STATUTORY INSTRUMENT NO. 42 OF 2010

The Biosafety Act, 2007
(Act No. 10 of 2007)

The Biosafety (Genetically Modified Organisms for Food, Feed and Processing) Regulations, 2010

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Copies of this Statutory Instrument can be obtained from the Government Printer, P.O. Box 30136, 10101 Lusaka. Price K14,500 each.

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IN EXERCISE of the powers contained in section *forty-six* of the Biosafety Act, 2007, the following Regulations are hereby made:

PART I

PRELIMINARY

Title

1. These Regulations may be cited as the Biosafety (Genetically Modified Organisms for Food, Feed and Processing) Regulations, 2010.

Interpretation

2. In these Regulations, unless the context otherwise requires

"Authority has the meaning assigned to it in the Act;

"feed" means any substance, whether processed, semi-processed, or raw, which is intended for animal consumption;

"final consumer" means the ultimate consumer who will not use the product as part of any business operation or activity;

"food" means any substance, whether processed, semi processed or raw, which is intended for human consumption, and includes drinks, chewing gum and any substance that is used in the manufacture of food, but does not include cosmetics, tobacco or substances used only as drugs;

"genetically modified organism" has the meaning assigned to it in the Act;

"import" has the meaning assigned to it in the Act;

"ingredient" means any substance, including a food or feed additive or a component of a compound ingredient, used in the manufacture or preparation of a foodstuff or feed and present in the final product, whether or not in a modified form;

"label" means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, a container of food or feed;

"operator" means a natural or legal person who places a product on the market or who receives a product that has been placed on the market in Zambia, or from another country, at any stage of the production and distribution chain, but does not include the final consumer;

"placing on the market" has the meaning assigned to it in the Act;

" pre packaged "means packaged or made up in advance in a container, ready for offer to the consumer, or for catering;

" produced from genetically modified organisms "means derived, in whole or in part from genetically modified organisms, but not containing or consisting of genetically modified organisms;

"Register" means the Register established under regulation 24;

"the first stage of the placing on the market of a product" means the initial transaction in the production and distribution chains, where a product is made available to a third party;

"traceability" means the ability to trace genetically modified organisms and products produced from genetically modified organisms at all stages of their placing on the market through the production and distribution chains;

" Tribunal " has the meaning assigned to it in the Act; and

" unique identifier " means a simple numeric or alphanumeric code which serves to identify a genetically modified organism on the basis of the authorised transformation event from which it was developed and providing the means to retrieve specific information pertinent to that genetically modified organism.

PART II
IMPORTATION OF GENETICALLY MODIFIED ORGANISMS

Prohibition of importation of genetically modified organism for food, feed or processing

3. A person shall not import a genetically modified organism for direct use as food or feed or for processing unless—

(a) the importation is duly authorised by the Authority;

(b) the genetically modified organism is authorised for commercial distribution as food or feed in the country of origin; and

(c) regardless of the intended use, the genetically modified organism poses no significant risks to human or animal health, biological diversity, non genetically modified crop or the environment.

Application for permit to import genetically modified organism for food, feed or processing

4. An application to import a genetically modified organism for direct use as food or feed or for processing shall be in Form I set out in the First Schedule.

Consideration of application

5. (1) The Authority shall, within fourteen days from the receipt of an application under regulation 4, examine the application to determine if it meets the requirements of the Act and these Regulations.

(2) The Authority shall, where the application meets therequirements of the Act and these Regulations—

(a) accept the application and inform the applicant in Form II set out in the First Schedule; and

(b) forward a copy of the application to the Scientific Advisory Committee.

(3) The Scientific Advisory Committee shall evaluate an application referred to it under sub regulation (2), particularly the risk assessment studies conducted and actions taken by the relevant regulatory authorities in the country of origin, and submit its report to the Authority within thirty days from its receipt of the application.

(4) The Authority shall, where an application is incomplete or defective, inform the applicant in Form III set out in the First Schedule and give the applicant a period within which to correct the defects in the application.

