



FEDERAL REPUBLIC OF NIGERIA

Decision Document for Importation of Genetically Modified (GM) Maize for Feed and Processing issued to WACOT Nigeria Limited

The *National Biosafety Management Agency Act 2015* is the regulatory framework controlling the practice of modern biotechnology as well as the development, handling and use of genetically modified organisms (GMOs) in Nigeria.

This decision document is issued by the National Biosafety Management Agency (NBMA) as permit in accordance with the *National Biosafety Management Agency Act 2015*.

The advice of National Biosafety Committee, National Biosafety Technical Sub-committee and public views, guided the decision of the National Biosafety Management Agency. The Agency is convinced that there are no known adverse impacts to the proposed use of the various GM maize Events in WACOT's application, taking into account risk to human health.

This Permit is issued without prejudice to other extant national laws and regulations, and the maize grains producer. It authorises the Permit holder and persons covered by the permit to conduct specified dealings with the genetically modified organism referred to in this decision document.

Note about countries where dealings with GMOs are being undertaken pursuant to this Permit

The genetically modified maize, for which this permit is issued, has been approved for use for various purposes, including for direct use for food, feed and processing (FFP), in the following countries: Argentina, Australia, Brazil, Canada, China, Colombia, El Salvador, European Union countries, Honduras, Indonesia, Japan, Korea, Malaysia, Mexico, New Zealand, Paraguay, Philippines, Singapore, South Africa, Switzerland, Taiwan, Turkey, United States, Uruguay and Vietnam.

Section 1 Interpretations and definitions

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*;

- (b) words importing a gender include any other gender;
- (c) words in the singular include the plural and words in the plural include the singular;
- (d) words importing persons 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.

2. **In this Permit:**

'Act' means the *National Biosafety Management Agency Act 2015* 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 unlikely event that adverse impact occurs either to human or animal health as a result of the consumption of the GM maize or to the environment, or used for unintended purpose, 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 event; and
- (b) recover and/or Destroy the GMOs; and
- (c) inspect for and Destroy any of its material that may exist as a result of the event.

'Maize' means plants of the species *Zea mays*

'Spill' means:

- (a) inadvertent fall or pour out of the GM maize; and
- (b) accidental release of the GM maize 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.

Note: 'As the case requires' has the effect that, depending on the circumstances, one or more of these techniques may not be appropriate.

'Equipment' includes, but is not limited to, storage equipment, transport, miller (e.g. bags, containers, trucks, etc.), clothing and tools.

'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, grain that is able to grow into live plants, and viable seed.

'Grain' means maize used for food, feed or processing. 'In this case' refers to the purpose for which permit is granted.

'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 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 (NBMA).

'Sign-off' means a notice in writing from the National Biosafety Management Agency, in respect of an area.

'Volunteers' means GM maize 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 ongoing suitability of the Permit holder.

1. This Permit prohibits the cultivation of the GM maize or for any other purpose other than the intended purpose
2. 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).*
3. The holder of this permit ('the permit holder') is ***WACOT Nigeria Limited without prejudice to the GM maize developer.***
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 and milling of the GMOs into poultry feed, and the possession, supply or use of the GMOs in the course of any of these dealings for the purpose of the permit.
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 all GMO materials are properly labelled in line with the provisions of the National Biosafety Management Agency Act 2015 and the National Biosafety Regulations 2017.

Note: *please address correspondence to nbma@nbma.gov.ng*

Prior to issuing a Permit the Agency considers suitability of the applicant to hold a Permit. The following conditions address ongoing 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 of the GM maize consignment and transportation to the storage facility at least one week before commencement;
 - ii. any relevant conviction of the Permit Holder occurring after the issue of this Permit; and
 - 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; and
 - 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 and control 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 GM maize, 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; and
Note: Examples of functions or positions are 'Plant manager', 'Store manager', 'Plant operator' 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 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.
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 and Milling facility shall be inspected and approved by the Agency before commencing the trial.
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 person has been trained on the dealing; and
 - (c) the Permit Holder has obtained from the person an Undertaking to the effect that he/she:
 - 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 and variations.
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 Undertaking 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 conditions require that any new information relevant to risk assessment and risk management are communicated to the Agency.

