

National Biotechnology Authority (Food, Feed, Food and Feed Additives and Seed) (Import, Export and Transit) 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 (Food, Feed, Food or Feed Additives and Seed) (Import, Export and Transit) Regulations, 2018.

Interpretation

2. In these regulations—

“Authority” means the National Biotechnology Authority;

“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;

“export” means to send food, feed, food and feed additives and seed out of Zimbabwe;

“food or feed additive” means substances that are added to food or feed during production, processing, treatment, packaging, transportation or storage of food and feed;

“form” means the appropriate form prescribed in the Second Schedule;

“genetically modified organism(GMO)” means an organism, the genes and genetic material of which have been modified in a way that does not occur naturally through mating or natural recombination or both, and the term “genetic modification” shall be construed accordingly;

“GMO declaration or certificate” means an official document stating the GMO status of a product authenticated by the Authority or other equivalent biosafety authority in the country of origin;

“import” means to bring into Zimbabwe food, feed, food or feed additives and seed;

“product” means food, feed, food or feed additives and seed;

“transit” means to transport food, feed, food or feed additives and seed *via* Zimbabwe.

Purposes of these regulations

3. (1) The purposes of these regulations are to—

- (a) ensure safe movement of food, feed, food and feed additives and seed into, out of and through Zimbabwe;
- (b) protect human and animal health and the environment.

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

PART II

APPLICATION FOR REGISTRATION CERTIFICATE, IMPORT, EXPORT AND BIOSAFETY TRANSIT PERMITS FOR FOOD, FEED, FOOD AND FEED ADDITIVES AND SEED

Register and Registrar of National Biotechnology Authority

4. (1) There shall be a Registrar of the National Biotechnology Authority.

(2) There shall be established a register of importers and exporters of food, feed, food and feed additives and seed to be kept by the Authority.

(3) The Registrar shall maintain at his or her office a register of importers and exporters of food, feed, food and feed additives and seed to be kept by the Authority in which he or she shall enter all such particulars in relation to their registration as he or she is required to enter by or in terms of these regulations.

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

(5) The register shall be open to inspection during office hours by any member of the public on payment of the prescribed fee, if any.

Application for registration

5. (1) Any person who wishes to import and or export food, feed, food and feed additives and seed listed in Form FFA1 must apply to be registered as such in the register established in terms of section 4.

(2) An application for a registration certificate shall be made in terms of Form FFA2, to the Authority, accompanied by the appropriate application fee prescribed in the First Schedule.

(3) Upon registration any such person may apply for a biosafety import, export or transit permit.

(4) The Authority shall consider an application 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.

Validity and renewal

6. (1) A registration certificate issued in terms of section 5 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 at least one month before the expiry of the issued registration certificate.

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

- (a) a copy of the expired certificate;
- (b) prescribed fee 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.

Application for a biosafety import permit

7. (1) Any person who wishes to import food, feed, food or feed additives and seed listed in the Second Schedule must apply to the Authority in Form FFA4, for a biosafety import permit accompanied by an application fee prescribed in the First Schedule.

(2) In considering an application for a biosafety import permit, the Authority shall require the applicant to—

- (a) specify the product and quantity to be imported;
- (b) specify the variety to be imported in the case of seed;
- (c) specify the country of origin of the product and the port through which the product will enter Zimbabwe;
- (d) state the intended use of the product;
- (e) state the mode of transportation and security measures to be taken to ensure no spillages and pilferage occur during loading, transportation and storage in the case of grain and seed;
- (f) provide a GMO certificate or declaration from a competent Authority in the country of origin. GMO declarations will only be accepted for milled products and for any other products excluding seed and grain which are not known to be genetically modified.

(3) 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, genetic modification status, quality and storage of the product and raw materials; this will be done according to the guidelines in Form FFA6. Circumstances under which pre-shipment inspections may be ordered may include but not limited to the following—

- (a) when a product is declared as a GM negative yet the country of origin has commercialised GM varieties of that particular product;
- (b) when a submitted GM certificate or declaration fails to meet requirements in Form FFA4

(4) As soon as possible after a decision on an application is made, the Authority shall notify the applicant of the granting or rejection of the application for a permit by giving the applicant a copy of the application whereon it is indicated whether the application is granted or rejected and, if rejected the reasons for the rejection:

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 16.

(5) Any person who imports any products specified in the Second Schedule without a biosafety import permit issued by the Authority 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 or such imprisonment.

Application for biosafety export permit

8. (1) Any person who wishes to export food, feed, food or feed additives and seed listed in the Second Schedule must apply to the Authority in Form FFA8 for a biosafety export permit, accompanied by an application fee prescribed in the First Schedule.

