Decision Document for a permit for the Commercial release of Pod Borer - Resistant Cowpea (PBR – Cowpea)-event AAT709A, genetically modified for lepidopteran insect pest (*Maruca vitrata)* resistance, issued to Institute for Agricultural Research (IAR), Zaria.

The *National Biosafety Management Agency Act 2015* 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 genetically modified Cowpea resistant to lepidopteran insect pest (*Maruca vitrata*).

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 risk assessment and risk management report provided by the applicant. The Agency was convinced that there are no known adverse impacts to the conservation and sustainable use to of biodiversity, taking into account risk to human health.

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

This Permit authorises the Permit Holder and persons covered by the Permit to commercialize the Pod Borer - Resistant Cowpea (PBR – Cowpea) genetically modified for lepidopteran insect pest (*Maruca vitrata*) resistant.

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 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.

'Periodic Report' means a written report provided to the National Biosafety Management Agency quarterly every year, 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.

'Cowpea' means plant of the species *Vigna unguiculata*. (L.) Walp

'GM' means genetically modified.

'GMOs' means the genetically modified organisms that are the subject of the dealings authorised 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;
   (c) ensure that planting area shall be 20 metres away from farm plots of non-GM related species.

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 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:

(a) By the provision of section 35(2)(a) of the Act, the Permit Holder will be taken to have become aware of the additional information, if he or she was reckless as to whether such information existed; and

(b) The Permit Holder will be taken to have become aware of contraventions, or unintended effects, of a kind mentioned in condition 2, 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.

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 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, if required.

3. If at any time the NBMA requests the Permit Holder to collect and provide information about any matter to do with the progress of the dealings authorised 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 authorised 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 authorised 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 authorised 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 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 NBMA, or a person authorised 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 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 in the form of isolation distance or planting time isolation on the farm.

5. Any intended grower of this GM cowpea of up to 50 hectares shall ensure that five percent of the plot is under afforestation.

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: nil plantings should 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 PBR Cowpea.

2. The permit holder shall also provide simple detection kits of the gene of insert to the NBMA prior to dealing.

Section 4

Authorization:

After a thorough analysis of the application dossier, Risk Assessment and Risk Management Plan prepared in connection with assessment of the application, it is unlikely that the proposed release will have adverse impact on the environment and human health. A permit is therefore granted to the Institute for Agricultural Research (IAR), Zaria, as applied for **with permit Code No: NBMA/CM/02**

Section 7

Duration of the Permit:

This Permit is with effect from 22nd January 2019 to 31st December 2022

Section 8

Signature and Date:

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Director-General/CEO

22nd January 2019.

Date

ATTACHMENT A

Full Title: Commercialization of Pod-Borer Resistant Cowpea (PBR-Cowpea) (*Vigna unguiculata*) - Event AAT 709A

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)
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GMO Description

GMO covered by this Permit:

The Cowpea event AAT 709A is expressing the Cry1Ab protein that confers protection from certain lepidopteran insect pests of cowpea, principally the pod borer (*Maruca vitrata* Fabricius [Lepidoptera: Crambidae])

Parent Organism

Common Name: Cowpea (Beans)
Scientific Name: (*Vigna unguiculata* (L.) Walp.)

Modified traits

Category: Resistance to lepidopteran insect pest pod borer (*Maruca vitrata).*
Description: The GM cotton has been genetically modified by introduction of two genes containing crystal proteins toxic to insects.

Genetic elements responsible for conferring the modified traits:

Gene: cry1Ab, NptII, S1

Promoter: Promoter region from subterranean clover stunt virus (SCSV)1 viral promoter.

Terminator: Terminator sequence from subterranean clover stunt virus *SCSV3*

Purpose of the dealings with the GMO

The purpose of the dealings is commercial production of the GM cowpea in Nigeria.