

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 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.

(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.

