Statutory Instrument 159 of 2018.

[CAP. 14:31

National Biotechnology Authority (Genetically Modified Food and Feed) (Labelling) Regulations, 2018

ARRANGEMENT OF SECTIONS

Section

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

Title

1. These regulations may be cited as the National Biotechnology Authority (Genetically Modified Food and Feed) (Labelling) Regulations, 2018.

Application

2. (1) These regulations shall apply to all food or feed irrespective of threshold of the content of genetically modified material but shall not apply to—

(a) products from animals fed with feed which was produced through genetic modification or containing genetically modified organisms;

(b) medical products for human and veterinary use;

(c) highly refined food, where the effect of the refining process is to remove novel DNA or novel protein.

(2) These regulations are in addition to any labelling regulations made in terms of—

(a) Food and Food Standards Act [*Chapter 15:04*];

(b) Fertilizers, Farm Feeds and Remedies Act [*Chapter 18:12*].

Interpretation

3. In these regulations—

"Act" means the National Biotechnology Authority Act [*Chapter 14:31*] of 2006;

"advertisement" means representation by any means for the purpose of promoting directly or indirectly the sale or disposal of any food and feed;

"Authority" means the National Biotechnology Authority established under section 4 of the Act;

"certificate" means a certificate of authorisation issued in terms of section 5;

"claim" means any statement made in labelling or advertising about food and feed or its ingredients intended to highlight

the presence or absence of specific characteristics of a food or feed;

"conventional food or feed" means food or feed produced without the use of genetic modification techniques and for which there is history of safe use;

"feed" means food given to animals with nutritive properties;

"final consumer" means the ultimate consumer of a product;

"food" means any substance intended for human consumption or intended for the manufacture of such substance;

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

"genetically modified material" means genetic material including DNA and RNA that has been changed by the process of genetic modification;

"ingredient" means any substance, including food additives, used in the manufacture or preparation of food or feed;

"inspection" means evaluation by observation and judgement accompanied as appropriate by measurement, testing, gauging or documentation;

"inspector" means a person appointed as a inspector in terms of section 32 of the Act;

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

"labelling' means any written, printed, or graphic matter that accompanies a food and feed or is displayed near the food and feed, including that for the purpose of promoting its sale or disposal;

"multi-ingredient food or feed" means an integral unit of food or feed consisting of a combination or more than one ingredient;

"novel DNA and novel protein" mean DNA or protein which, as a result of use of genetic modification, is different in chemical sequence or structure from DNA or protein present in counterpart food that has not been produced using genetic modification, other than:

(a) protein that is used as a processing aid or food additive; and

(b) has an amino acid sequence that is found in nature;

"operator" means a person or company that runs a business of manufacturing or trading of food, feed or ingredients;

"organism" means any biological entity, whether microscopic or not, capable of replication;

"person" includes a company or association or body of persons corporate or unincorporated;

"pre-packaged" means prepared and wrapped beforehand and ready for sale;

"processing aid" means any substance that is used in the course of manufacturing of food or feed ingredient;

"product of genetic modification" means food and feed containing organisms whose genetic material has been changed through genetic modification, or food and feed produced from genetically modified organisms;

"source" means a quantity of food or feed produced under uniform conditions;

"verification" means the process by which the correctness of a claim is established by either examination or demonstration.

Application for authorisation to label products of genetic modification

4. (1) No person shall label any food or feed containing at least 1% of products of genetic modification as such without certificate of authorisation from the Authority.

(2) An application for certificate of authorisation shall be made in form 1 of the Second Schedule and shall be accompanied by appropriate fee prescribed in the Third Schedule.

(3) Before issuing a certificate in respect of an application referred to in subsection 2, the Authority may—

(a) carry out a safety assessment;

(b) test or validate methods proposed by the applicant;

(c) request for further documents or information.

Certificate of authorisation to label

5. (1) Where the Authority is satisfied that the applicant meets the required standards, the Authority may issue the applicant a certificate of authorisation.

(2) Where the Authority rejects an application, the Authority shall, within two working days of making that decision, inform an applicant of its decision together with reasons and afford the applicant an opportunity to address those reasons.

(3) A certificate of authorisation issued under this section shall be subject to such conditions as may be prescribed or as may be specified in the certificate and shall remain valid for five years, and may be renewed for such further period as may be prescribed or specified in such certificate.

(4) An application for renewal in terms of subsection (2) shall be—

(a) made one year before expiry of the preceding certificate;

(b) in form 2 of the Second Schedule;

(c) accompanied by the appropriate fee prescribed in the Third Schedule.

(5) The certificate granted shall have the Authority's logo.

Food safety assessment before labelling

6. Operators who produce or sell—

(a) food; or

(b) feed; or

(c) ingredients;

containing genetically modified organisms or products derived from genetically modified organisms shall ensure that such food, feed or ingredients undergo appropriate safety assessments before being labelled and packaged.