(2) In considering an application for a biosafety export permit made in terms of subsection (1), the Authority shall require the applicant to—

- (a) highlight the product and quantity to be exported;
- (b) the country which the product is being exported to and port through which the product will leave Zimbabwe;
- (c) highlight the intended use of the product;
- (d) obtain a GMO declaration and or a GMO certificate.

(3) As soon as possible after a decision on an application is made, the Authority shall notify the applicant of the granting or rejection of the application for a permit by giving the applicant a copy of the application whereon it is indicated whether the application is granted or rejected and, if rejected the reasons for the rejection:

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 16.

(4) Any person who exports any products specified in the Second Schedule without a biosafety export permit issued by the Authority shall be guilty of an offence and liable to a fine not exceeding level twelve or to imprisonment for period not exceeding five years or to both such fine and such imprisonment.

Application for biosafety transit permit

9. (1) Any person who wishes to transit consignments of food, feed, food or feed additives and seed listed in the Second Schedule

through Zimbabwe must provide the Authority with the required information to obtain a biosafety transit permit (Form FFA12), accompanied by an application fee prescribed in the First Schedule.

(2) any consignment in transit may be subject to inspection at ports of entry by the Authority, and the transporter shall pay an inspection fee prescribed in First Schedule.

(3) A person transiting consignment of GMOs or GM products shall at the port of exit, provide a copy of the approval granted by the Authority or clearance at port of entry.

(4) Any person transiting GMOs or GM products shall ensure that the products are 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.

(5) Any person who transits any products specified in the Second Schedule without a biosafety transit permit issued by the Authority 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 or such imprisonment.

(6) In the event of an accident involving GMOs or GM products, it shall be the responsibility of the owner of the consignment to immediately—

- (a) notify the Authority of the accident both orally and in writing;
- (b) provide the Authority with information regarding—
 - (i) the circumstances of the accident;
 - (ii) the identity and the quantity of GMOs or GM products released;
 - (iii) the procedures necessary to assess the impact on human and animal health and the environment; and
 - (iv) any emergency measures taken to avoid adverse impact of the accident on the environment and human and animal health;

- (c) meet any cost relating to the containment and remedial actions resulting from the unintentional release;
- (d) take all appropriate measures to avoid adverse impacts of such an accident on environment and human and animal health;

(7) The Authority must inform or advise the public, of the accident if it is in the public interest to do so.

(8) As soon as possible after a decision on an application is made, the Authority shall notify the applicant of the granting or rejection of the application for a permit by giving the applicant a copy of the application whereon it is indicated whether the application is granted or rejected and, if rejected the reasons for the rejection:

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 16.

Conditions attaching to every permit

10. (1) It shall be deemed to be a condition of every permit that no person issued a permit, whether individual or corporate, shall transfer his or her or its permit to another person during the currency of the permit except with the prior written permission of the Authority:

Provided that where such approval is given the authority shall not amend the permit or corresponding entry in the register of permits except on the date when the permit is next renewed.

Issuance, duration, surrender and renewal of permits

11. (1) every permit shall be valid for a period of three months from the date of its issue, unless it is earlier surrendered to or cancelled by the licensing authority, and shall only be valid for use for the product or products specified for import, export or transit.

(2) If an application for a permit is successful (whether approved with or without conditions by the Authority), the Authority shall—

- (a) inform the applicant accordingly in accordance with section 6(4), 7(3) and (4) and 9(8);

- (b) issue to the applicant a Biosafety Import Permit (FFA5) or a GMO declaration (FFA9) or GMO certificate (FFA10), or biosafety transit permit (FFA12) whichever is appropriate; and
 - (c) make an appropriate entry in the permits register.
- (3) Upon expiry of a permit, a permit holder may renew it by making an application for a new permit.

(4) if upon receipt of an application for the renewal of a permit the Authority is satisfied that that there has been no material change of the details of the existing permit, and if so satisfied, shall renew the permit accordingly.

Suspension or cancellation of permit

12. (1) Subject to subsections (2) and (4), the Authority may at any time suspend for a period not exceeding 30 days or 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 by the permit holder; or
- (b) the permit holder has contravened any provision of the Act or these regulations or any condition of his or her permit; or
- (c) the permit holder has ceased the operations which are the subject of the permit.

(2) The Authority shall notify the permit holder in writing of its intention to suspend or cancel his or her or its permit and the reasons for doing so, and shall call upon the permit holder to show cause, within 14 days from the date of the notice, why the permit should not be suspended or cancelled, as the case may be:

Provided that if in the opinion of the Authority the permit needs to be immediately suspended or cancelled in the public interest or to avert an environmental emergency, the Authority can issue the notice requiring the permit holder to show cause after suspending or cancelling 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 permit holder, the Authority is satisfied for any reason specified in subsection (1) that the permit concerned should be suspended or cancelled, the Authority shall, by notice in writing to the permit holder, suspend or cancel the permit or take such other action as it considers appropriate.

