

# FEDERAL REPUBLIC OF NIGERIA



## **Decision Document for a Permit for Importation and use of Genetically Modified (GM) Wheat for Food, Feed and for Processing issued to Trigall Genetics S. A.**

This decision document is issued by the National Biosafety Management Agency (NBMA) to Trigall Genetics S. A. as part of permit in accordance with the *National Biosafety Management Agency Act 2015 (as amended) for the Genetically modified wheat: IND-00412-7*.

This Permit is without prejudice to other extant national laws and regulations.

This Permit authorises the Permit holder and persons covered by the permit to conduct the specified dealing with the genetically modified organism( *Genetically modified wheat: IND-00412-7*) referred to in this decision document.

### ***Section 1 Interpretations and definitions***

#### **1.1 In this Permit:**

- (a) unless defined otherwise, words and phrases used have the same meaning as they do in the *National Biosafety Management Agency Act 2015 (as amended)*;
- (b) words referring to gender include any other gender;
- (c) words in the singular include the plural and words in the plural include the singular;
- (d) words importing person include a partnership and a body whether corporate or otherwise;
- (e) references to any statute or other legislation (whether primary or subordinate) are a reference to the constitution of the Federal Republic of Nigeria or other legislation of the Federal Republic of Nigeria as amended or replaced from time to time and equivalent provisions, if any, in corresponding States Law, to the extent of any inconsistency with the above-mentioned legislations;
- (f) where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word has a corresponding meaning;
- (g) specific conditions of this permit shall prevail over standard conditions to the extent of any inconsistency.

#### **1.2 In this Permit:**

**'Act'** means the National Biosafety Management Agency Act 2015 (*as amended*) or the corresponding national legislation under which this Permit is issued.

**'Clean'** (or **'Cleaned'**) means, as the case requires:

- (a) in relation to an area specified in this Permit as requiring cleaning, the destruction of the GMOs in that area, to the reasonable satisfaction of the National Biosafety Management Agency; or
- (b) in relation to equipment, the removal and destruction of the GMOs from the equipment, to the reasonable satisfaction of the National Biosafety Management Agency.

**'Contingency Plan'** means a written plan, detailing measures to be taken in the event of the unintended presence of the GMOs outside an area that shall be inspected or manifestation of risk. A Contingency Plan shall include procedures to:

- (a) ensure the National Biosafety Management Agency is notified immediately if the Permit holder becomes aware of the events causing any harmful effects or being used outside approved purpose or intentionally released or spilled;
- (b) recover and/or destroy the GMOs;
- (c) destroy of spills or Volunteers.

**'Wheat'** means plant b of the species *Triticum aestivum*

**'Spill'** means:

- (a) inadvertent fall or pour out of the GMO; and
- (b) accidental release of the GMO in a place it is not meant.

**'Destroy'** (or **'Destroyed'** or **'Destruction'**) means, as the case requires, killed by one or more of the following methods:

- (a) stalk pulling; or
- (b) root cutting and mulching/slashing; or
- (c) ploughing; or
- (d) burning/incineration; or
- (e) treatment with herbicide; or
- (f) hand weeding; or
- (g) autoclaving; or
- (h) burial under at least one (1) metre of soil; or
- (i) grinding seeds; or
- (j) a method approved in writing by the National Biosafety Management Agency.

**'Equipment'** includes, but not limited to storage equipment, transport, miller bags, containers, trucks, clothing and tools, etc.

**'GM'** means genetically modified.

'**GMOs**' means the genetically modified organisms that are the subject of the dealings authorised by this Permit. GMOs include live plants, grains that are able to grow into live plants, and viable seed or not.

'**Grain**' means Wheat used for feed or food.

'**Logbook**' means a written or electronic record containing information required to be maintained by this Permit holder and which is able to be presented to the NBMA on request.

'**Monitoring Zone**' means an area of land extending at least 100 metres in all directions from the outer edge of a Milling or storage Area.

'**NBMA**' means the National Biosafety Management Agency.

'**Personal Information**' means information or an opinion (including information forming part of a database), whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

'**Agency**' means the National Biosafety Management Agency.

'**Volunteers**' means GM or non-GM wheat plants, which have not been intentionally grown.