(5) Where an applicant to whom a notice is sent under sub regulation (4) fails to correct the defect within the period specified by the Authority, the Authority shall reject the application.

(6) An applicant whose application is rejected under sub regulation (5) may re submit the application after the defect is corrected.

(7) The Authority may request an applicant to submit additional information in relation to the application in Form IV set out in the First Schedule.

Referral to other agencies

6. (1) The Authority shall furnish the following agencies with a copy of an application for their comments:

(a) the Plant Quarantine and Phytosanitary Service, if the genetically modified organism is a raw agricultural commodity intended for direct use as food or processing into food; and

(b) the authorised veterinary services, if the genetically modified organism is intended for direct use as feed or for processing into feed.

(2) The agencies refered to under sub regulation (1) shall submit their comments to the Authority within thirty days of receipt of the application.

Public consultation

7. (1) An applicant shall, within fifteen days from the receipt of the acceptance of the application by the Authority, publish a notice, in at least two daily newspapers of general circulation in Zambia, inviting interested parties to send their comments or objections on the proposed importation for direct use as food or feed, or for processing, to the Authority within a period of thirty days from the date of publication of the notice.

(3) An applicant shall submit to the Authority proof of the publication within fifteen days from the date of publication.

Grant of permit

8. (1)The Authority shall, within thirty days from the acceptance of an application, approve the application if the use of the genetically modified organism for food or feed, or for processing, does not pose any significant risks to human or animal health, biological diversity, non genetically modified crops or the environment.

(2) In calculating the thirty day period refered to under sub regulation (1), the period of time during which the Authority awaits further information from an applicant or from any relevant regulatory authority in the country of origin of the genetically modified organism in respect of which an application is made shall not be included.

(3) A permit to import a genetically modified organism for food, feed or processing shall be in Form V set out in the First Schedule.

(4) A permit may be renewed for a further period of five years where the holder shows that the continued importation of the genetically modified organism as food or feed, or for processing, does not pose any risks to human or animal health, biological diversity, non genetically modified crop or the environment.

Rejection of application

9 (1) The Authority shall reject an application—

(a) if the genetically modified organism in respect of which the application is made poses risks to human or animal health, biological diversity, non genetically modified crop or the environment; or

(b) if the application does not meet the requirements of the Act or these Regulations.

(2) A notification of a rejection of an application shall be in Form VI set out in the First Schedule.

Permit conditions

10. A permit holder shall comply with the following conditions:

(a) the genetically modified organism shall be imported solely and exclusively for direct use as food or feed, or for processing into food or feed, and not for field testing or propagation;

(b) the genetically modified organism shall be maintained and disposed of in such a manner as to prevent any risks to human or animal health,biological diversity, non genetically modified crop or the environment;

(c) all packing materials, shipping containers and all other materials accompanying the genetically modified organism shall be treated or disposed of in such a manner as to prevent any risks to human or animal health, biological diversity, non genetically modified crop or the environment;

(d) the permit holder shall give an inspector access, during regular business hours, to the facility where the genetically modified organism is located and to any records relating to the importation of the genetically modified organism;

(e) the genetically modified organism shall be identified with a label showing the permit number, name of the genetically modified organism and the date of importation;

(f) the genetically modified organism shall be subject to the application of measures including final disposal, which the Authority considers necessary to prevent its accidental or unauthorised release;

*(g)*the permit holder shall—

(i) in the event of any accidental or unauthorised release of the genetically modified organism, report to the Authority verbally, immediately upon discovery, or in writing, within twenty four hours; and

(ii) notify the Authority in writing, as soon as possible, but not exceeding three working days, if the genetically modified organism or associated host organism is found to have characteristics substantially different from those listed in the application for a permit, or suffers from any excessive mortality or morbidity, unanticipated effect on non target organisms or other unusual occurrence;

(h) if new information becomes available indicating that the genetically modified organism could pose significant risks to human or animal health, biological diversity, non—genetically modified crop or the environment, the applicant shall

report to the Authority who shall immediately take measures to protect human or animal health, biological diversity, non genetically modified crop or the environment;

(i) the permit holder shall import the genetically modified organism only at the port of entry designated in the permit;

(j) the permit holder shall comply with such other conditions as the Authority may consider necessary or desirable to prevent any risks to human or animal health, biological diversity, non genetically modified crop or the environment; and

(k) the permit holder shall comply with such other conditions specified under the Act.