(4) The penalty of suspension is only available where there has been a contravention of any provision of the Act or these regulations or any condition of a permit which, in the opinion of the Authority, is a contravention that can be easily or speedily remediated by the permit holder.

Provided that —

- (a) if after the expiry of the period of suspension the permit holder has not taken the remedial action, the Authority shall forthwith cancel the permit; or
- (b) on good cause shown by the permit holder, the Authority may extend the suspension for a period not exceeding 30 days to allow the licensee to take the required remedial action.

(5) The Authority shall immediately make an appropriate entry in the register of permits it suspends or lifts a suspension of any permit or cancels it in accordance with this section.

Amendment and replacement of permits

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

- (a) to correct any error in the permit; or
- (b) if the permit holder requests the amendment; or
- (c) if the Authority considers the amendment necessary to reflect the true nature of the activities; or
- (d) if for any other reason the Authority considers the amendment necessary or desirable in the interests of the environment or 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), (c) or (d) and shall call upon the permit holder to show cause, within 14 days from the date of the notice, why the permit should not be amended.

(3) Where a permit holder requests an amendment to his or her permit he or she shall make an application to the Authority, together with the prescribed fee.

(4) If in the opinion of the Authority the amendment sought by the permit holder is a material amendment the Authority treats the matter as if the application for the amendment is an application for new permit.

(5) Where a permit is lost or destroyed, the permit holder may apply to the Authority, together with the prescribed fee, for a replacement permit:

Provided that if the permit holder finds the lost permit he or she or it 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 3 or imprisonment for a period not exceeding one month or both such fine and such imprisonment.

Register of permits

14. (1) The Authority shall establish and maintain a register of permits to be known as the Biosafety Import, Export and Transit Permit Register and which shall be divided into three parts, for Biosafety Import Permit, Biosafety Export Permit and Biosafety Transit Permit in which the following shall be recorded—

- (a) the name and address of every permit holder and the addresses at which he or she or it operates; and
- (b) the date of issue of every permit and of any renewal thereof; and
- (c) any special terms or conditions subject to which any permit is issued or renewed; and

(d) the particulars of any suspension or cancellation or amendment of a permit.

(2) Any person may—

- (a) inspect the register of permits free of charge at all reasonable times at the premises of the Authority or at such other place that the Authority may direct; or
- (b) obtain copies of or extracts from the register for a prescribed fee.

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

Non-commercial imports

15. (1) Non-commercial imports of food, feed, and food or feed additives may be subjected to inspection or testing by the Authority officials at ports of entry.

(2) Imported products which are less than 500 kg shall be considered as non-commercial imports and shall attract a non-commercial fee prescribed in First Schedule.

(3) Any person whose product is tested in terms of subsection (1) shall pay a testing fee prescribed in First Schedule.

(4) The Authority shall not consider imports of seed or other propagating material as non-commercial imports.

PART III

MISCELLANEOUS

Appeals

16. (1) Any person who is aggrieved by a decision of the Authority—

- (a) to reject an application for a permit in terms of sections 7 and 8; or
- (b) or grant an application for a permit subject to conditions in terms of section 10; or

- (c) cancel a licence in terms of section 12; or
- (d) suspend a licence in terms of section 12; or
- (e) amend a licence in terms of section 13;

may appeal to the Board in writing together 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 30-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

17. 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)

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

Confidential information

19. (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) name and address of applicant;
- (b) unique identifier of the product;
- (c) a summary of the risk assessment;
- (d) any methods and plans for emergency response.

(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

20. Any person who violates the provisions of these regulations 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 5, 7, 8, 9 and 15)

FEES

Section	Description	Form	Fees \$US
5(2)	Application for registration	FFA2	500
7(1)	Application for a biosafety import permit:	FFA4	
	1 000 MT/m ³ or Less		30
	1001 MT/m ³ - 5 000 MT/m ³		40
	5 001 MT/m ³ - 10 000 MT/m ³		50
	10 001 MT/m ³ - 15 000 MT/m ³		60
	Above 15 000 MT/m ³		80
	Additional cost for emergency permits		20
	Permit renewal		Fee for new permit
	Amendment of permit		10
	Inspection fee per truck		20

Section	Description	Form	Fees \$US
8(1)	Application for a biosafety export permit: GMO declaration certificate	FFA8	100
8(2)	GMO Testing fee per sample		250
9(1)	Application for a biosafety transit permit	FFA12	20
	Inspection: Human expertise fee per inspector per day		50
15(1)	Non-commercial imports		
	200kg or less		5
	201kg-500kg		10
	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

NB: Sample collection 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.

