis including: sample number, PCR Cycles, Limit of Detection (which should be not more than 0.02%). **Please note that only the PCR method of analysis should be used.**
   - Provide the test result and interpretation.
   - Make a declaration/statement about the testing laboratory facilities and procedures.

5. **Only GMO declarations issued by the biosafety office of the government in the country of origin of the consignment will be accepted.**

ABP3

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P. O. Box CY379, Harare.
Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

SECTION B

TITLE: Application for a Biosafety Import Permit In Accordance with the National Biotechnology Authority Act [*Chapter 14:31*]

Part I: Nature of Applicant

We/I hereby apply for a Biosafety Import Permit in accordance with the National Biotechnology Authority Act:

Select Appropriate Category:

Individual ☐

Organisation ☐

Company ☐

Part II: Applicant's Particulars

Registered Name	
NBA Certificate of Registration Number	
Physical Address	
Email Address	
Phone Number	

ABP3

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P. O. Box CY379, Harare.
Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

Part III: APPLYING FOR:

Please tick the appropriate box:

New	☐	Renewal	☐
Extension	☐	Amendment	☐
Replacement	☐	Appeal	☐

Part IV: Product Details

NBA Product Registration Number: .....

Product Name (Include Trade Name): .....

Product Type

(a) Biofertilizer ☐
(b) Biopesticide ☐
(c) Biostimulants ☐
(d) Other ☐

GM Status: Negative ☐ Positive ☐ Traces ☐

Quantity: .....

Country of origin: .....

Supplier: .....

Port of entry: .....

Mode of transport: .....

Purpose of import: .....

ABP3

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21, Princess Drive, Newlands
P. O. Box CY379, Harare.
Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

Part V: Justification for the request

If you ticked Renewal/Extension/Amendment/Replacement/Appeal in **Part III** above, please state the reasons for your request: .....

.....

.....

Part VI: Applicant's Checklist

Valid NBA Product Registration Certificate ☐

GMO Certificate (Please Attach) ☐

GMO Declaration (Please Attach) ☐

Documents to be renewed/extended/ amended ☐

Part VII: Declaration

I, ..., (full name) declare that the information provided in this form is accurate and hereby apply for a Biosafety Import Permit under the National Biotechnology Authority Act [*Chapter 14:31*] of 2006.

Designation ..... Date: .....

Signature: .....

ABP4

National Biotechnology Authority

21 Princess Drive, Newlands, Harare
Tel: +263 4 782167, +263 4 782155, +263 4 782856/9
Email: nba@nba.ac.zw

Government of Zimbabwe

Biosafety Import Permit

National Biotechnology Authority Act (Chap: 14:31)

Permit No: 0000

Ref Number: NBA/RA/00-00-0000

Issue Date: **Expiry Date:**

Authority is given to:

To Import

Product:

Quantity:

Supplier:

Country of Origin:

GM Status:

Purpose:

Permit subject to Condition(s): Post Shipment testing of the consignment by the NBA at your cost. Therefore you are required to inform the NBA on arrival of the consignment prior to distribution or use.

This permit is granted to the applicant in terms of the provisions of The National Biotechnology Authority Act and does not in any way absolve the applicant from complying with any other statutory conditions governing the import and use of the above in Zimbabwe.

Permit issued by: **Signature**.....
CEO & Registrar, National Biotechnology Authority

A hub for Biotechnolgy, Biosafety, Research & Development

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ABP5

ZIMBABWE

21, Princess Drive, Newlands
P. O. Box CY379, Harare.
Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

ATTENTION TO ALL REGISTRANTS OF AGRICULTURAL BIOTECHNOLOGY PRODUCTS

RE: SPECIFICATIONS FOR PRE-SHIPMENT INSPECTIONS

The National Biotechnology Authority would like to highlight the following procedures to be adhered to by registrants of agricultural biotechnology products where a pre-shipment inspection is required.