Labelling of consignment for importation

11. A consignment for importation shall be labelled in accordance with the requirements specified under Part III.

Approval of genetically modified organisms for direct use to be entered in Register

12. The Authority shall record in the Register the genetically modified organisms or products of genetically modified organisms that have been approved for importation for direct use as food or feed, or for processing.

Notice of arrival of shipment

13. A holder of a permit for the importation of genetically modified organisms for direct use as food or feed or for processing shall, within fifteen days from the date of arrival of every shipment of the genetically modified organism, notify the Authority of such arrival in Form VII set out in the First Schedule.

Suspension, revocation or cancellation of permit

14. (1) A permit shall be revoked if—

(a) the permit holder provides false information in the application or declaration relating to any shipment of genetically modified organisms;

(b) the permit holder refuses to allow the inspection of the physical containment facility or intermediate destination of the genetically modified organism;

(c) the permit holder violates the relevant phytosanitary and biosafety regulations and measures or any condition imposed in the permit;

(d) the authority to commercially distribute the genetically modified organism in the country of origin is suspended or revoked; or

(e) new information becomes available to the Authority indicating that the genetically modified organism, if allowed for its intended use will result in significant risks to human or animal health, biological diversity, non genetically modified crop or the environment.

(2) The Authority may suspend, for any period, revoke or cancel any permit issued under this Act, if in the opinion of the Authority, any genetically modified organism or product of a genetically modified organism to which the permit relates poses any risk to human or animal health, non-genetically modified crop, biological diversity or the environment.

(3) A suspension, revocation or cancellation of a permit shall be in Form VIII set out in the First Schedule.

(4) A suspension, revocation or cancellation of a permit shall be endorsed on the permit.

PART III
LABELLING AND TRACEABILITY

Scope of Part

15. This Part applies, at all stages of the placing on the market, to

(a) products consisting of, or containing, genetically modified organisms, placed on the market in accordance with the Act; and

(b) food and feed produced from genetically modified organisms, placed on the market in accordance with the Act.

Traceability

16. (1) At the first stage of the placing on the market of a product, including bulk quantities, consisting of, or containing, genetically modified organisms an operator shall transmit the following information in writing to the operator receiving the product:

(a) that the product contains or consists of genetically modified organisms; and

(b) the unique identifier assigned to the genetically modified organisms in accordance with these Regulations.

(2) An operator shall, at all subsequent stages of the placing on the market of products, ensure that the information received in accordance with sub regulation (1) is transmitted in writing to the operators receiving the products.

(3) In the case of products consisting of or containing mixtures of genetically modified organisms to be used only and directly as food or feed or for processing, the information referred to in sub regulation (1) may be replaced by a declaration of use by the operator, accompanied by a list of the unique identifiers for all the genetically modified organisms that have been used to constitute the mixture.

(4) An operator shall put in place systems and standardised procedures to allow the holding of information specified in sub regulations (1), (2) and (3) and the identification, for a period of five years from each transaction, of the operator by whom, and the operator to whom, the products have been made available.

Labelling

17. (1) For products consisting of or containing genetically modified organisms, an operator shall ensure that—

(a) for pre packaged products consisting of, or containing genetically modified organisms, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' appear on a label; and

(b) for non pre packaged products offered to the final consumer, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' shall appear on, or in connection with, the display of the product.

(2) An operator shall label genetically modified food and feed in a manner that ensures that accurate information is available to operators and consumers to enable them to exercise their freedom of choice in an effective manner and to enable the control and verification of labelling claims.

