

FEDERAL REPUBLIC OF NIGERIA



This decision document is issued by the National Biosafety Management Agency (NBMA) to Syngenta South Africa (Pty) Limited, as part of permit in accordance with the *National Biosafety Management Agency Act 2015 for genetically modified Maize Bt. 11/PAT Event for Food, Feed and for Processing (FFP) and it supersedes the earlier one issued in respect of this subject.*

The advice of National Biosafety Committee, National Biosafety Technical Sub-committee and public views guided the decision of the National Biosafety Management Agency in granting this permit. The Agency was convinced that there are no known adverse impacts to human and animal health by this genetically modified event. 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 dealings with the genetically modified organisms referred to in this decision document.

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

Information about where the GMO has been approved for use for various purposes, including for direct use for food, feed and processing (FFP), pursuant to this Permit is that they have been approved in Argentina, Australia, Belarus/Kazakhstan, Brazil, Canada, China, Colombia, European Union, Indonesia, Japan, Korea, Malaysia, Mexico, New Zealand, Paraguay, Philippines, Russia, South Africa, Switzerland, Taiwan, Turkey, United States, Uruguay and Vietnam.

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*;
- (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 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.

1.2 In this Permit:

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

'Agency' means the National Biosafety Management Agency

'Event' is a plant variety that is developed by inserting the desired gene into the plant genome as a result of a single transformation process. It is term used to differentiate genetically modified crop varieties.

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

'GM' means genetically modified.

'GMO' means the genetically modified organism that is the subject of the dealings authorised by this Permit. It includes a live plant, a grain that is able to grow into a live plant, and a viable seed.

'Grain' means Maize used for food, feed and/or processing.

'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.

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 guide the suitability of the Permit holder:

1. The Permit holder shall, at all times, remain a person with authorised dealings with the GMO and shall comply with the terms and conditions of the Permit.
2. The Permit does not authorise this GMO for cultivation purposes.

3. This Permit remains in force until it is suspended, cancelled or surrendered or when the authorization period elapses. *(No dealings with GMO are authorised during any period of suspension).*
4. The persons covered by this Permit are the Permit holder and employees, agents or contractors of the Permit holder.
5. The dealings authorised by this Permit are for food, feed and for processing.
6. The Permit Holder shall at all times comply with the content of the decision document.
7. The Permit Holder shall inform the Agency in writing of:
 - i. any relevant conviction of the Permit Holder occurring after the issue of this Permit;
 - ii. 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;
 - iii. 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
 - iv. provide any information related to the Permit holder's ongoing suitability to hold a Permit, if requested, within the stipulated period.

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.

8. 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
9. The Permit Holder shall not permit a person covered by this Permit to conduct any dealing unless:
 - (a) the Permit Holder has obtained from the person an undertaking 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.
10. 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 immediate 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.

1. 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 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 immediate 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.

If the Permit Holder informs the Agency under the immediate 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

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

Section 3

Authorization:

After a thorough analysis of the application dossier, risk assessment and risk management measures/ risk mitigation and contingency options available, it is unlikely that the proposed use of the **GM Maize** for food, feed and processing, including in combination with any other approved events, would cause adverse impact on human and animal health. A permit is therefore granted to **SYNGENTA SOUTH AFRICA (Pty) LIMITED with permit Code: NBMA/FFP/D/001**

Section 4.

Authorization Period:

This Permit is with effect from 10th April 2019 to 31st December 2022

Section 5.

Signature and Date:

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Director-General/CEO

10th April 2019

Date



ATTACHMENT A

PERMIT CODE: NBMA/FFP/ D/001

Full Title: Genetically Modified Maize for use as Food, Feed and for Processing

Purpose of the dealings with the GMO:

Authorization for use as food, feed and for processing.

Organisation Details

Postal address: Syngenta South Africa (Pty) Limited

Phone No: +27 115414073

GMO Description

GMO covered by this Permit:

Zea mays containing Bt. 11// **PAT** gene.

Parent Organism:

Common Name: Maize

Scientific Name: *Zea mays*

Modified traits:

S/N	EVENT ID	INSERTED GENE
1.	Bt. 11	Cry1AB & PAT confers resistance to lepidopteran insects and Herbicide tolerance