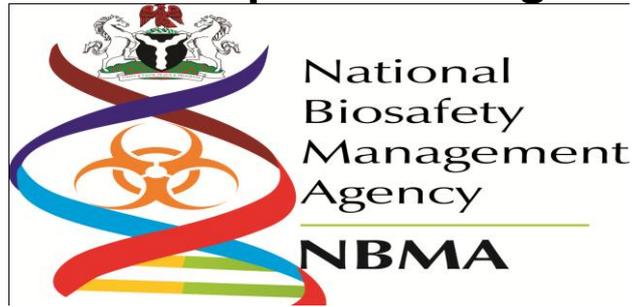


Federal Republic Of Nigeria



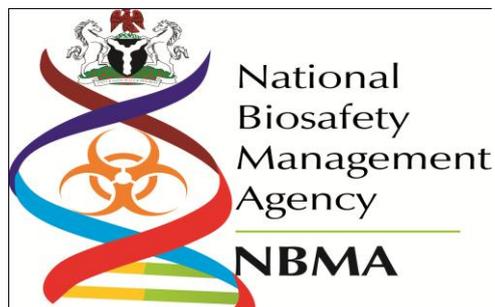
Decision Document For a

Permit for Commercial release/ Placing on Market of Cotton(MON15985) genetically modified for lepidopteran insect pest resistance issued to Monsanto Agriculture Nigeria Limited.

Permit No: NBMA/CM/IM/001

Date of Issue: 1st May 2016

More information about the decision to issue this Permit is contained in the Risk Assessment and Risk Management Plan prepared in connection with the assessment of the application for the Permit. This document can be obtained from the [National Biosafety Management Agency Office or the website, www.nbma.gov.ng](#) or by phoning the Office on +234 818 080 5451.



Decision Document for a permit for commercial release/ placing on Market of Cotton (MON 15985) genetically modified for lepidopteran insect pest resistance issued to Monsanto Agriculture, Nigeria Limited.

The *Biosafety Act 2015* is a nationally consistent regulatory framework controlling the practice of modern biotechnology, 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 *Biosafety Act 2015*.

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 public views. 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.

The Permit authorises the Permit Holder and persons covered by the Permit to conduct specified dealings with the genetically modified organism(s) listed in Attachment A of this Permit.

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;
- (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 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.

‘**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.

‘**Cotton**’ means plants of the species *Gossypium hirsutum* and *Gossypium babadensis*.

‘**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 Permit holder shall, at all times, remain an accredited or an affiliate of an accredited organisation and shall comply with its terms and conditions of accreditation.
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.

4. 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.

5. 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.

6. 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 environment, associated with the dealings authorised by the Permit, whether or not the Permit Holder has provided 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.

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

8. 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.

Section 3 Reporting and Documentation Requirements

3.1 Annual Report

9. The Permit holder shall provide an Annual Report to the NBMA. 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 volumes of the GMOs grown for commercial purposes, including seed increase operations, in each State for each growing season in the period;
- (d) informations 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 under conditions 20(b) and 20(c).

3.2 Testing methodology

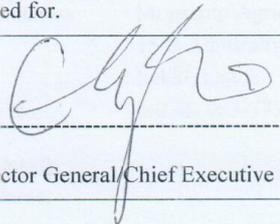
10. Prior to conducting any dealings with the GMOs, the Permit Holder shall provide to the NBMA a written methodology to reliably detect the GMOs, and the presence of the genetic modifications described in this Permit in a recipient organism. The detection method shall be capable of reliably distinguishing between the specific genetic modifications in the GMOs described in this Permit and other genetic modifications in the GM cotton.

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ATTACHMENT A

Section 4. Authorization:

After a thorough analysis of the application dossier, Risk Assessment and Risk Management Plan prepared in connection with the assessment of the application for the Permit, it is unlikely that the proposed release will cause adverse impact on the environment and on human health. A permit is therefore granted to the Monsanto Agriculture Nigeria Ltd as applied for.



Director General/Chief Executive Officer

Date: 04/05/16

Full Title: Commercial release of cotton (Boll guard II) genetically modified for resistance to lepidopteran insect pests.

Organisation Details

Postal address: Monsanto Agriculture Nigeria Ltd
15 B Admiralty Way, Lekki
Lekki, Lagos.
Phone No: (+234- 903-7736893)

IBC Details

IBC Name:

GMO Description

GMO covered by this Permit:

Gossypium hirsutum genetically modified by introduction of only the gene and genetic elements listed below, by the OECD unique identifier MON 15985-7

Parent Organism

Common Name: Cotton
Scientific Name: *Gossypium hirsutum*.

Modified traits

Category: Resistance to lepidopteran insect pest.
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: Cry2Ab2, Cry1Ac, NptII, GUS E377K
Promoter: Promoter region from e35S plant viral promoter.
Terminator: Terminator sequence from *A 3'Soy bean seed storage protein*.

Purpose of the dealings with the GMO

The purpose of the dealings is commercial production of the GM cotton in all areas of Nigeria where cotton is cultivated and for products of the GMO to enter general commerce.