Exemptions

18. (1) Regulation 5 does not apply —

(a) to traces of genetically modified organisms in products in a proportion of less than the 0.9 percent threshold:

Provided that the traces of genetically modified organisms are adventitious or technically unavoidable and the genetically modified organisms have been subject to a scientific risk assessment; and

(b) to traces of genetically modified organisms in products intended for direct use as food, feed or for processing in a proportion of less than the 0.9 percent threshold:

Provided that the traces of genetically modified organisms are adventitious or technically unavoidable.

(2) These Regulations do not apply to food which contains or has genetically modified organisms in a proportion of less than 0.5 percent:

Provided that the presence of such genetically modified organisms is considered technically unavoidable and the organisms have been subjected to a scientific risk assessment and considered to be safe.

Traceability requirements for food and feed produced from genetically modified organisms

19. (1) An operator shall, when placing a product produced from genetically modified organisms on the market, transmit the following information in writing to the operator receiving the product:

(a) an indication of each of the food ingredients which is produced from genetically modified organisms;

(b) an indication of each of the feed materials or additives which is produced from genetically modified organisms; and

(c) in the case of products for which no list of ingredients exists, an indication that the product is produced from genetically modified organisms.

(2) An operator shall put in place systems and standardised procedures to allow the holding of the information specified in sub regulation (1) and the identification, for a period of five years from each transaction, of the operator by whom, and to whom, the products referred to in sub regulation (1) have been made available.

(3) Sub regulations (1) and (2) do not apply to traces of genetically modified organisms in products for food and feed produced from genetically modified organisms in a proportion of less than the 0.9 percent threshold established for those genetically modified organisms, if the traces of genetically modified organisms are adventitious or technically unavoidable.

Application to place on market food, feed or product derived from genetically modified organisms

20. (1) An application for the placing on the market of food and feed and products derived from genetically modified organisms shall be made to the Authority and shall include a unique identifier for each genetically modified organism.

(2)An application under sub-regulation (1) shall be in Form 1 set out in the First Schedule.

(3)The Authority shall, where the application meets the requirements of these Regulations, accept the application and inform the applicant of such acceptance in Form II set out in the first Schedule.

(4) A permit to place on the market food, feed and products derived from genetically modified organisms shall be in Form IX set out in the First Schedule.

Unique identifiers

21. (1)A producer of a genetically modified organism for food or feed shall develop a unique identifier for each genetically modified organism.

(2) Where consent or authorisation is granted under sub-regulation (3) of regulation 20, for the placing on the market of a genetically modified organism, the Authority shall communicate the unique identifier for the genetically modified organism in writing, to the Biosafety Clearing House.

(3) The unique identifier for each genetically modified organism shall be recorded in the Register.

Withdrawal of certain genetically modified organisms

22. (1) The Authority shall withdraw a genetically modified product where it has adverse effects on human and animal health, biological diversity, non genetically modified crops or the environment, including socio economic conditions.

(2) If new information or a re assessment of the existing information reveals that the use of food or genetically modified food approved by these Regulations endangers human health, or the feed endangers animal health, the Authority shall immediately suspend the sale of such food.

(3) A notice of withdrawal of genetically modified food, feed or products, or suspension of the sale of such food, feed or products shall be in Form X set out in the First Schedule, and such withdrawal or suspension shall be endorsed on the permit.

(4)The Authority shall require the person whosubmitted the application for approval to import, store, transport, distribute or sell food or feed withdrawn or suspended under this regulations, as the case may be, to withdraw the product from the market and such person shall immediately comply with the requirement.

Risk management measures

23. Risk management measures shall be implemented in accordance with the provisions of the Act.

Inspection and control measures

24. An inspector may, subject to the provisions of the Act, conduct inspections, as maybe appropriate, to ensure compliance with these Regulations.

Register

25. (1) The Authority shall establish and maintain a Register for purposes of these Regulations.

(2) The Authority shall record in the Register all available sequencing information, reference material for, and any other information relating to, genetically modified organisms that are authorised or not authorised to be put into circulation in Zambia.

Appeal to Tribunal

26. Any person aggrieved with the decision of the Authority under these Regulations may appeal to the Tribunal in Form XI set out in the First Schedule.