Pre-shipment inspections (PSI) are required when further information on production, quality, storage of the product and raw materials is needed thereby preventing substandard goods from entering or leaving the country. Clients should take note of the following;

1. First, the organisation must be registered with NBA and its certificate of registration should be valid. To register, the organisation must provide the following documents:
   - Completed Registration Form
   - CR14
   - Certificate of incorporation
   - Company profile
   - Current ZIMRA tax clearance
   - Registration fee
2. Upon an order for a pre-shipment inspection, the applicant should kindly
   - Liaise with the Authority to arrange dates for the pre-shipment inspection.
   - Meet costs of the inspection exercise; upon obtaining an invoice from the Authority.

ABP5

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Website: www.nba.ac.zw

3. During the inspection, the inspectors shall:
   - Assess handling, testing and packaging of the product.
   - Collect random samples for testing
   - Assess suitability of the production facility
   - Assess test and trial reports
   - Check quality management system certificates
   - Check factory test records
   - Check product technical data sheets
   - Assess safety and conformity marks from other markets
   - Ask for the distribution license
   - Ask for the facility registration certificates
4. Once the inspection is complete, the Authority will either issue;
   - A Pre-shipment Inspection certificate and/or GM certificate

   Or
   - A rejection note; if inspection findings demonstrate non compliance.
   - If issued with a rejection note, the applicant may appeal against the decision 30 days after receiving the note.
   - When the Authority receives the appeal note, a meeting will be convened for discussing the issues.

ABP6

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P. O. Box CY379, Harare.
Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

ATTENTION TO ALL IMPORTERS OF AGRICULTURAL BIOTECHNOLOGY PRODUCTS

RE: SPECIFICATIONS FOR POST-SHIPMENT INSPECTIONS

The National Biotechnology Authority (NBA) would like to highlight the following procedures to be adhered to by all importers of agricultural biotechnology products where a post-shipment inspection is required.

Post-shipment inspections (PSI) are required when the NBA intends to verify the exact GM status and microbial composition of the imported product thereby ensuring that agricultural biotechnology products imports comply with regulations prior to their distribution, processing or any other intended use. Clients should take note of the following:

1. First, the organisation must be registered with NBA and its certificate of registration should be valid. To register, the organisation must provide the following documents:
   - Completed Company Registration Form
   - CR14
   - Certificate of incorporation
   - Company profile
   - Current ZIMRA tax clearance
   - Registration fee
2. Upon an order for a post-shipment inspection, the applicant should kindly
   - Liaise with the Authority to facilitate inspection of the imported product including sample collection in accordance with the conditions specified on the respective biosafety import permit.
   - Meet costs of the inspection exercise including GM testing, transport and any eventualities, upon obtaining an invoice from the Authority.

ABP6

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Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

3. During the inspection, the Authority shall:
   - Check the biosafety import permit of the respective product for conformity with conditions on which the permit was issued.
   - Check goods/cargo manifest.
   - Collect random samples for testing.
   - Issue a copy of proof of sampling to the client or a representative of the client.
4. Once the testing is complete, the Authority will either issue;
   - A GMO certificate and/or an acceptance note giving the importer the right to distribute, process or use the product as intended

   Or
   - A rejection note; if inspection findings demonstrate non compliance.
   - If issued with a rejection note, the applicant may appeal against the decision within 30 days after receiving the note.
   - When the Authority receives the appeal note, a meeting will be convened for discussing the issues.

ABP7

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Email: nba@nba.ac.zw
Website: www.nba.ac.zw

ATTENTION TO ALL EXPORTERS OF AGRICULTURAL BIOTECHNOLOGY PRODUCTS

SECTION A

RE: SPECIFICATIONS FOR APPLICATION FOR CERTIFICATION OF GMO DECLARATIONS AND OR GMO CERTIFICATES FROM THE NATIONAL BIOTECHNOLOGY AUTHORITY

The National Biotechnology Authority would like to highlight the following procedures to be adhered to by exporters when submitting applications for GMO declarations and/or GMO certificates for the export of agricultural biotechnology products.

1. First, the organisation must be registered with NBA and its certificate of registration should be valid. To register the organisation must provide the following documents:
   - Completed Company Registration Form
   - CR14
   - Certificate of incorporation
   - Company profile
   - Current ZIMRA tax clearance
   - Registration fee
2. Complete and submit **Section B**.
3. If a sample is to be tested; the NBA inspectorate will collect and test samples at the client's cost.