17. 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 authorised 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 17(a) if he or she was reckless as to whether such information existed; and*
- ii. *the Permit Holder will be taken to have become aware of contraventions, or unintended effects, of a kind mentioned in paragraph 17 any contraventions of the Permit by a person covered by the Permit; or or 17(c) if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.*

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, which provides emergency numbers 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.*

18. 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.

2.3 Obligations of persons covered by the Permit

19. Persons covered by this Permit shall not deal with the GMOs except as expressly permitted by this Permit.

20. 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

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, and on other activities that can be undertaken.

21. The only GM maize that may be milled at a Milling Plant or stored at the storage facility are:
- (a) the GM Events covered by this Permit as described in Attachment A of the Permit;
 - (b) the volume of Grains applied for and approved for importation by the Agency.
22. Storage and milling of the GMOs may only occur within the following limits:

Events and duration

Events of GMOs	Duration
As listed in attachment A	Three years

Location of Milling Plant

Ajanla Farms, Lagos/Ibadan Express Way, IBADAN

23. Grains shall not be used, sold or otherwise disposed of for any purpose which would involve or result in its use as crops for planting or food for human.

Confinement measures

The following permit conditions maintain the risk assessment context within which the application was assessed by restricting spread and persistence of the GMOs.

Physical confinement and site security

The GMOs shall not be planted and shall not be allowed to grow anywhere pursuant to this permit; and

Prevention of dispersal of GMOs through:

24. Transportation of GMOs from Entry Port to storage facility should be adequately secure;
25. Storage facility should be well-fortified to prevent dispersal of grains by rodents;

26. Any Equipment used in connection with the GMOs shall be cleaned as soon as practicable and before use for any other purpose.

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

Dispersal of the GMOs during transport or storage

27. 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 Grain is transported in a bag, it 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.

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.

28. Methods and procedures used to transport GMOs shall be recorded, and shall be provided to the Agency, if requested.

Persistence of the GMOs or Volunteers post-cleaning

29. After Cleaning, areas of land 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 until signoff.	At least once every 30 days	Volunteers	Destroy immediately
(b) Milling areas that have been cleaned and where the GMOs may be able to thrive.				

30. 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 including current land use and recent management practices applied;
- (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.

Contingency plan

31. If any unintentional presence of the GMOs is detected outside the areas requiring inspection, the Contingency Plan shall be implemented, which include:
- i. Notification of the Agency
 - ii. Completion of incident and corrective action forms for each case of accidental release.
 - iii. The incorporation of the completed incident and corrective action forms into the compliance binder maintained at the storage and/or milling sites.
 - iv. 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.
 - v. If GM plants 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.
 - vi. In the unlikely event of civil unrest or natural disaster that affects the integrity of storage facility beyond recovery, the NBMA should be notified by the Permit holder and requisite action would be taken.

Section 4 Sign-off

32. The Permit Holder may make written application to the *Agency* that inspection conditions no longer apply to storage and/or milling area if:
- (a) all post-cleaning inspection activities have been conducted for at least 12 months on the area and all associated areas; and
 - (b) no volunteers have occurred on these areas in the most recent six-month inspection period.

Note: Associated areas refer to a storage area and the milling areas requiring post-cleaning inspections in respect of dealings with the GMO. Associated areas will be signed-off as a group rather than individually. Permit conditions require total cleaning of the area of the GMO prior to a Sign-off application. The Agency will take into account the management and inspection history for all associated areas, including occurrence of Volunteers, in deciding whether or not further inspections are required to manage persistence of the GMO.

Section 5 Reporting and Documentation

The following Permit conditions are imposed to demonstrate compliance with other conditions, facilitate monitoring/inspection for compliance by staff of the Agency, and emphasise appropriate selection of the Planting Area.