## **Section 2**      **General conditions and obligations**

### **2.1**      **Obligations of the Permit Holder**

*Prior to issuing a Permit, the NBMA considers suitability of the applicant to hold a Permit. The following conditions address the suitability of the Permit holder:*

1. The Permit holder shall, at all times, remain an organisation with an authorised dealings with the GMO or an affiliate of such an organisation and shall comply with its terms and conditions of the Permit.
2. This Permit does not authorise dealings with GMOs that are otherwise prohibited for cultivation purposes.
3. This Permit remains in force until it is suspended, cancelled or surrendered or authorization period elapses. *(No dealings with GMOs are authorised during any period of suspension).*

The holder of this permit ('the permit holder') is **Trigall Genetics S. A.**

4. The persons covered by this permit are the permit holder and employees, agents or contractors of the permit holder and other persons who are, or have been, engaged or otherwise authorised by the permit holder to undertake any activity in connection with the dealings authorised by this permit.
5. **The dealings authorised by this Permit are for importation, transport, storage , commercialization, food, feed and processing,**
6. The Permit Holder shall notify the Agency as soon as practicable if any of the contact details of the project supervisor changes.
7. The Permit Holder shall ensure that the GMO or product thereof are properly labelled in line with the provisions of the National Biosafety Management Agency Act 2015 (as amended) and the National Biosafety Regulations 2017.

*Note: please address correspondence to [nbma@nbma.gov.ng](mailto:nbma@nbma.gov.ng)*

*Prior to issuing a Permit the Agency considers suitability of the applicant to hold a Permit. The following additional conditions also address the suitability of the Permit Holder:*

8. The Permit Holder shall at all times comply with the content of the decision document.
9. The Permit Holder shall:
  - (a) inform the Agency in writing; of
    - i. The date for off-loading GM wheat consignment and transportation to the storage facility at least 2 weeks before commencement;
    - ii. any relevant conviction of the Permit Holder occurring after the issue of this Permit;
    - iii. any revocation or suspension of a permit held by the Permit Holder under a law of the Nigerian Government, a State or a foreign country, being a law relating to the health and safety of people or the environment;
    - iv. any event or circumstances occurring after the issue of this Permit that would affect the capacity of the holder of this Permit to meet the conditions thereto; and
  - (b) provide any information related to the Permit holder's ongoing suitability to hold a Permit, if requested, within the stipulated period.
10. The Permit Holder shall be able to access all distribution points, commercial points, all Milling Plant Areas, storage and other approved facilities to the extent necessary to comply with this Permit, for the duration of the life of the Permit.

*The following conditions seek to ensure that persons conducting the dealings are aware of the Permit conditions and appropriate processes are in place to inform people of their obligations.*

11. Prior to conducting any dealings with the GMO, the Permit Holder shall provide to the Agency:
  - (a) names of all organisations and persons or functions or positions of the persons who will be covered by the Permit, with a description of their responsibilities if possible; and  
*Note: Examples of functions or positions are distributors, Plant manager, Store manager etc.*
  - (b) detail of how the persons covered by the Permit will be informed of Permit conditions; and
  - (c) detail of how the Permit Holder will access all commercial points, distribution points Milling Plant Areas, storage and other approved facilities to the extent necessary to comply with this Permit, for the duration of the life of the Permit  
*Note: this may include a description of any contracts, agreements, or other enforceable arrangements.*
  - (d) a Contingency Plan to respond to inadvertent presence of the GMOs outside an area that shall be inspected or manifestation of risks.
12. Any changes to the information provided under the immediately preceding condition shall be communicated in writing to the Agency within 7 days of the changes occurring.
13. The storage facility shall be inspected and approved by the Agency before distribution.
14. The Permit Holder shall inform any person covered by this permit, to whom a particular condition of the permit applies, of the following:

- (a) the particular condition (including any variations of it); and
- (b) the cancellation or suspension of the permit; and
- (c) the surrender of the permit

15. The Permit Holder shall not permit a person covered by this Permit to conduct any dealing unless:

- (a) the person has been informed of any applicable permit conditions, including any variation of them;
- (b) the Permit Holder has obtained from the person an undertaken that the person:
  - i. has been informed by the Permit Holder of the Permit conditions including any variation of them; and
  - ii. has understood and agreed to be bound by the Permit conditions, or variation.

16. The Permit Holder shall:

- (a) inform the persons covered by this Permit that any Personal Information relevant to the administration and/or enforcement of the Permit may be released to the Agency; and
- (b) provide the Agency, if requested, with copies of the undertaken referred to in the immediately preceding condition.

## 2.2 Provision of new information to the Agency:

*Permit conditions are based on the risk assessment and risk management plan developed in relation to the application using information available at the time of assessment. The following condition requires that any new information that may affect the risk assessment is communicated to the Agency.*

The Permit holder shall inform the Agency if the Permit holder becomes aware of:

- a. additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the Permit; or
- b. any contraventions of the Permit by a person covered by the Permit; or
- c. any unintended effects of the dealings authorized by the Permit.