ABP7

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P. O. Box CY379, Harare.
Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

SECTION B

TITLE: Application for GMO declarations and/or GMO certificates In Accordance with the National Biotechnology Authority Act [*Chapter 14:31*] of 2006

Part I: Nature of Applicant

We/I hereby apply for a GMO declaration and/or GMO certificate in accordance with the National Biotechnology Authority Act:

Select Appropriate Category:

Individual ☐
Organisation ☐
Company ☐

Part II: Applicant's Particulars

Registered Name	
NBA Certificate of Registration Number	
Physical Address	
Email Address	
Phone Number	

ABP7

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P. O. Box CY379, Harare.
Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

Part III: APPLYING FOR:

GMO certificate ☐ GMO declaration ☐

Please tick the appropriate box:

New ☐ Renewal ☐
Extension ☐ Amendment ☐
Replacement ☐ Appeal ☐

Part IV: Product Details

NBA Product Registration Number: .....

Product Name (Include Trade Name): .....

Product Type

(a) Biofertilizer ☐
(b) Biopesticide ☐
(c) Biostimulants ☐
(d) Other ☐

GM Status: Negative ☐ Positive ☐ Traces ☐

Quantity: .....

Country of origin: .....

Recipient country: .....

ABP7

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Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

Supplier: .....

Port of exit: .....

Mode of transport: .....

Purpose of export: .....

Part V: Justification for the request

If you ticked Renewal/Extension/Amendment / Replacement/Appeal in **Part III** above, please state the reasons for your request: .....

.....

.....

.....

Part VI: Applicant's Checklist

Valid NBA Product Registration Certificate ☐

GMO Certificate (Please Attach) ☐

Documents to be renewed/extended/ amended ☐

Part VII: Declaration

I, ...(full name), declare that the information provided in this form is accurate and hereby apply for a Biosafety Import Permit under the National Biotechnology Authority Act [*Chapter 14:31*] of 2006.

Designation: ..... Date: .....-

Signature: .....

ABP8

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21 Princess Drive
Newlands
P. O. Box CY379
Harare
Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

00/00/00

To whom it may concern

GMO DECLARATION

GM DECLARATION FOR PRODUCT XYZ –COMPANY ABC

This is to certify that 00.00MT of product XYZ to be exported to country A. is to the best of our knowledge not genetically modified. The product XYZ will be transported by road via exit port P.

Please note that this declaration only covers this consignment and should not serve as a general declaration for future consignments that the National Biotechnology Authority has not put its endorsement on.

The declaration is made in terms of the National Biotechnology Authority Act and should not be regarded as covering other export requirements.

Chief Executive Officer and Registrar, National Biotechnology Authority

This declaration is valid from 00/00/00 to 00/00/00

Promoting Development Anchored on Biotechnology

ABP9

National Biotechnology Authority

21 Princess Drive, Newlands, Harare
Tel: +263 4 782167, +263 4 782155, +263 4 782856/9
Email: nba@nba.ac.zw

Government of Zimbabwe

Certificate No: 00000/00/00

Genetically Modified Organisms Certificate

National Biotechnology Authority Act (Chap: 14:31)

Date of Issue: 00/00/00
Date Sample Collected: 00/00/00
Analysis Date: 00/00/00

Customer Address: ABC
No 123
Industrial Area

Sample Collection Site: ABC

Sample Type	Customer Sample Ref. #	Results
Product Name	0000000000	35S promoter + NOS Terminator Not detected

GMO ANALYSIS DONE USING PCR BASED TESTS (METHOD 001).

35S: The 35S PCR system detects transgenic DNA sequences that are characteristic for the 35S promoter of the Cauliflower Mosaic Virus (CaMV).

NOS: The NOS PCR system detects transgenic DNA sequences that are characteristic for the NOS terminator derived from *Agrobacterium tumefaciens*.

Interpretation: The sample was analysed by PCR for the presence of Genetically Modified DNA. According to the analysis genetically modified DNA was not detected in the sample.

