





# **Biosafety Clearing-House (BCH)**

## COUNTRY'S DECISION OR ANY OTHER COMMUNICATION (DEC)

BCH-DEC-NG-113975-1

LAST UPDATED: 01 NOV 2018

#### **Amendment**

Is this an amendment to a decision or communication already published on the BCH?

No

## **General information**

Country

Nigeria

PARTY TO THE CARTAGENA PROTOCOL ON BIOSAFETY

**ENTRY INTO FORCE: 13 OCT 2003** 

Competent National Authority(ies) responsible for the decision or communication

- COMPETENT NATIONAL AUTHORITY: BCH-CNA-NG-7237-5 | BCH-CNA-NG-7237-5

#### **COMPETENT NATIONAL AUTHORITY**

NATIONAL BIOSAFETY MANAGEMENT AGENCY.

National Parks Building, Umaru Musa Yar'adua Expressway, Airport Road

ABUJA, FCT-ABUJA

Nigeria

Phone: 2348033147778 Fax: 234-9-5234119

Email: biosafetyng@gmail.com

Title / Reference number of the decision or communication

Decision Document for a Permit for Importation and use of Genetically Modified (GM) Maize for Feed Processing issued to Chi Farm LTD/NBMA/FFP/IM/08

ΕN

Date of the decision

18 Oct 2018

Is the decision taken prior to entry into force of the Protocol?

No

## Subject of the decision, notification, communication or declaration

Decision on LMOs for direct use as food or feed, or for processing (Article 11, LMOs-FFP)

# LMOs for direct use as food or feed, or for processing (LMOs-FFP)

Use(s) of LMO

LMOs for processing

Has the decision been taken in the absence of a domestic regulatory framework and in accordance with Article 11.6?

No

### Result of the decision

Result of the decision

Approval of the import and/or use of the LMO(s) with conditions

#### Conditions

- 1. The Permit holder shall, at all times, remain an organisation with an authorise dealings with the GMOs or an affiliate of such an organisation and shall comply with its terms and conditions of the Permit.
- 2. This Permit does not authorise dealings with GMOs that are otherwise prohibited for cultivation purposes.
- 3. 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). The holder of this permit ('the permit holder') is Chi Farm LTD
- 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 GM Maize consignment and transportation to the storage facility at least 2 weeks 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

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- 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 GMOs, 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 processing.
- 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) Trained on the dealing and
- (c) the Permit Holder has obtained from the person an undertaken 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.
- 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 undertaken 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 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. For example, if it is a condition of the Permit that grains are milled prior to bagging and large quantities of whole grains are bagged, then the person responsible for quality control will have contravened that Permit condition.

2. 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.

- 3. 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
- 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 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

3.1. 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.

- 1. 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 approved for importation in writing by the Agency.
- 2. Storage and milling of the GMOs may only occur within the following limits:
- 3.2. Volume and duration

Maximum volume of the import Duration

100,000 MT As approved by NBMA

3.3. Location of Milling Plant

KM 20, LAGOS-IBADAN EXPRESSWAY, AJANLA VILLAGE, IBADAN, OLUYOLE, OYO STATE.

- 1. 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.
- 3.4. 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.

3.5. Physical confinement and site security

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

- 3.6. Dispersal of GMOs
- a. Transportation of GMOs from Entry Port to storage
- b. Storage facility should be well-fortified to prevent dispersal of grains by rodents and theft.
- c. 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.

- 3.7. Dispersal of the GMOs during transport or storage
- a. Transport and storage of GMOs outside the Storage Area shall:
- b. only occur to the extent necessary to conduct the dealings permitted by this Permit or other valid authorisation; and
- c. be in accordance with the Agency's Guidelines for the Transport, Storage and Disposal of GMOs or
- d. if Grain is transported in a bag 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.

- e. Transport of GMOs for the purpose of export is permitted on notification to the Agency as the permit holder would have authorisation to import the GMOs to the destination country.
- f. Methods and procedures used to transport GMOs shall be recorded, and shall be provided to the Agency, if requested.
- 3.8. Persistence of the GMOs or Volunteers post-cleaning
- 1. 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
- (b) Milling areas that have been cleaned and where the GMOs may be able to establish\*. From the day of Cleaning until

Same as above At least once every 30 days Same as above Volunteers

Same as above Destroy before immediately Same as above

- 2. 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.
- 3.9. Contingency plan
- 1. If any unintentional presence of the GMOs is detected outside the areas requiring inspection, the Contingency Plan shall be implemented, which include:
- a. Notification of the Agency
- b. incident and corrective action forms shall be completed for each case of accidental release.
- c. The incorporation of the completed incident and corrective action forms into the compliance binder maintained at the storage and/or milling sites.
- d. 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.
- e. 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.
- f. 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 Reporting and Documentation

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

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

Notice Contents Timeframe

- (a) Intention to import i. Details of the consignment, volume, entry port, name of vessel and final destination including, the state, local government area and city/town, a street address and any other directions
- ii. Identity of the GMOs to be imported
- iii. Date on which the GMOs will 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 used packaged At least 7 days prior to importation
- (b) Milling of grain 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 i. Actual date(s) on which any areas needing Cleaning were Cleaned
- ii. Method of Cleaning,

- iii. Method of waste disposal Within 7 days of completion of any Cleaning
- (d) Inspection activities i. Information recorded in a Logbook Within 30 days of inspection

Reasons

Applicant met the requirements necessary for approval

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# Information sharing with other databases

Is this decision related to an LMO for commercial use?

