



FEDERAL REPUBLIC OF NIGERIA

Decision Document for a Permit for the Commercial Release of MON87460 x MON 89034 (TELA) Maize Genetically Modified for Drought Tolerance, Resistance to Stem Borer and Fall Armyworm, Issued to Institute for Agricultural Research (IAR), Zaria.

The *National Biosafety Management Agency Act 2015 (as amended)* is the law that guides the regulation of the practice of modern biotechnology, development, handling and use of genetically modified organisms (GMOs) in Nigeria. This decision document is prepared in line with Act and issued by the National Biosafety Management Agency (NBMA) as part of permit granted, to the Institute for Agricultural Research, for the commercialization of MON87460 x MON 89034 (TELA maize) and its singles genetically modified for drought tolerance and insect resistance.

In arriving at this decision, the National Biosafety Management Agency took into consideration the advice of National Biosafety Committee, National Biosafety Technical Sub-committee and the review of data and information submitted by the applicant including the risk assessment and risk management reports. The Agency also invited comments from the general public. The National Biosafety Management Agency concluded that there were no known adverse impacts to the conservation and sustainable use to of biodiversity, taking into account risk to human health. The Agency concludes that the breeding stack MON87460 x MON 89034 (TELA maize) and its singles, do not exhibit any characteristic that would result in unintended environmental effects following commercial release. The review also concludes that the breeding stack, its singles, and food and feed products derived from it are as safe and nutritious for human and animal consumption as conventional maize.

The Permit, pursuant to this decision, is without prejudice to other extant legal requirements.

This Permit authorizes the Permit Holder and persons covered by the Permit to commercialize the MON87460 x MON 89034 (TELA maize) and its singles genetically modified for drought tolerance and insect resistance.

Section 1 Interpretations and Definitions

1.1 In this Permit:

- (a) unless defined otherwise, words and phrases used in this Permit have the same meaning as they do in the NBMA Act 2015 (as amended) and the National Biosafety Regulations, 2017;
- (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 State 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).

‘Periodic Report’ means a written report provided to the National Biosafety Management Agency as may be required, containing all the information required by this permit.

‘Annual Report’ means a written report provided to the National Biosafety Management Agency by the end of December every year, containing a comprehensive report of the activities, progress or otherwise of the permit holder for the preceding year.

‘Maize’ means plant of the species *Zea mays*

‘GM’ means genetically modified.

‘GMOs’ mean the genetically modified organisms that are the subject of the dealings authorized by this Permit.

‘NBMA’ means the National Biosafety Management Agency.

Section 2 Terms and Conditions

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. The holder of this permit ('the permit holder') is ***Institute for Agricultural Research, Zaria***
2. The Permit Holder shall:
 - (a) inform the NBMA immediately in writing, of:
 - i. any relevant conviction of the Permit Holder occurring after the commencement of this Permit; and
 - ii. any revocation or suspension of a Permit or 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
 - iii. any event or circumstances occurring after the commencement of this Permit that would affect the capacity of the holder of this Permit to meet the conditions in it; and

- (b) provide any information related to the Permit Holder's ongoing suitability to hold a Permit, if requested, within the stipulated period;
3. 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.

2.2 Provision of new information to the NBMA.

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 that may affect the risk assessment is communicated to the NBMA.

1. The Permit Holder shall inform the NBMA 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 authorized 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:

By the provision of section 35(2)(a) of the Act, the Permit Holder will be taken to have contravened the provisions of the Act if he or she, after the permit has been granted,

- (a) becomes aware of the additional information which could change the evaluation of risk posed by the intended activity; and*
- (b) becomes aware of new information which indicates that the genetically modified organism poses possible risk to human health, animal, plant or the environment but fails to disclose such information to the Agency.*

Note: Contraventions of the Permit may occur through the action or inaction of a person.

2. If the Permit Holder is required to inform the NBMA under the immediately preceding condition, the NBMA shall be informed without delay.

Note: An example of informing without delay is contact being made within 24 hours of the incident via the NBMA phone numbers +2348180805451 and +2347086117730 which are 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, as appropriate, and if required.

3. The NBMA, at any time, may request the Permit Holder to collect and provide information about any matter to do with the progress of the dealings authorized by this Permit, including but not limited to:
- (a) additional information as to any risks to the health and safety of people, or to the provided environment, associated with the dealings authorized by the Permit, whether or not the Permit Holder has information to the NBMA under condition 15(a);

- (b) any contraventions of the Permit by a person covered by the Permit, whether or not the Permit Holder has provided information to the NBMA under condition 15(b);
- (c) any unintended effects of the dealings authorized by the Permit, whether or not the Permit Holder has provided information to the NBMA under condition 15(c);
- (d) research, including by way of survey, to verify predictions of the risk assessment, or for any purpose related to risks to the health and safety of people, or to the environment;
- (e) scientific literature and reports in respect of the GMOs authorized by this Permit, for a period of time that the Agency may deem fit in the circumstance;
- (f) details of any refusals of applications for Permit or permits (however described) to deal with the GMOs made pursuant to the regulatory laws of a foreign country; and the request is reasonable, having regard to consistency with the Act and relevance to its purpose, then the Permit holder shall collect the information and provide it to the NBMA at a time and in the manner requested by the NBMA.

Note: The NBMA may invite the Permit holder to make a submission on the reasonability of a request, collect and provide information relevant to the progress of the dealings with the GMOs.