Authorised by: _____
XYZ
CEO and Registrar, National Biotechnology Authority

A hub for Biotechnology, Biosafety, Research & Development

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ABP10

ZIMBABWE

21, Princess Drive, Newlands
P. O. Box CY379, Harare.
Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

ATTENTION TO ALL CLEARING AGENTS HANDLING TRANSIT CONSIGNMENTS OF AGRICLUTURAL BIOTECHNOLOGY PRODUCTS (ABPs) PASSING THROUGH ZIMBABWE

SPECIFICATIONS FOR APPLICATION FOR A BIOSAFETY TRANSIT PERMIT FROM THE NATIONAL BIOTECHNOLOGY AUTHORITY

The National Biotechnology Authority would like to highlight the following procedures to be adhered to by clearing agents when submitting applications for authority to transit ABPs through Zimbabwe.

Any organisation seeking to be granted authority by the NBA to transit ABPs through Zimbabwe should meet the following requirements:

1. Complete a transit application at the port of entry or NBA Head Office supplying the following information
   - Name and address of registered clearing agent in Zimbabwe.
   - Name and address of importer.
   - Name and address of exporter.
   - Details of products to transit through Zimbabwe.
   - A GM certificate or declaration from a competent authority (e.g. NBA in Zimbabwe) in the country of origin.
   - Port of entry through which the product will enter into Zimbabwe.
   - Port of exit through which the product will exit Zimbabwe.
   - Undertaking to meet the cost of supervision in the case of genetically modified products.
2. The GM certificate must meet the following requirements:
   - Be on **original letterhead** of the laboratory conducting the test. The letterhead should have the logo, physical and postal addresses and telephone numbers.

ABP10

ZIMBABWE

21, Princess Drive, Newlands
P. O. Box CY379, Harare.
Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

National Biotechnology Authority

- The testing laboratory should be accredited to a competent authority in the country in which the testing facilities are located.
- Have the original signature of the person responsible for the testing facilities.
- Bear the official stamp of the testing institute.
- **The date of testing must not be more than three months old.**
- State the date of **testing** of the product and date of issue of the certificate.
- Bear the certificate number.
- State the name and address of the importing organization.
- Provide clear description of the sample i.e. type, variety, quantity.
- State the place of sampling, sampling method and quantity of source material.
- **Please note that sampling must be done by the testing laboratory and this should be indicated on the GMO certificate.**
- The PCR test should be used, and the certificate should provide clear specifications of the PCR analysis including: PCR Cycles, Limit of Detection (which should be not more than 0.02%).
- Provide the test result and interpretation.
- Make a declaration/statement about the testing laboratory facilities and procedures.

ABP11

ZIMBABWE

21, Princess Drive, Newlands
P. O. Box CY379, Harare.
Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

National Biotechnology Authority

TITLE: Application for a Biosafety transit permit for Agricultural biotechnology products in accordance with the provisions of the National Biotechnology Authority Act [*Chapter 14:31*]

Part I: Nature of Applicant

We/I hereby apply to transit goods in accordance with the National Biotechnology Authority Act:

Select Appropriate Category:

Individual ☐

Organisation ☐

Company ☐

Part II: Applicant's Particulars

Name of Applicant (Clearing Agent)	
Physical Address	
Postal Address *(if different from above)*	
Email Address	
Phone/Mobile Number	

ABP11

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P. O. Box CY379, Harare.
Tel: +263 4 782856/9
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Website: www.nba.ac.zw

National Biotechnology Authority

Name of Exporter	
Physical Address	
Postal Address *(if different from above)*	
E-mail Address	
Phone/Mobile Number	
Name of Importer	
Physical Address	
Postal Address *(if different from above)*	
Email Address	
Phone/Mobile Number	

Part III: Product details

Product Name (*Trade Name*)	
Volume or Mass of Product	

ABP11

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Tel: +263 4 782856/9
Email: nba@nba.ac.zw
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National Biotechnology Authority

Genetic Modification Status

Negative ☐ Positive ☐

NB: Please attach GMO certificate or declaration

Part IV: Transit Details

Country of Origin	
Port of Entry	
Destination Country	
Port of Exit	
Horse Registration Number	
Trailer registration Number	

Part V: Scope of Application for Registration

I, ...(full name), declare that the information provided in this form is accurate and hereby apply for a Biosafety Transit Permit in accordance with the provisions of the National Biotechnology Authority Act and guidelines therein.

Name: ..... Date: .....-

Signature: .....