Fees

27. The fees set out in the Second Schedule are payable for the matters set out therein.

FIRST SCHEDULE

(Regulations 4, 5(2), 5(4), 5(7), 8(3), 9(2), 13, 14(3), 20(2), 20(3), 22(3) and 26)

Form I
(Regulations 4 and 20 (2))
(To be completed in triplicate)

REPUBLIC OF ZAMBIA

The Biosafety Act, 2007
(Act No. 7 of 2007)

The Biosafety (Genetically Modified Organisms for Food, Feed and Processing), Regulations, 2010

APPLICATION TO IMPORT GENETICALLY MODIFIED ORGANISM OR PRODUCT OF GENETICALLY MODIFIED ORGANISM FOR USE AS ( ) FOOD ( ) FEED ( ) FOR PROCESSING OR TO ( ) PLACE GENETICALLY MODIFIED ORGANISM OR PRODUCT OF GENETICALLY MODIFIED ORGANSIM ON MARKET

(Tick as appropriate)

	Shaded fields for official use only	**Licence code**
		Date and Time

Information Required		*Information Provided*	√
1.	Name(s) of applicant(s)		
2.	Type of applicant	Individual ☐ Company ☐ Co-operative ☐ Partnership ☐	
3.	*(a)* Nationality		
	(b) Identity card (National Registration Card No. or Passport No.) – Attach copies		
4.	Notification address		
	Tel:		
	Fax:		
	Email:		

5.	*(a)* **Company/Institution/ Cooperative/Partnership/ NGO name and address**				
	(b) **Company/Institution/ Cooperative/Partnership/ NGO Registration No. (Attach copies of Certificate of registration)**				
	*(c)***Shareholders:**	Shareholder	Shares held	Nationality	NRC/ Passport No.
		.....	.....	.....	.....
		.....	.....	.....	.....
		.....	.....	.....	.....
		.....	.....	.....	.....
		.....	.....	.....	.....
		.....	.....	.....	.....
	(d) **Directors**	Director	Shares held	Nationality	NRC/ Passport No.
		.....	.....	.....	.....
		.....	.....	.....	.....
		.....	.....	.....	.....
		.....	.....	.....	.....
		.....	.....	.....	.....
		.....	.....	.....	.....
	(e) **Chief Executive Officer**	Name		Nationality	
	(f) **Company Secretary**	Name		Nationality	
6.	**Details of Genetically Modified Organism (GMO)** *(a)* **Name (Scientific, common and trade names, constituents, etc)**				
	*(b)***Country of origin**				

7.	**Location of Projects**				
8.	**Use of genetically modified organism/ product of GMO**	( ) Food	( ) Feed	( ) Processing	( ) Placing on the market
9.	**Previously held licences in Zambia, if any, by applicant issued under the Biosafety Act, 2007**	Permit/licence (Type and Licence No.)		Name and Type of Genetically Modified Organism/Location	
		(a) (b) (c) (d) (e) (f)		(a) (b) (c) (d) (e) (f)	
10.	**Currently held licences in Zambia, if any, by applicant issued under the Biosafety Act, 2007**	Permit/Licence (Type and Licence No.)		Name and Type of Genetically ModifiedOrganism/Location	
		(a) (b) (c) (d) (e) (f)		(a) (b) (c) (d) (e) (f)	
11.	**Currently held Zambia, if any, by subsidiary companies issued under the Biosafety Act, 2007**	Permit/Licence (Type and Licence No.)		Name and Type of Genetically Modified Organism/Location	
		(a) (b) (c) (d) (e) (f)		(a) (b) (c) (d) (e) (f)	

12. **Have you been convicted of an offence involving fraud or dishonesty or of any offence under the Biosafety Act, No. 7 of 2007, or any other law within or outside Zambia?**

Ifyes,specify details:.....
Nature of offence:.....
Date of Conviction:.....
Sentence:.....

