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:—

## ARRANGEMENT OF SECTIONS

#### PART I

#### PRELIMINARY

#### Section

- 1. Title.
- 2. Interpretation.
- 3. Purpose.

#### PART II

Applications for Registration Certificate, Import, Export and Biosafety Transit Permits for Food, Feed, Food and Feed Additives and Seed

- 4. Register and Registrar of National Biotechnology Authority.
- 5. Application for registration.
- 6. Validity of renewal.
- 7. Application for biosafety import permit.
- 8. Application for biosafety export permit.
- 9. Application for biosafety transit permit.
- 10. Conditions attaching to every permit.
- 11. Issuance, duration, surrender and renewal of permits.
- 12. Suspension or cancellation of permit.
- Amendment and replacement or permits.

#### Section

- 14. Register of permits.
- 15. Non-commercial imports.

#### PART III

#### **MISCELLANEOUS**

- 16. Appeals.
- 17. Review of decisions.
- 18. Registration of decisions with the National BCH.
- 19. Confidential Information.
- Offences.

FIRST SCHEDULE: Fees.

SECOND SCHEDULE: Forms.

#### 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 maybe subject to inspection at ports of entry by the Authority, and the transporter shall pay an inspection fee prescribed in First Schedule.
- (3) Aperson 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;
    - (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—
  - 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/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
	Inspection fee per truck		20

S.I. 157 of 2018

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		5
	201kg-500kg		10
	Transport: Clients will meet transport costs and using the prevailing Automobile Association		_

Key Assumptions  $1m3 = 1000 \text{ litres} \qquad 1kg = 1 \text{ litre}$   $1MT = 1000kg \qquad 1MT = 1M3 = 1 000kg = 1000 \text{ litres}$ 

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.



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



SECOND SCHEDULE (Sections 2, 7, 8 and 9)

#### **FORMS**

TITLE: LIST OF FOOD, FEED, FOOD AND FEED ADDITIVES AND SEED PRODUCTS THAT ARE REGULATED UNDER THE NATIONAL BIOTECHNOLOGY AUTHORITY ACT [CHAPTER 14:31]

All propagation material	Seeds	
	Enoupsulated (c.g. 0863) of haked	
	Cells ganger a Tie	
	Vegetative	
	1 Topus area	
of the seasonly could be redimen.	Live grain	
Barley	Live grain	
	Dried grain	
	Meal	
	Malt	
	Processed	
Beans	Dried grain	
	Bean meal	
	Processed e.g. canned beans	
	Raw	
Bran		
Bone and meat meal		





Flours, meals and pellets of meat or meat offals unfit for human consumption	
Carcass meal	planting and a last of the
Meat	Fresh
	Dried
	Frozen
	Processed
Livestock	Live
Fish	Dried
	Frozen/fresh
	Processed or not
Milk and products thereof	Liquid
	Whey
	Ice cream
	Milk powder, granules and other solid forms
	Fermented products e.g. cheese, yoghurt
Butter, fats and oils	
Poultry	Live Carcass
Stock feed	
Coffee and tea	Raw or processed

# FFA1





Cotton	Seed cotton
	Fuzzy seed
	Cake
Cultures of microorganisms	Static, active or innate
Edible nuts	Dried
	Fresh
	Processed
Food and feed additives	
Fruits and products thereof	Fresh
	Dried
	Fruit juice
	Fruit preparations
	Preserved Preserved
Wines	4.8
Glucose Syrup	998
Maize and products thereof	Grain
	Crushed
	Samp
	Meal
	Green
	On cob
	Grits
	Processed e.g. cornflakes





Millet and products thereof	Grain
	Meal
	Malt
	Processed
Plants and grasses	Lawn
	Flowers
	Live or dried
Potatoes	Raw
	Semi processed
	Processed
Products of Fermentation	Alcohols
	Acids, vitamins and derivatives thereof
	Precursors for acids, vitamins and derivatives thereof
	Spirits
	Beer
Rice	Grain
	Processed
Sorghum	Grain
	Meal
	Malt





Soya beans grain	Grain Crude oil Cake Chunks Other processed soya-bean products
Spices	Raw or Processed
Sugar	W 193
Sunflower	Colo
Vegetables	Vegetable oil Fresh Dried Seed
	Grain Processed Bran Flour
Other oleaginous products	Oil cake Oil meal Oil seeds residues Crude oil extracted from oil seeds

NB: The list cannot be exhaustive since it is impossible to list each and every food, feed, food and feed additive or seed.





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 Certificate for handling imports/ exports offood, feed, food and feed additives and seed in accordance with the provisions of the National Biotechnology Authority Act [Chapter 14:31] of 2006.