33. Notifications shall be sent to the Agency as follows:

Notice	Contents	Timeframe
(a) Intention to import	<ul style="list-style-type: none"> i. Details of the consignment, volume, entry port, name of vessel and final destination including, the state, local government area and city/town, GPS coordinates, a street address and any other directions ii. Identity of the GMOs to be imported, including Events iii. Date on which the GMOs will be off-loaded iv. Period when the GMOs are expected to be transported to storage facility v. Period when milling is expected to commence vi. How the processed product is intended to be packaged and used 	At least 7 days prior to importation
(b) Milling of grain	<ul style="list-style-type: none"> i. Period when milling is expected to commence, actual date(s) of milling the GMOs ii. Any changes to the details provided under part Intention to 	Within 7 days of any milling
(c) Cleaning	<ul style="list-style-type: none"> i. Actual date(s) on which any areas needing Cleaning were Cleaned ii. Method of Cleaning 	Within 7 days of completion of any Cleaning
(d) Inspection activities	<ul style="list-style-type: none"> i. Information recorded in a Logbook 	Within 30 days of inspection

Section 6**Authorization:**

After a thorough analysis of the application dossier, risk mitigation and contingency options available, it is unlikely that the proposed use of the GM maize for processed poultry feed will cause adverse impact on the environment or on human and animal health. A permit is therefore granted to WACOT Nigeria Limited as applied for.

Section 7**Authorization Period:**

The duration of this permit is from **13th December 2017 to 31st December 2020**

Section 8**Signature and Date:**

Director-General/CEO

13th Dec.2017

Date

ATTACHMENT A

DIR No: REF CODE NBMA/CM/FFP/IM/001
Full Title: Genetically modified Maize for Processing

Organisation Details

Postal address: WACOT Nigeria Limited,
Ajanla Farms (along Lagos/Ibadan Express Way)
Ibadan, Oyo State.

Phone No: +234 803 6980526

GMO Description

GMOs covered by this Permit:

Zea mays containing only the events and genes listed below.

Parent Organism:

Common Name: Maize
Scientific Name: *Zea Mays*

Modified traits:

S/N	Selectable marker	Description	Genes responsible for conferring trait	Event
1	<i>pat</i> gene <i>Tu494</i>	Maize line Bt11 was developed through a specific genetic modification to be resistant to attack by European corn borer (ECB; <i>Ostrinia nubilalis</i>)	<i>Cry1Ab</i>	Bt11
2	<i>pDPG434</i>	GA21 was developed to provide tolerance to glyphosate	EPSPS	GA21
3.	<i>nptII</i>	Maize MON810 was developed to provide protection against certain lepidopteran target pests (such as the European corn borer (<i>Ostrinia nubilalis</i>))	<i>Cry1Ab</i>	MON810
4.		Maize developed for tolerance to glyphosate	<i>CP4 EPSPS</i>	NK603
5	phosphinothricin-N-acetyltransferase (PAT)	Maize developed for protection against specific lepidopteran pests such as the European corn borer (<i>Ostrinia nubilalis</i>) and for tolerance to the herbicide glufosinate.	<i>Cry1F</i>	DAS1507

6	pmi gene	Maize genetically modified to confers protection against a number of significant lepidopteran insect pests feeding as larvae on maize.	<i>Vip3Aa1</i>	MIR162
7		Maize genetically modified to be resistant to corn rootworm.	<i>mCry3A</i>	MIR604
8	<i>nptII</i>	Maize developed as a second-generation insect-resistant maize product to provide enhanced benefits for the control of lepidopteran insect pests.	Cry1A.105 and the Cry2Ab2	MON89034
9.		Maize developed to confer protection against corn rootworm and tolerance to glyphosate.	<i>Cry3Bb1</i> and <i>CP4 EPSPS</i>	MON88017

Purpose of the dealings with the GMOs:

The purpose of the importation of the GM maize is for processing as poultry Feed.

ATTACHMENT B

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

When	What	Timeframe
Prior to conducting any dealings	Details of persons covered	14 days prior to arrival of consignment
	Location of and 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 licence	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 GM maize, 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; and - Prior to conducting any dealings with the GM maize, 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.	Within 14 days of the changes
	Signed statements from persons covered under the licence	If and when requested

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