13. **Have you ever applied for a Permit to import GMOs or Products into Zambia or outside Zambia?If yes, please give details below-**

Type of Permit applied for and country in which permit was applied for	Name and Type of Genetically Modified Organism	Use of Genetically Modified Organism	Date of application	Status of application (Granted, rejected or pending)*

If application was rejected, give reasons for rejection:

14. **Appendices** (This is in addition to the information required in the Second Schedule, the Third Schedule and other information required under the Act)

Appendix No. 1	Project details and outline (Should include steps to be taken in implementation; monitoring and evaluation; and disposal of waste)		
Appendix No. 2	Names and qualifications of person(s) responsible for the planning and carrying out of the use of the genetically modified organism, including those responsible for supervision, monitoring and safety, in particular qualifications of the responsible scientist		
Appendix No. 3	Photocopies of curricula vitae, work permits and other relevant permits issued by the Immigration Department, in the case of foreign individual		
Appendix No. 5	Published scientific literature relating to the genetically modified organism or product of a genetically modified organism (Should include information on risks posed by the Genetically Modified Organism to human or animal heath, biological diversity, non-genetically modified crop or the environment		
Appendix No. 6	Risk Assessment(Should include measures required under the Biosafety Act, 2007)		
Appendix No. 7	Notification from the exporter or country of origin in accordance with existing international agreements on the transboundary movement of the genetically modified organism		
Appendix No. 8	Documentation to show that the genetically modified organism or product of a genetically modified organism is allowed for commercial distribution as food or feed by the relevant regulatory authority in the country of origin and does not pose any significant risk to human or animal health, biological diversity, non-genetically modified crop or the environment		
Appendix No. 9	If the genetically modified organism is intended for use as feed or for processing into feed, attach documentation to show that the relevant regulatory authority in the country of origin have determined that the genetically modified organism does not pose any significant risk to human or animal health, biological diversity, non-genetically modified crop or the environment		
Appendix No. 10	Public liability insurance		
Appendix No. 11	Any other information which the Authority may consider necessary or require to prevent any significant risk to human or animal health, biological diversity, non-genetically modified crop or the environment		

I hereby declare that the genetically modified organism is to be imported solely and exclusively for direct use as food or feed, or for processing into food or feed, not for field testing or propagation

_____ _____

Applicant (Name) *Date*

_____

Signature of Applicant

FOR OFFICIAL USE ONLY

Received by:_____ _____

Officer (Name and signature) *RECEIPT NO.*

Amount Received _____

Serial No. of application: _____ STAMP

Form II
(Regulations 5(2) and 20(3))

REPUBLIC OF ZAMBIA

The Biosafety Act, 2007
(Act No. 7 of 2007)

The Biosafety (Genetically Modified Organisms for Food, Feed and Processing) Regulations, 2010

NOTICE OF ACCEPTANCE OF APPLICATION

To (1).....
.....

(1) Here insert the full names and address of the applicant

IN THE MATTER OF (2) ..... you

(2) Here insert the reference No. and type of application

are hereby notified that your application for (3) .....

has been accepted and you are directed to –

(3) Here insert the type of application

(a) publish your application for public notification in two newspapers of general circulation in Zambia within fifteen days hereto;

(b) include in your public notice, provision to solicit comments from the general members of the public relating to yourapplication;

(c) ensure that the comments from the public are submitted to the Authority within thirty days from the date of publication of the notice; and

(d) submit proof of the publication to the Authority within fifteen days from the date of the publication.

Dated this ..... day of 20

.....
National Biosafety Authority

Form III
(*Regulation* 5(4))

REPUBLIC OF ZAMBIA

The Biosafety Act, 2007
(Act No. 7 of 2007)

The Biosafety (Genetically Modified Organisms for Food, Feed and Processing) Regulations, 2010

NOTICE TO RECTIFY DEFECTS RELATING TO APPLICATION

(1) Here insert the full names and address of the applicant

To (1).....
.....

(2) Here insert the reference No. and type of application

IN THE MATTER OF (2) .....
you are hereby notified that your application for (3) .....

3) Here insert the type of application

has not been accepted on the following grounds:

(a).....
(b).....
(c).....
(d).....