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BIOSAFETY TRANSIT PERMIT

National Biotechnology Authority Act [*Chap 14:31*] of 2006

Permit No: XXXXX

Ref No: NBA/RA/.....

Issue Date.....Expiry Date.....

Name of Applicant: .....

Physical Address: .....

Product: .....

GM Status: .....

Quantity: .....

Country of Origin: .....

Purpose: .....

Port of Entry: .....

Port of Exit: .....

Trailer Reg No: .....

In Transit through Zimbabwe to: .....

Permit subject to the following condition(s):

1. *To leave Zimbabwe within 72 hours*
2. .....
3. .....
4. .....
5. .....

Permit issued by: ..... Signature.....
(For the CEO & Registrar, National Biotechnology Authority)

21 Princess Drive, Newlands, Harare, P.O Box CY379 Causeway. Tel:- +263 4 782856-9, Email nba@nba.ac.zw

ABP13

ZIMBABWE

21, Princess Drive, Newlands
P. O. Box CY379, Harare.
Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

National Biotechnology Authority

ATTENTION

TO ALL REGISTRANTS OF AGRICULTURAL BIOTECHNOLOGY PRODUCTS

RE: SPECIFICATIONS FOR APPLICATION FOR REGISTRATION WITH THE NATIONAL BIOTECHNOLOGY AUTHORITY

The National Biotechnology Authority would like to highlight the following procedures to be adhered to by Registrants when submitting applications for authority to: commercialize, experiment, renew or amend an existing registration of agricultural biotechnology products. Please note that this general information will help the Registrant to complete the forms

Any organisation seeking authority from the NBA to commercialize, experiment, renew or amend an existing registration for agricultural biotechnology products in Zimbabwe should meet the following requirements:

1. **Registration**

   First, the organisation must be registered with the NBA and its certificate of registration should be valid. To register the organisation must provide the following documents:

   - Completed Company Registration Form
   - CR14
   - Certificate of incorporation
   - Company profile
   - ZIMRA tax clearance
   - Registration fee

2. **Pre-Submission Consultation**

   To facilitate the registration of agricultural biotechnology products, prospective registrants should request for a pre-submission consultation

ABP13

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Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

with the Authority prior to making a full and formal application, unless if they are very familiar with the registration procedure. Requests can be done over the phone, email or in person. The Authority will schedule an appropriate date and time.

3. Submission of Application

The Registrant should provide detailed information on the application form and questionnaire. All attachments should bear official stamps (where applicable), be accurate and valid. Required information or details includes:

- Full details of Registrant, manufacturer and/or owner of trade name or patent.
- Physical and postal addresses and telephone numbers of the company (Registrant), manufacturer/or owner of trade name.
- Full details of the identity of the product, both biological aspects (taxonomic identity) and compositional details.
- Indication of origin of product ingredients.
- Reports of analysis of product from accredited /approved laboratories.
- Details of formulations.
- Concentration of active ingredients in the supplied formulation.
- A sample of the product (Follow import application guidelines).
- Toxicology and data on potential adverse impacts; please note that responses should be accompanied by comprehensive scientific justifications.
- Supply all indicative safety data and supplement with full safety data sheet.
- Where applicable, details of packaging should be supported by a sample.

ABP13

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- A full description of a post registration monitoring plan including product use, efficacy, adverse impacts, training etc. Please note that the Authority should be engaged throughout the monitoring process.
- Original signature of the Registrant.
- Date and official company stamp.

NB Application form and questionnaire should be completed with indicative data and relevant attachments should be accompany the application package.

ABP14

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21, Princess Drive, Newlands
P. O. Box CY379, Harare.
Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

TITLE: Application for registration for trial release/commercialisation/use of Agricultural Biotechnology Products in accordance with the National Biotechnology Authority Act [*Chapter 14:31*] of 2006.

TO: **The Chief Executive Officer and Registrar**
National Biotechnology Authority

1. Contact Details

(a) Name of Organisation: .....

.....

.....

(b) Physical address: .....

.....

.....

(c) Postal address: .....

.....

.....

(d) Telephone: .....

(e) Fax Number: .....

(f) E-Mail Address: .....

(g) Company Registration Number: .....