**Note:** *The Act requires, for the purposes of the above condition, that:*

- i. *the Permit Holder will be taken to have become aware of additional information of a kind mentioned in paragraph 2.2*
- ii. *the Permit Holder will be taken to have become aware of contraventions, or unintended effects, of any kind,*

**Note:** *Contraventions of the Permit may occur through the action or inaction of a person. If the Permit holder is required to inform the Agency under the immediately preceding condition, the Agency shall be informed without delay.*

**Note:** *An example of informing without delay is contact made at the time of the incident via the NBMA phone number (+2348180805451), which provides emergency number for incidents that occur out of business hours. Notification without delay will allow the NBMA to conduct a risk assessment on the incident and attend to the location if required.*

2.3 If the Permit Holder informs the Agency under the immediately preceding condition and the Agency requests further information, the further information shall be provided in a manner, and within the period, stipulated by the Agency.

#### 2.4 Obligations of persons covered by the Permit

1. Persons covered by this Permit shall not deal with the GMOs except as expressly stated in this Permit.
2. If a person is authorised by this Permit to deal with the GMOs and a particular condition of this Permit applies to the dealing by that person, the person shall allow the Agency, or a person authorised by the Agency, to enter premises where the dealing is being undertaken, for the purposes of auditing, monitoring, inspecting the dealing or enforcement by the Agency.

### **Section 3 Limits and control measures**

#### **3.1. Limits on the release**

*The following permit conditions maintain the risk assessment context within which the application was assessed, by imposing limits on where and when the GMOs may be imported which is at Lagos sea Port, and on other activities that can be undertaken.*

- i. The only GM wheat that may be stored at storage facility, sold, processed are:
  - a. the GM wheat covered by this Permit as described in Attachment A of the Permit;
  - b. the volume of Grains approved for importation in writing by the Agency.
- ii. Importation, Storage, sale and processing of the GMO may only occur within the following limits:

#### **3.2. Volume and duration**

<b>Maximum volume of the import</b>	<b>Duration</b>
150,000 MTS	As approved by NBMA

#### **3.3. Locations of store**

As communicated to the Agency by permit holder prior to importation

#### **3.4. Additional Conditions:.**

- i. The GM wheat shall not be planted and shall not be allowed to grow anywhere pursuant to this permit;
- ii. Storage facility should be well-fortified to prevent volunteering due to dispersal of grains by rodents and theft,

*Note: The Contingency Plan shall be implemented if the GMOs are detected outside under cultivation.*

### 3.5. Dispersal of the GMOs during transport or storage

Transport and storage of GMOs outside the Storage Area shall:

- a. only occur to the extent necessary to conduct the dealings permitted by this Permit or other valid authorisation; and
- b. be in accordance with the Agency’s Guidelines for the transport, storage and disposal of GMOs or
- c. if grains are transported in a bag shall be:
  - i. completely wrapped in cellophane; or
  - ii. completely enclosed within metal/plastic container;
  - iii. labelled for the transport, storage and disposal of GMOs as current at the time of transportation.

*Note: Signed statements by persons transporting or disposing of the GMOs should be made.*

- d. Transport of GMOs for the purpose of export is permitted on notification to the Agency as the permit holder would have authorisation to export the GMOs to the destination country.
- e. Methods and procedures used to transport GMOs shall be recorded, and shall be provided to the Agency, if requested.

### 3.6. Persistence of the GMOs or Volunteers post-cleaning at large scale processing plants

- i. After Cleaning, related areas shall be inspected by persons trained by the Permit holder to recognise volunteers and actions taken as follows:

Area	Period of inspection	Inspection frequency	Inspect for	Action
(a) Storage Area	From the day of Cleaning.	At least once every 30 days.	Volunteers.	Destroy immediately.
(b) Processing areas that have been cleaned and where the GMOs may be able to establish*.	Same as above	Same as above	Same as above	Same as above

- ii. Details of any inspection activity shall be recorded in a Logbook and shall include:

- (a) date of the inspections;
- (b) name of the person(s) conducting the inspections;

- (c) details of the experience, training or qualification that enables the person(s) to recognise Volunteers, if not already recorded in the logbook;
- (d) details of areas inspected,
- (e) details of any Volunteers observed including number, developmental stage and approximate position of the Volunteers within each area inspected and
- (f) date(s) and method(s) of destruction of any Volunteer plants.

### 3.7. Contingency plan

1. If any unintentional presence of the GMO is detected outside the areas requiring inspection, the Contingency Plan shall be implemented, which include:
  - a. Notification of the Agency
    - a. incident and corrective action forms shall be completed for each case of accidental release.
    - b. The incorporation of the completed incident and corrective action forms into the compliance binder maintained at the storage and/or milling sites.
    - c. in the event that transgenic material falls out of its sealed packaging and carrying bag during the transport process the transgenic material will be immediately recovered and returned to its storage which will be marked for subsequent destruction through incineration.
    - d. if GM grains are accidentally removed from the storage facility, the NBMA should be notified immediately of the event and efforts should be undertaken to recover the material by the Permit Holder under the guidance of the Agency.
    - e. In the unlikely event of civil unrest or natural disaster that affects the integrity of storage facility beyond recovery, NBMA should be notified by the Permit holder and requisite action would be taken.