Labelling and packaging requirements

7. (1) Operators who produce or sell food or feed containing at least 1% of products of genetic modification shall ensure that the label has the words specified in the appropriate part of the First Schedule.

(2) Operators who produce or sell food or feed containing less than 1% of products of genetic modification shall not be compulsorily required to label their products as such, and if they so wish, the operators shall ensure that the label has the appropriate words specified in the appropriate part of the First schedule.

(3) Operators must ensure that—

(a) labels are printed in clear, indelible, visible legible letters;

(b) printed in contrasting colour to that of background;

(c) indicators about the genetic modification status of feed and food appear in a foot note close to the list of ingredients and the font size of the foot note is not less than six point.

(4) Operators may also add the following—

(a) information on properties or characteristic that make the food and feed different from its conventional counterpart with respect to composition, nutritional value, intended use and health effects on humans or animals;

(b) information on methods used to test for the presence of GMOs in the final product;

(c) information on source of the genetic material.

Claims

8. (1) Genetically modified organisms shall not be described or labeled in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding their character in any respect.

(2) Any claim on a label that a product does not contain or consist of genetically modified materials shall have clear printed statement indicating that the claim is true and not misleading, and shall be supported by validated testing and documentation of the handling practices and procedures.

(3) Validated testing shall be carried out in appropriate accredited laboratories and analytical procedures used shall be consistent with national and internationally laid down procedures and protocols.

Verification of labels

9. (1) The Authority shall verify labels pertaining to the genetic modification through testing, validation of detecting methods, inspection and audit tracking.

(2) Operators who label food or feed shall ensure that they—

(a) obtain the required information preferably in documentation form and shall keep it for five years;

(b) have well annotated data on the origin of the food and feed and or ingredients;

(c) have a practical plan for tracing of food and feed or ingredient, which shall include necessary precautions taken during but not limited to seed production, cultivation, harvest, transportation, processing and storage;

(d) use internationally validated methods for testing for the presence of particular GMOs and sampling methods. Where these do not exist, the manufacturer and or food and feed processor and or retailers shall propose the most suitable method and this shall be validated by the Authority at the client's cost;

(e) furnish the Authority with information on appropriate methods for sampling, identification and detection of particular GMOs in food and feed;

(f) provide the Authority with samples of the food and feed for which certificate of authorisation is sought.

Existing products

10. (1) Products which have been lawfully placed on the market by manufacturers, before the commencement of these regulations shall continue to be placed on the market provided that the retailer notifies the Authority, within 90 days after the commencement of these regulations.

(2) The notification made in terms of subsection (1) shall be in a form of application as required in terms of section 4.

(3) Sections 5, 9, 12 and 13, of these regulations shall apply with necessary changes when the Authority considers the notification made in terms of this section.

(4) The Authority may withdraw the product or any of its derivatives from the market where the retailer fails to notify or submits incorrect information or submits information late to the Authority.

Imported products

11. Products which were lawfully placed on the market in countries of origin and were labelled prior to their importation into Zimbabwe may be placed on the market provided that the retailers comply with necessary labelling guidelines as advised by the Authority.

Monitoring, inspection and compliance

12. (1) The Authority shall liaise with other relevant regulatory agencies to monitor any products consisting or containing genetically modified material for compliance with these regulations.

(2) Where the Authority is satisfied that a product consisting of or containing genetically modified ingredients has not been labeled in accordance with these regulations, the inspector shall serve the operator with a notice in writing—

(a) prohibiting the placing on the market of the product until it is correctly labeled;

(b) prohibiting the removal of the product from the premises described in the notice other than to facilitate the correct labeling of the product;

(3) A notice under subsection (1) may —

(a) contain such conditions as the inspector is satisfied are reasonable; and

(b) may be amended, suspended or revoked by a further notice in writing by the inspector at any time.

(4) A notice under these regulations shall be complied with at cost of the operator on whom it is served.

(5) If —

(a) a notice in terms of these regulations; or

(b) an action required by the notice to be taken;

is not complied with within the period specified in the notice, an inspector may arrange for it to be complied with all reasonable costs of taking such action shall being recoverable by the Authority as a penalty due from the operator on whom the notice was served.

(6) Where the product has been placed on the market prior to the date of the notice, the inspector may require the withdrawal of the product within such period as may deem fit.

(7) The Authority shall, at the applicant's cost, inspect authorised products for compliance at least once every two years.

Revocation or suspension of authorisation

13. The Authority may, in writing, revoke or suspend an approval to label granted in terms of section 5 where the authorised person—

(a) contravenes any provision of these regulations;

(b) fails to comply with any conditions specified in the certificate;

(c) if the Authority considers it in the public interest to do so.

Offences and penalties

14. A person who—

(a) contravenes sections 4(1), 7(1), 8(1) and 9(2)(a) and (e);

(b) uses the Authority's logo without authorisation;

commits an offence and is liable on conviction, to a fine of level 11 or to imprisonment for a term not exceeding five years, or to both such fine and imprisonment.