ABP14

ZIMBABWE

21, Princess Drive, Newlands
P. O. Box CY379, Harare.
Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

2. In accordance with the National Biotechnology Authority Act, I hereby apply for:

(a) Registration of Product/Commercialisation ☐

(b) Trial Release ☐

(c) Renewal ☐

(d) Amendments ☐

3. Product Type

(a) Biofertilizer ☐

(b) Bioherbicide ☐

(c) Bioinsecticide ☐

(d) Biopesticide ☐

(e) Other ☐

4. Product Registration/Commercialisation

(a) Name of product: .....

(b) Product Trade Name: .....

(c) Product Details: .....

ABP14

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Name of Biological component	Taxonomic Details	Percentage Composition in product	Origin of Biological component

(d) Concentration of final product

(e) Country of Origin

(f) Is the product registered in the Country of origin

YES ☐ NO ☐

NB: If yes please attach Registration Certificate

(g) Manufacturer's Details

(i) Name of Manufacturer: .....

.....

.....

ABP14

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P. O. Box CY379, Harare.
Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

(ii) Physical Address:

.....

.....

(iii) Postal Address: .....

.....

.....

(iv) Telephone Number: .....

.....

.....

(v) Fax Number: .....

.....

.....

(vi) Email Address: .....

.....

.....

(h) Intended use: .....

.....

.....

ABP14

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(i) Brief Product description: .....

.....

.....

(j) Packaging:

(i) Bulk ☐

(ii) Prepackaged ☐

NB: Samples of final packaging will be required

5. Application Components

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

(i) Completed Questionnaire.

(ii) Material Safety Data Sheet (MSDS)/Product Data Sheet (PDS).

(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) Certificate of limits of Compositions.

(viii) Post Registration Monitoring Plan.

ABP14

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Tel: +263 4 782856/9
Email: nba@nba.ac.zw
Website: www.nba.ac.zw

Name of Applicant: .....

Position within the applying organisation: .....

Date: .....

Signature: .....

Official Stamp of applying Organization should be placed here

ABP15

PROCEDURES

FOR ASSESSMENT OF A

TRIAL RELEASE

OR

GENERAL RELEASE

OF

AGRICULTURAL

BIOTECHNOLOGY

PRODUCTS

SECTION I

Introduction

Biotechnology is any technique that uses living organisms or parts of organisms to make or modify products, to improve plants or animals, or to develop microorganisms for specific purposes. Modern agricultural biotechnology employs a range of biotechnology tools in the production and/or processing of products to increase yield, reduce pest damage, and increase general productivity among others. Agricultural biotechnology products (ABPs) include biofertilizers, biopesticides and biostimulants. These ABPs contain living

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microorganisms and/or components thereof which, when applied to seeds, plant surfaces, or soil; promotes growth by increasing the supply or availability of nutrients to the host plant or control plant diseases, pests and weeds. The use of ABPs offer potential benefits compared to the use of agrochemicals since they are environmentally friendly, biodegradable, and cheaper when produced locally and tend to have long term benefits. The use of ABPs is a good agricultural technological innovation as it addresses issues of food security issues, safety and efficacy. However, if not properly regulated, ABPs may pose unintended consequences e.g. lethal and nonlethal risks for non-target native pollinators due to the use of broad spectrum biopesticides and ecological and genetic challenges imposed by the broad application of symbiotic microbes. Regulation of these ABPs therefore becomes paramount.

This document sets out points that have to be considered by the investigator in the preparation and assessment of a proposal for the trial or general release of ABPs. It should be considered in conjunction with the National Biotechnology Authority Act [*Chapter14:31*] and Biosafety Guidelines. In terms of the National Biotechnology Authority Act [*Chapter 14:31*], all institutions carrying out work involving biotechnology products and/or biotechnology applications must be registered with the Authority and should set up an Institutional Biosafety Committee (IBC). The proposal shall be prepared by the responsible investigator and reviewed by the IBC before submission to the Authority.

It is recognised that questions relating to possible risks may not be answerable with certainty. However, it is the responsibility of those engaged in the preparation of the proposal to give the fullest and best consideration of which they are capable to do, to the possible impacts of the proposal, and to make full disclosure of relevant matters to the IBC and the Authority. The impacts to be considered include those on public health, other organisms and the environment.