You are hereby given ..... days within which to correct the defects in your application failure to which your application shall be rejected in accordance with regulation 9 of the Biosafety (Genetically Modified Organisms for Food, Feed and Processing) Regulations, 2010.

Dated this ..... day of 20

.....

National Biosafety Authority

Form IV
(*Regulation* 5(7))

REPUBLIC OF ZAMBIA

The Biosafety Act, 2007
(Act No. 7 of 2007)

The Biosafety (Genetically Modified Organisms for Food, Feed and Processing) Regulations, 2010

REQUEST FOR ADDITIONAL INFORMATION

To (1).....
.....

(1) Here insert the full names and address of applicant

IN THE MATTER OF (2) .....
you are hereby requested to furnish the following information or documents in respect of your application for ..... within ..... days:

(2) Here insert the Reference No. and type of application

(a).....
(b).....
(c).....
(d).....

If you fail to furnish the requested information within the stipulated period, your application will be treated as invalid and shall be rejected.

Dated this ..... day of 20

(3).....

(3)Signature of Registrar of Authority

.....
Registrar

Form V
(*Regulation* 8(3))

REPUBLIC OF ZAMBIA

The Biosafety Act, 2007
(Act No. 7 of 2007)

The Biosafety (Genetically Modified Organisms for Food, Feed and Processing) Regulations, 2010

PERMIT No. .....

PERMIT

(Section ..... of the Biosafety Act, No. 7 of 2007)

Holder's name .....
Address .....
.....
This Permit shall apply to the following genetically modified organism product of a genetically modified organism.....
.....
..... which shall be used for
.....
The Genetically Modified Organism/product of a Genetically Modified Organism shall be imported through .....
The Permit is granted for a period of 5 years commencing on the ..... day of ....., 20 .....
The conditions of grant of the Permit are as shown in the Annexures attached hereto.

Issued at ..... this ..... day of ....., 20 .....

ENDORSEMENT OF REGISTRATION

This Permit has this ..... day of ....., 20..... been registered in the Register.

.....
National Biosafety Authority

Form VI
(*Regulation* 9(2))

REPUBLIC OF ZAMBIA

The Biosafety Act, 2007
(Act No. 7 of 2007)

The Biosafety (Genetically Modified Organisms for Food, Feed and Processing) Regulations, 2010

NOTICE OF REJECTION OF APPLICATION

To (1).....
.....

(1) Here insert the full names and address of applicant

IN THE MATTER OF (2) .....

(2) Here insert the reference No. and type of application

you are hereby notified that your application for (3) ..... has been rejected on the following grounds:

(3) Here insert the type of application

(a).....
(b).....
(c).....
(d).....

Dated this ..... day of ..... 20.....

.....

National Biosafety Authority

Form VII
(*Regulation* 13)

REPUBLIC OF ZAMBIA

The Biosafety Act, 2007
(Act No. 7 of 2007)

The Biosafety (Genetically Modified Organisms for Food, Feed and Processing) Regulations, 2010

NOTICE OF ARRIVAL OF SHIPMENT OF GENETICALLY MODIFIED ORGANISM

TO: THE NATIONAL BIOSAFETY AUTHORITY

IN THE MATTER OF (1) .....

you are hereby notified of the arrival of the shipment of (2) .....whose details are as follows:

(a) name of the carrier: .....

(b) date of arrival of the consignment: .....

(c) address at which consignment is being kept at time of this notice:

.....

(d) country of origin: .....

(e) name of the shipper: .....

(f) name and address of the importer: .....

(g) quantity of the genetically modified organism imported:

.....

Dated this ..... day of ..... 20 .....

(3) .....

Signature of Permit holder

(4) .....

Full names of Permit holder

(1) Here insert the Permit No.

(2) Here insert the name and type of Genetically Modified Organism

(3) Here insert the signature of the permit holder

(4) Here insert the full names of permit holder

Form VIII
(*Regulation* 14(3))

REPUBLIC OF ZAMBIA

The Biosafety Act, 2007
(Act No. 7 of 2007)

The Biosafety (Genetically Modified Organisms for Food, Feed andProcessing) Regulations, 2010

NOTICE OF SUSPENSION, REVOCATION OR CANCELLATION OF PERMIT

TO (1) .....
.....
.....