## Part I: Nature of Applicant

Select Appropriate Category:

We/I hereby apply to be registered in accordance with the National Biotechnology Authority Act:

Individual			
Organisation			
Company			
Part II: Applica	nt's Particulars		
Registered Nam	ne		
Registration No Incorporation No National ID num Registration organisations)	umber (Certificate of lumber for companies, nber for individuals, Number for other	finition moment the felt	3 y 1
Physical Addres	SS		
Postal Addres above)	s (if different from		







Email Address	on for Registration ( leed, food and feet a	Heoligg A. H. ITI Legal to stroop.
Phone Number	of 2006	Obsoles 14:31]
Number of Employees	to day!	Annual Maria
Working Hours Indicate shifts where applicable	Fromhrs	Tohrs
Part III: Head of Organisation's d		minqonqq A 1 x 10
Name		manage me
Position	, 0	fueduo
Contact Details	- Audulit-ori	
Part IV: Contact Person Details	To straffents of their recommen	nost eralodasya god materiospe ne
Name	authors, a dutar	W. Brainestan, 12 (2000es: 1994)
Position		RESIDENT AUTORS
Email Address		
Phone/Mobile Number	(if different from	SERVIDIA INICCI



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## Part V: Scope of Application for Registration

What are the goods intended to be imported/exported?

## Part VI: Applicant's Checklist

	Submit the following requirements on application submission		
Registered Company	Current Tax Clearance		
	Certificate of Incorporation		
	CR14		
	Company profile		
Individual	Current Tax Clearance		
	Certified National ID Copy		
	Proof of residence		
Other Organisations	MoU/Proof of registration		
	Current Tax Clearance		

#### Part VII: Declaration

Signature: .....

I,	(full name) declare that
	this form is accurate and hereby apply for registration
for handling food, feed, foo	d and feed additives and seed regulated by the NBA.
Designation	Date:

#### FFA3



# **National Biotechnology Authority**

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



# Certificate of Registration

NO: 000000

CERTIFICATE NUMBER NBARA 00 00 00 00

THE NATIONAL BIOTECHNOLOGY AUTHORITY HEREBY GRANTS TO-

CHEREAFTER CALLED THE REGISTERED INSTITUTION) THE RIGHT TO HANDLE IMPORTS EXPORTS OF FOOD, FEED, FOOD PROCESSING AIDS AND SEED IN ACCORDANCE WITH THE PROVISIONS OF THE NATIONAL BIOTECHNOLOGY AUTHORITY ACT ICHAP 1431/OF 2006.

CHIEF EXECUTIVE OFFICER AND REGISTRAR, NBA ISSUE DATE 29:07:15
EXPIRY DATE: 3(10)15

A hub for Biotechnology, Biosafety, Research & Development

www.nba.ac.zw



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 IMPORTERS

#### 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 food, feed, food and feed additives, and seed.

Any organisation seeking to be granted authority by the NBA to import food, feed, food and feed additives, and seed into Zimbabwe should meet the following requirements:

- 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
- 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.



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## 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 organisation.
- 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.



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5. 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. For seed and grain only PCR tests and GMO certificates which meet guidelines in number 4 above will be accepted. Only GMO declarations issued by the biosafety office of the government in the country of origin of the consignment will be accepted.

#### SECTION B

TITLE: Application for a Biosafety Import Permit In Accordance with the National Biotechnology Authority Act [Chapter 14:31] of 2006.

#### 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	n mil kat an
NBA Certificate of Registration Number	Programmed throughout the
	managed myst had to be a constraint
Email Address	
Phone Number	







Part III: APP	LYING FO					
Please tick the	appropriate	box:				
New			Ken	ewal		
Extension			Amo	endment		
Replacement			App	eal		
Part IV: Prod						
Product Name	(indicate br	and/variet	ty if applicat	ole):	adseloiti las	IOUENIA.
GM Status:	Negative		Positive		Traces	
Quantity:				est line	lina yesho et	
Country of Or	igin:			Prospection of	lia rovenso A	ryslor
Supplier:						
Port of Entry:.						
Mode of Trans	sport:					
Purpose of Im	port:					
Part V: Justif	ication for t	he reque				
If you ticked F above, please						
					2492004-1	





Part VI: Applicant's Checklist	
Valid NBA Certificate of Registration	
GMO Certificate (Please Attach)	
GMO Declaration (Please Attach)	
Documents to be renewed/extended/ amende	d $\square$
Part VII: Declaration	
that the information provided in this form a Biosafety Import Permit under the Natio [Chapter 14:31] of 2006.	is accurate and hereby apply for
Designation D	ate:
Signature:	

#### FFA5



## National Biotechnology Authority

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# Biosafety Import Permit

Notional Biotechnology Authority Act /Chan: 14:811

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



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# ATTENTION TO ALL IMPORTERS OF FOOD, FEED, FOOD AND FEED ADDITIVES AND SEED

#### RE: SPECIFICATIONS FOR PRE-SHIPMENT INSPECTIONS

The National Biotechnology Authority would like to highlight the following procedures to be adhered to by all importers and exporters of food, feed, food and feed additives and seed where a pre-shipment inspection is required.