Answers to the questionnaire are to be supported by appropriate, comprehensive data and references. If none are available, the basis on which the answer is given should be stated. Where any doubt exists about the appropriate answer to a question, the nature of the doubt is to be stated. Where a potential hazard is noted the clearest possible description of the relative risks involved shall be provided, and possible steps to eliminate or manage the hazard are to be considered and suggested.

Accidental release

All procedures for handling ABPs shall be designed to ensure that no accidental release occurs, and that all releases are planned as provided for by set guidelines.

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Should any accidental release of the agricultural biotechnology products occur, it shall be reported immediately to the respective IBC and Authority, together with details of mitigating action taken, and, the persons or authorities who have been notified. *Reporting a matter to the Authority does not relieve the applicant of any other obligations he or she may have under law or statute to notify relevant authorities or persons who may be affected.*

Submission of proposal

The applicant shall provide answers to all questions appropriate for the ABP which is planned for release (Section II). When the IBC is satisfied with the proposal, it shall forward it to the NBA. Where a proposal includes commercial sensitive information, the applicant may mark relevant portions as "Commercial-in-confidence". Substantial reasons why specific sentences or passages should be so treated shall be given. Where material is clearly so marked, the Authority will treat it as confidential unless it forms the view that some disclosure is necessary. In that event the NBA will notify the applicant in writing, and subsequently negotiate a mutually agreed resolution. If an agreement is not reached the proposal may be withdrawn, without disclosure or prejudice, at any time prior to the necessary disclosure in pursuit of approval.

SECTION II:

QUESTIONNAIRE

A. AIMS AND OBJECTIVES

1. Is the ABP a biofertilizer, biopesticide, or biostimulant?
2. What kind of ABP is to be released? (Directly-associated or free living)
3. What type of ABP is it? (e.g. fungi, bacterial, or combinations)
4. What is the function of the ABP? State function of each component if the ABP is comprised of a mixture of different organisms.
5. If the release is successful, is it intended that a general release of the ABP is to be proposed? If so, when, where and by who is it proposed that the general release takes place?

B. THE NATURE OF THE MICROORGANISMS AND THEIR GENOTYPE

1. Is the organism known to have symbiotic relations with named plant species?

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2. Is there any adverse health effects due to infectivity, toxicity, alleginicity and immunogenicity associated with the use of the microbe or its related pathogenic strain? If yes, what steps are to be taken to minimise such risks?
3. Has the ABP been genetically modified? If Yes,
   (a) How closely related is the ABP to its native organisms?
   (b) Give a detailed description of the steps taken in ABP development.
   (c) Based on previous data and/or research, explain the likelihood of transferability of the inserted gene/s, including likely targets.
   (d) Provide data if any to suggest that the inserted trait has no deleterious effects on any other organisms especially the external environment.
4. What is the mechanism of action of the ABP?
5. Do the organisms constituting the ABP have potentially unstable genotypes?
6. In what form/state is the ABP produced, (e.g. dry and powdered, suspensions, dry and granular).
7. —
   (a) Give details of physical and chemical properties such as moisture content, particle size, concentration of microorganisms.
   (b) What methods are to be used to test for batch to batch consistency?
   (c) Give details of measures taken to avoid or minimise contamination during production.
   (d) Comment on the relative stability of ABP over time under named appropriate storage conditions.

C. SIZE AND LOCATION OF RELEASE

1. Describe the size and characteristics of land on which the ABP is to be tried? Give reasons for your choice.
2. Describe the distribution of plants, animals and microbes present on site of release.
3. Describe in detail the relevant environmental conditions which may minimise or exacerbate any undesirable effects.

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D. HABITAT AND ECOLOGY

1. What is the natural habitat of the organism/s constituting the ABP?
2. State where the organism/s constituting the ABP were originally isolated. State plant species if it was isolated from roots.
3. Does the organism/s constituting the ABP exist in Zimbabwe or its exotic? If present, please give the geographic distribution of the organisms.
4. Is the organism already present in the trial area? If Yes, provide available data on populations.
5. Are there any known predators or parasites of the organism in Zimbabwe? If Yes, describe them.
6. Has the organism/s constituting the ABP or related strain been known to have any effect on plants, animals and microbes.