(1) Here insert the full names and address of the permit holder.

IN THE MATTER OF (2) .....

(2) Here insert Permit No.

you are hereby notified that your Permit for the following genetically modified

organism/product of a genetically modified organism:.....
.....issued at ..... the ..... day
....., 20 .....Has been *revoked, cancelled or suspended on the following grounds:

(a).....
(b).....
(c).....
(d).....

Dated this ..... day of ..... 20.....

.....
National Biosafety Authority

*Delete as appropriate

Form IX
(Regulation 20(4))

REPUBLIC OF ZAMBIA

The Biosafety Act, 2007
(Act No. 7 of 2007)

The Biosafety (Genetically Modified Organisms for Food, Feed and Processing) Regulations, 2010

PERMIT No. .....

PERMIT TO PLACE ON MARKET FOOD, FEED AND PRODUCTS DERIVED FROM GENETICALLY MODIFIED ORGANISM

(Section ..... of the Biosafety Act, No. 7 of 2007)

Holder's name .....

Address .....

.....

This Permit shall apply to the following genetically modified organism/product of a genetically modified organism

.....

.....

The genetically modified organism/product of a genetically modified organism shall be placed on the market at the following places:

(a).....

(b).....

(c).....and

(d).....

as ( ) food, ( ) feed, or for ( ) processing

The Permit is granted for a period of .....

commencing on the ..... day of ....., 20 .....

The conditions of grant of the Permit are as shown in the Annexures attached hereto.

Issued at ..... this ..... day of ....., 20 .....

ENDORSEMENT OF REGISTRATION

This Permit has this ..... day of....., 20..... been registered in the Register.

.....

National Biosafety Authority

Form X
(*Regulation* 22(3))

REPUBLIC OF ZAMBIA

The Biosafety Act, 2007
(Act No. 7 of 2007)

The Biosafety (Genetically Modified Organisms for Food, Feed andProcessing) Regulations, 2010

NOTICE OF WITHDRAWAL OF GENETICALLY MODIFIED FOOD, FEED OR PRODUCTS FROM THE MARKET/THE SUSPENSION OF THE SALE OF GENETICALLY MODIFIED FOOD, FEED OR PRODUCTS

TO (1) .....

(1) Here insert the full names and address of the permit holder.

IN THE MATTER OF (2) .....

(2) Here insert Permit No.

you are hereby notified of the *withdrawal/suspension of sale of the following genetically modified food, feed or products placed on the market by yourself under the authority of permit No. (3) ..... issued at ..... the ..... day of ..... 20 .....

(3) Here insert Permit No.

(a).....

(b).....

(c).....

(d).....

The *withdrawal/suspension of sale of the genetically modified is based on the following grounds:

(a).....

(b).....

(c).....

(d).....

Dated this ..... day of ..... 20.....

.....

National Biosafety Authority

*Delete as appropriate

Form XI
(*Regulation* 26)

REPUBLIC OF ZAMBIA

The Biosafety Act, 2007
(Act No. 7 of 2007)

The Biosafety (Genetically Modified Organisms for Food, Feed and Processing) Regulations, 2010

NOTICE OF APPEAL TO THE TRIBUNAL

IN THE MATTER OF ..... I hereby

(Applicant reference and matter of appeal)

appeal against the decision of the Authority on the following grounds:*

(a).....

(b).....

(c).....

(d) .....

Dated this ..... day of ..... 20 .....

.....
Signature of Appellant

*Attach brief if necessary.

SECOND SCHEDULE

FEES

1.	Application for permit for importation of GMO	28	5,040
2.	Application to place on market food, feed or product derived from GMO	50,000	9,000,000

B. CHITUWO,
Minister of Science, Technology and Vocational Training

LUSAKA
2nd June , 2010
[MSTVT.19/8/2]