No

Should this decision be forwarded to the OECD Secretariat for possible inclusion in the BioTrack Product Database?

No

Is this decision related to food safety?

No

Was it conducted in accordance with the Codex Alimentarius *Guideline for the Conduct of Food Safety*Assessment of Foods Derived from Recombinant-DNA Plants?

No

Should this information be forwarded to the Secretariat of the FAO GM Foods Platform?

No

#### LMO identification & risk assessment

LMO identification

BCH-LMO-SCBD-14778-15 LIVING MODIFIED ORGANISM | MON-ØØ863-5 - YIELDGARD™ ROOTWORM™ MAIZE |

Resistance to antibiotics - Kanamycin Resistance to diseases and pests - Insects - Coleoptera (beetles)

BCH-LMO-SCBD-104814-1 LIVING MODIFIED ORGANISM | DAS-4Ø278-9 - ENLIST™ MAIZE

Dow AgroSciences GmbH Resistance to herbicides Tolerance to 2,4-Dichlorophenoxyacetic acid Tolerance to aryloxyphenoxypropionate

BCH-LMO-SCBD-14809-8 LIVING MODIFIED ORGANISM | MON-ØØ863-5 X MON-ØØ81Ø-6 X MON-ØØ6Ø3-6 - ROUNDUP READY™ YIELDGARD™ MAIZE |

Resistance to antibiotics - Kanamycin Resistance to diseases and pests - Insects - Coleoptera (beetles), Lepidoptera (butterflies and moths) Resistance to herbicides - Glyphosate

BCH-LMO-SCBD-46305-16 LIVING MODIFIED ORGANISM | MON-89Ø34-3 X MON-ØØ6Ø3-6 - GENUITY® VT DOUBLE PRO™ MAIZE |

Monsanto Europe S.A. | Resistance to antibiotics (Kanamycin), Resistance to diseases and pests (Insects, Lepidoptera (butterflies and moths)), Resistance to herbicides (Glyphosate)

Risk assessment

BCH-RA-NG-113974-1 RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS | NATIONAL BIOSAFETY COMMITTEE OPINION ON AN APPLICATION BY CHI FARM LIMITED FOR THE PLACING ON THE MARKET OF GENETICALLY MODIFIED SOYBEAN FOR FOOD OR FEED IMPORT AND PROCESSING FOR THE IMPORT AND EXPORT OF GM MAIZE CONTAINING EVENTS, MON 863 (INSECTS RESISTANCE) DAS-40278-9 (TO CONTAIN DETOXIFIES 2, 4 -D HERBICIDE) MON 863 X MON810 X NK603 ( CRY 1AB CONFERS RESISTANCE TO LEPIDOPTERAN) (CRY 3BB1: CONFERS RESISTANCE TO COLEOPTERAN AND CP4 EPSPS (GLYPHOSATE HERBICIDE TOLERANCE), MON 8934 X NK603 (CP4 EPSPS (GLYPHOSATE HERBICIDE TOLERANCE), ( CRY 1A CONFERS RESISTANCE TO LEPIDOPTERAN INSECT) AND ( CRY 1AB2 (CONFERS RESISTANCE TO LEPIDOPTERAN INSECT)

MON-ØØ863-5 - YieldGard™ Rootworm™ maize | Resistance to diseases and pests, Resistance to antibiotics | DAS-4Ø278-9 - Enlist™ Maize | Resistance to herbicides | MON-ØØ863-5 x MON-ØØ81Ø-6 x MON-ØØ6Ø3-6 - Roundup Ready™ YieldGard™ maize | Resistance to diseases and pests, Resistance to herbicides, Resistance to antibiotics | MON-89Ø34-3 x MON-ØØ6Ø3-6 - Genuity® VT Double Pro™ Maize | Resistance to diseases and pests, Resistance to herbicides, Resistance to antibiotics

## Document on the decision, communication, notification or declaration

? chi\_farm\_decision sept. 2018.pdf ( English )

BCH-DEC-NG-113975-1

# **Further Information**

Questions about the Cartagena Protocol on Biosafety or the operation of the Biosafety Clearing-House may be directed to the Secretariat of the Convention on Biological Diversity.

Secretariat of the Convention on Biological Diversity 413 rue Saint-Jacques, suite 800

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