E. GENERAL DETAILS AND PROVISIONS

1. What is the method of administration used?
2. What are the possible exposure mechanisms e.g. inhalations, ingestion or inoculation?
3. Has the ABP been tested in a range of host plants? If Yes, state them.
4. What are the ideal dosages and how long did it take for normal microflora to stabilise?
5. What guidelines have been put in place to dispose waste containing any organism/s constituting the ABP and/or any residues during processing and trial?
6. What is the existing evidence with regard to level of efficacy and persistence of the organism/s constituting the ABP?

F. PUBLIC INFORMATION

The information provided under this subsection is for possible public distribution. It should be written in plain language. No commercial-in-confidence information should be included. Applicants should ensure that information provided does not prejudice their rights to patent protection.

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The information required must include:

1. The name of the applicant's organisation.
2. Address of the applicant's organisation.
3. Name of contact person.
4. E-mail address, telephone and fax number of contact person.
5. ABP to be introduced.
6. Location and size of planned introduction.
7. Purpose of planned introduction.
8. Brief summary of the nature and results of any genetic modification. Use of technical terms should be minimised.
9. Agencies consulted before release of the product.

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National Biotechnology Authority

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Email: nba@nba.ac.zw

Government of Zimbabwe

Permit of Trial Release

National Biotechnology Authority Act (Chap: 14:31)

This permit approves

COMPANY ABC to conduct a trial release of

Product name XYZ

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

Permit Number TP000001
Permit Issue Date 20/2/00
Permit Expiry Date 20/2/00

CEO & Registrar, National Biotechnology Authority

www.nba.ac.zw

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National Biotechnology Authority

21 Princess Drive, Newlands, Harare
Tel: +263 4 782167, +263 4 782155, +263 4 782856/9
Email: nba@nba.ac.zw

Government of Zimbabwe

Biosafety Import Permit

National Biotechnology Authority Act (Chap: 14:31)

Permit No. 0000

Ref Number: NBA/RA/00-00-0000

Issue Date: **Expiry Date:**

Authority is given to:

To Import

Product:

Quantity:

Supplier:

Country of Origin:

GM Status:

Purpose:

Permit subject to Condition(s): Post Shipment testing of the consignment by the NBA at your cost. Therefore you are required to inform the NBA on arrival of the consignment prior to distribution or use.

This permit is granted to the applicant in terms of the provisions of The National Biotechnology Authority Act and does not in any way absolve the applicant from complying with any other statutory conditions governing the import and use of the above in Zimbabwe.

Permit issued by: **Signature**
CEO & Registrar, National Biotechnology Authority

A hub for Biotechnology, Biosafety, Research & Development

www.nba.ac.zw

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National Biotechnology Authority

21 Princess Drive Borrowdale, Harare
Tel: +263-4 782162, +263 4 782155, +263-4 782556/9
Email: boq@nba.ac.zw

Government of Zimbabwe

NO: P0000000000

Certificate of Product Registration

National Biotechnology Authority Act [Chap. 10:33] of 2006

Certificate Number: NBA/BV/00/00/00

PURSUANT TO THE PROVISIONS OF THE NATIONAL BIOTECHNOLOGY AUTHORITY ACT *[CHAP 10:33]* OF 2006, THE PRODUCT DESCRIBED HEREUNDER HAS BEEN FOUND TO CONFORM TO THE REQUIREMENTS AND STANDARDS FOR REGISTRATION OF AGRICULTURAL BIOTECHNOLOGY PRODUCTS

PRODUCT NAME:	XYZ
MANUFACTURER:	A
IMPORTER/DISTRIBUTOR	B

CONDITIONS: THERE SHALL BE NO CHANGE INTO FORMULATION, LABELLING AND COMMERCIAL PRESENTATION OF THIS PRODUCT WITHOUT PRIOR APPROVAL FROM THE AUTHORITY

SIGNED: _____

ISSUE DATE: 00/00/00

CHIEF EXECUTIVE OFFICER AND REGISTRAR, NBA

EXPIRY DATE: 00/00/00

A hub for Biosciences, Biosafety, Research & Development

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