Register of certificates

15. (1) The Authority shall maintain a register of all certificates issued under these regulations.

(2) The register shall be a public document and may be inspected between 8.00 a.m. and 4.00 p.m. hours on working days by any person on the payment of a prescribed fee.

(3) The Authority shall record all approved products on the register and on the Authority's website.

Fees

16. (1) The fees prescribed in the Third Schedule shall be paid for the various applications under these regulations.

(2) Where a fee is fixed in terms of subsection (1)—

(a) the fee shall be tendered with the appropriate application;

(b) half the fee shall be refunded to the applicant if his or her application is unsuccessful.

Confidential information

17. (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 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 regardless of whether the applicant has withdrawn the application or not.

(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.

FIRST SCHEDULE (*Section 7*)

LABELS

PART 1

LABELS FOR PRE-PACKED PRODUCTS

(a) single ingredient food and feed:

"This [name of product] is a product of genetic modification" or contains [name of ingredient] produced from genetically modified [name of organism] or "contains genetically modified [name of organism]"

(b) multi-ingredient food and feed:

"[name of ingredients] are products of genetic modification" or contains "name of ingredients] produced from genetically modified [name of organism]" or contains genetically modified [name of organism/s]"

PART II

DISPLAY PANEL LABEL FOR PRODUCTS OFFERED TO THE FINAL CONSUMER IN BULK AND THOSE PREPARED AT POINT OF SALE

(a) single ingredient food and feed:

"This [name of product] is a product of genetic modification" or contains [name of ingredient] produced from genetically modified [name of organism]" or contains genetically modified [name of organism]"

(b) multi-ingredient food and feed:

"[name of ingredients] are produced of genetic modification" or contains [name of ingredient] are products of genetic modification" or "contains [name of ingredient] produced from genetically modified [name of organism]" or contains genetically modified [name of organism/s]"

PART III

NON COMPULSORY LABELLING

(a) Labels for prepacked products shall be—

(i) for single ingredient food or feed—

"[name of product] is not a product of genetic modification" or "[name of ingredient] not a product of genetic modification" or "[name of organism] is not genetically modified"

(ii) for multi-ingredient food and feed:

"[name of ingredient]" not a product of genetic modification" or "[name of organism/s] and genetically modified"

(b) Display panel labels for products offered to the final consumer in bulk and those prepared at point of sale, the label shall have the following words on the display panel—

(i) single ingredient food and feed—

"[name of product] not a product of genetic modification" or "[name of ingredient] not a produce of genetic modification" or [name of organism] is not genetically modified"

(ii) multi-ingredient food and feed:—

"[name of ingredients] not a product of genetic modification" or "name of organism/s] are not genetically modified.

SECOND SCHEDULE (*Section 4*)

Form 1

APPLICATION FOR AUTHORISATION FOR LABELLING

I hereby apply for a genetic modification status label of which particulars are given below:.....

.....

Name and address of applicant: .....

.....

The product to be labeled and its specification: .....

.....

The intended use of the product: .....

.....

A detailed description of method of production: .....

.....

Copies of studies carried out whether independent or peer reviewed to demonstrate safety: .....

.....

Comprehensive information and data comparing characteristics between GM product and conventional counterpart: .....

.....

The proposed label: .....

.....

Method of sampling and detection: .....

.....

Samples of the product and their control sample and information as to where reference material can be accessed: .....

.....

Summary of dossier: .....

.....

Any other information: .....

.....

.....

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

Signature .....

Designation/Title .....

FOR OFFICIAL USE ONLY

Application received by..... on ..... 20 .....

Fee paid US $

.....

(in words)

.....

.....

FOR Chief Executive Officer and Registrar National Biotechnology Authority.

Form.2

APPLICATION FOR RENEWAL OF GENETIC MODIFICATION STATUS LABELLING CERTIFICATE

I hereby apply for a renewal of the genetic modification status label certificate of which particulars are given below:

Name and address of applicant: .....

.....

Expired certificate number: .....

.....

A detailed description of method of production: .....

.....

Copies of studies carried out whether independent or peer reviewed to demonstrate safety: .....

.....

Comprehensive information and data comparing characteristics between GM product and conventional counterpart: .....

.....

The proposed label: .....

.....

Method of sampling and detection:.....

.....

Sampling of the product and their control sample and information as to where reference material can be accessed

Summary of dossier: .....

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Any other information: .....

.....

.....

Date: ..... Signature:.....

Application received by..... on ..... 20 .....

Fee paid US $

.....

(in words)

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FOR Chief Executive Officer and Registrar National Biotechnology Authority.

THIRD SCHEDULE (*Sections 4, 5, and 16*)

Fees

Application for Authorisation to label	US$1,000,00
Renewal of approval	US$1,000,00
Inspection fees	US$150,00

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