2.3 Obligations of persons covered by the Permit.

1. Persons covered by this Permit shall not deal with the GMOs except as expressly permitted by this Permit.
2. If a person is authorized 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 NBMA, or a person authorized by the NBMA, to enter the premises where the dealing is being undertaken, for the purposes of auditing, inspecting, monitoring the dealing or enforcement of compliance.
3. All persons covered by the Permit shall ensure that all GMO materials are properly labelled in line with the provisions of the National Biosafety Management Agency Act 2015 (as amended) and the National Biosafety Regulations 2017.
4. The permit holder or grower of this GMO under this permit shall ensure adequate measures of coexistence between related species of the GMO.
5. Any intended grower of MON87460 x MON 89034 (TELA maize) and its singles, on a farm size of 50 hectares or more shall ensure that five percent of the plot is under afforestation.
6. The permit holder shall provide to the NBMA, test protocols or primers to help identify the specific events in the breeding stack at least a week before the commercial release.

Section 3 Reporting and Documentation Requirements

3.1 Annual Report

1. The Permit holder shall provide periodic report of activities at various stages of the dealing period and a detailed Annual Report to the NBMA at the end of the dealing. An Annual Report shall include the following:

- (a) the locations where dealings on the GMOs are taking place within Nigeria,
- (b) information about any adverse impacts, unintended effects, or new information relating to risks, to human health and safety or the environment caused by the GMOs or material from the GMOs;

- (c) information about the initial volumes of the GMOs grown for commercial purpose, including seed increase operations, in each State for the first growing season in the period;
- (d) information about the volumes of the GMOs grown for non-commercial (e.g. research) purposes in each State for each growing season in the period.

Note: Instances of no planting of the approved breeding stack shall also be reported.

3.2 Testing methodology

1. Prior to conducting any dealings with the GMOs, the Permit Holder shall provide to the NBMA a written methodology to reliably detect the GMOs, and the presence of the genetic modifications described in this Permit in a recipient organism. The detection method shall be capable of reliably distinguishing between the specific genetic modifications in the GMOs described in this Permit and other genetic modifications in the MON87460 x MON 89034 (TELA maize) and its singles.
2. The permit holder shall also provide to the NBMA, test protocols or primers to help identify the specific events in the breeding stack, prior to dealing.

Section 4

Authorization:

After a thorough analysis of the application dossier, risk mitigation and contingency plan options available, a permit is hereby granted to the **INSTITUTE FOR AGRICULTURAL RESEARCH (IAR), ZARIA**, as applied for with permit Code No: **NBMA/CM/003**

Section 5

Duration of the Permit:

This Permit is with effect from 08th October 2021 to 08th October 2024

Section 6

Signature and Date:

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Director-General/CEO

7th October 2021

Date

Full Title: Commercial Release of Breeding Stack MON 87460 and MON 89034 (TELA maize) and its singles Genetically Modified for Drought Tolerance and Insect Resistance (resistance against stem borer and fall armyworm)

Organisation Details

- a) Postal address: Institute for Agricultural Research, Ahmadu Bello University, P.M.B 1044, Zaria, Nigeria.
- b) Email: mffaguji@hotmail.com, mfishiyaku@abu.edu.ng.
- c) Telephone: (+2348051316887, +23469551355)
- d) Fax: +23469550563

GMO Description

GMO covered by this Permit:

This Permit covers events MON 87460 and MON 89034 and its breeding stack MON 87460 x MON 89034 (TELA maize). This will ensure the applicant is able to access parental singles to facilitate TELA maize hybrid seed production and stewardship compliance. MON 87460 contains the cold shock protein B(CspB) gene derived from *Bacillus subtilis* and expresses neomycin phosphotransferase II(*NptII*) from *Escherichia coli* as a selectable marker. MON 89034 contains insect protection gene Cry1A.105, a modified *Bacillus thuringiensis* (*Bt*) Cry1A protein and Cry 2Ab2, a *Bt*(*subsp.kurstaki*) protein that confer protection from lepidopteran insect pests.

Parent Organism

Common Name: Maize

Scientific Name: *Zea mays*

Modified traits

Category: Resistance to stem borer and fall army worm

Description: The event stack contains the *CspB* gene from *Bacillus subtilis*, the *Cry1A.105* and *Cry2Ab2* genes isolated from *Bacillus thuringiensis* (*Bt*), and the *NptII* gene from non-pathogenic strain of *Escherichia coli* strain K12.

Genetic elements responsible for conferring the modified traits:

Gene: *Cry1A.105*, *Cry2Ab2*, *NptII*, *CspB*

Promoter:

MON 87460

CspB coding sequence under the regulation of the Ract1 promoter (for *CspB* expression cassette);

NptII coding sequence under the regulation of the 35S promoter (for *NptII* expression cassette)

MON 89034

Cry1A.105 coding sequence under the regulation of the e35S promoter (for the first cassette in T-DNA I)

NptII coding sequence under the regulation of the CaMV 35S promoter (for T-DNA II)

Terminator

Terminator for an aminoglycoside-modifying enzyme, 3'(9)-Onucleotidyltransferase from the transposon Tn7

Purpose of the dealings with the GMO

The purpose of the dealings is for commercial release of MON 87460 x MON 89034 (TELA maize) and its singles in Nigeria.