Pre-shipment inspections (PSI) are required when further information on the exact nature of the product including production, GM status, quality and storage of the product and raw materials is needed thereby ensuring that imports or exports comply with regulations. Clients should take note of the following;

- 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. If a pre-shipment inspection is ordered, the applicant should kindly
  - Liaise with the Authority to arrange dates, time and location for the pre-shipment inspection.
  - Meet costs of the inspection exercise including GM testing and any associated costs; upon obtaining an invoice from the Authority.

#### FFA6



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- 3. During the inspection, the Authority shall;
  - Assess handling, testing, sampling and packaging of the product.
  - Assess suitability of the production or storage facility.
  - Check quality management records.
  - Check factory or storage facility product records.
  - Check product data sheets.
  - Assess safety and conformity marks from other markets.
  - Request for the distribution license.
  - Request for the Facility Registration Certificates.
  - Collect random samples for testing.
- 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 within 30 days after receiving the note.
- When the Authority receives the appeal note, a meeting will be convened for discussing the issues.





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# ATTENTION TO ALL IMPORTERS OF FOOD, FEED, FOOD & FEED ADDITIVES AND SEED

#### 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 food, feed, food & feed additives and seed where a post-shipment inspection is required.

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

- 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 other associated costs, upon obtaining an invoice from the Authority.

#### FFA7



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## 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.

### Once the testing is complete, the Authority will either issue;

 A GMO certificate and 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.





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#### ATTENTION TO ALL EXPORTERS

#### 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 food, feed, food and feed additives, and seed.

- 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.
- If a sample is to be tested; the NBA inspectorate will collect and test samples at the client's cost.





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#### SECTION B

TITLE: Application for an Export Permit In Accordance with the National Biotechnology Act [Chapter 14:31] of 2006

#### Part I: Nature of Applicant

We/I hereby apply for an Export Permit in accordance with the National Biotechnology Authority Act:

# Select Appropriate Category: Individual

Organisation

Company

# Part II: Applicant's Particulars

Registered name	Current ZBARA necduraria
NBA Certificate of Registration Number	e gel at affectivity of
Physical Address	II a sample is to be tested; use Net A in at the chem a cost.
Email Address	
Phone Number	

# ZIMBABWE



Please tick the	appropriate box:		
New		Renewal	
Extension		Amendment	
Replacement		Appeal	
Part IV: Produ	ict Details		
Product Name (	(indicate brand/variet	y if applicable):	
GM Status:		Positive	
Quantity:		e Pea E Plankeborer	
Country of Orig	gin:		
Recipient Coun	try:		
Supplier:			
Port of Exit:			
Mode of Transp	ort:		
Purpose of Exp	ort:		
Part V: Justific	cation for the reques	st	
		nendment/Replacement/	

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Part VI: Applicant's Checklist		
Valid NBA Certificate of Registration		
GMO Certificate (Please Attach)		
Documents to be renewed/extended/amended	Product Details	
Part VII: Declaration		
I,that the information provided in this form is accurate a Permit under the National Biotechnology Authority A	and hereby apply for a	<b>Export</b>
Designation Date:		
Signature:		



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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 seed 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.

This 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.

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#### FFA10



# National Biotechnology Authority

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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		promoter inator detected	•	NOS

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

355: The 355 PCR system detects transgenic DNA sequences that are characteristic for the 355 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



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ATTENTION TO ALL CLEARING AGENTS HANDLING TRANSIT CONSIGNMENTS OF FOOD, FEED, FOOD AND FEED ADDITIVES AND SEED PASSING THROUGH ZIMBABWE

# SPECIFICATIONS FOR APPLICATION FOR A 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 food, feed, food and feed additives and seed through Zimbabwe.

Any organization seeking to be granted authority by the NBA to transit food, feed, food and seed additives and seed through Zimbabwe should meet the following requirements:

- Complete a transit application form at the port of entry or Head Office supplying the following information:
  - Name and address of clearing agent registered 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 product will enter into Zimbabwe.
  - Port of exit through which product will exit Zimbabwe.
  - Undertaking to meet the cost of supervision in the case of genetically modified products.

#### FFA11



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## 2. The GM certificate must meet the following requirements:

- Be on original letterhead of the laboratory conducting the test and 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 3 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 and 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.



BIOSAFETY TRANSIT PERMIT  National Biotechnology Authority Act [Chap. 14:31] of 2006
Permit No: XXXXX  Ref No: NBA/RA/
Name of Applicant:
Product:  GM Status:  Quantity:  Country of Origin:
Purpose:  Port of Entry:  Port of Exit:
Trailer Reg No:
1. To leave Zimbaiswe within 72 hours 2
21 Fraces Dr. oc. New ands, Hanne, P.O. Bert CV179 Carroway, Tel., =261 4 7824 569. Festal philips at the