## Section 4 Reporting and Documentation

*The following Permit conditions are imposed to demonstrate compliance with other conditions, facilitate monitoring/Inspection of compliance by staff of the Agency.*

Notifications shall be sent to the Agency as follows:

Notice	Contents	Timeframe
(a) Intention to import	<ol style="list-style-type: none"> <li>i. Details of the consignment, volume, entry port, name of vessel and final destination including, the state, local government area and city/town, a street address and any other directions</li> <li>ii. Date on which the GMOs will off-loaded</li> <li>iii. Period when the GMOs are expected to be transported to storage facility</li> <li>iv. Period distribution / sale is expected to commence</li> </ol>	At least 7 days prior to importation

	v. How processed product is intended to be used is packaged	
(b) Processing of grain	i. Period when processing is expected to commence on a large scale, actual date(s) ii. Any changes to the details provided	Within 7 days of any milling
(c) Cleaning	i. Actual date(s) on which any areas needing Cleaning were Cleaned ii. Method of Cleaning, iii. Method of waste disposal	Within 7 days of completion of any Cleaning
(d) Inspection activities	i. Information recorded in a Logbook	Within 30 days of inspection

**Section 5**

<p><b>Authorization:</b></p> <p>After a thorough analysis of the application dossier, risk mitigation and contingency options available, a permit is hereby granted to <b>TRIGALL GENETICS S. A. with permit Code No. NBMA/FFP/IM/021</b></p>	
<p><b>Section 6</b></p> <p><b>Authorization Period:</b></p> <p><b>This Permit is with effect from 13<sup>th</sup> July 2022 to 12<sup>th</sup> July 2024</b></p>	
<p><b>Section 7</b></p> <p><b>Signature and Date:</b></p> <p>.....</p> <p>Director-General/CEO</p>	<p>13<sup>th</sup> July 2022</p> <p>Date</p>

## ATTACHMENT A

**PERMIT CODE: NBMA/FFP/IM/021**

**Full Title:** Genetically modified Wheat for Food, Feed and for Processing

### **Organisation Details**

**Postal address:** Trigall Genetics S. A.,  
Avda. Dr. Arturo Frondizi No. 1150, Parque Industrial,  
B2700Pergamino, Provincia de Buenos Aires

**Phone No:** +542477409400  
**Email:** abiagioni@rizobacter.com

### **GMO Description**

#### **GMOs covered by this Permit:**

*Triticum aestivum* containing only the event and gene listed below.

#### **Parent Organism:**

**Common Name:** Wheat  
**Scientific Name:** *Triticum aestivum*

#### **Modified traits:**

<b>S/N</b>	<b>EVENT ID</b>	<b>Gene of Insert</b>	<b>Purpose of Modification</b>
1	IND-00412-7	Bar, Hahb-4	Tolerance to drought, tolerance to glufosinate

#### **Purpose of the dealings with the GMOs:**

The purpose of the importation of the GM wheat is for food, feed and for processing.

## ATTACHMENT B

#### **Checklist of documents that shall be sent to the Agency:**

<b>When</b>	<b>What</b>	<b>Timeframe</b>
	Details of persons covered	14 days prior to arrival of consignment

When	What	Timeframe
Prior to conducting any dealings	Location of Storage facility	At least 7days before issuance of permit and before arrival of consignment
	Contingency plan	14 days prior to taking delivery of GMO at the entry Port
Prior to off-loading and transferring to storage	Intention to offload consignment	At least 7 days prior to transfer of GMO to storage facility
Any time after issue of the Permit	Any changes of the project supervisor contact details	As soon as practically possible
	Any relevant conviction, revocation, suspension or cancellation of any relevant permit or circumstances that may affect compliance to licence conditions	Immediately, if occurs
	Any information relevant to on-going suitability	If and when requested
	Any changes to details provided under conditions Prior to conducting any dealings with the GMO, the Permit Holder shall provide to the names of all organisations and persons or functions or positions of the persons who will be covered by the Permit, with a description of their responsibilities if possible; and - Prior to conducting any dealings with the GMO, the Permit Holder shall provide to the a Contingency Plan to respond to inadvertent presence of the GMOs outside an area that shall be inspected or manifestation of risks.	Within 14 days of the changes
	Signed statements from persons covered under the licence	If and when requested
	Any additional information regarding health and safety of the people and the environment, contraventions of this licence or any unintended effects of the dealings authorized by the licence	As soon as practically and reasonably possible, after becoming aware

When	What	Timeframe
	Extreme weather conditions	As soon as practically and reasonably possible, if expected or occurs
	Methods and procedures for transport	If and when requested

