

FEDERAL REPUBLIC OF NIGERIA

Ref. No. NBMA/CFT/012

Decision Document for a Permit for Confined Field Trial of Genetically Modified Potato for late blight resistance issued to the National Root Crops Research Institute (NRCRI), Umudike.

This decision document is issued by the National Biosafety Management Agency (NBMA) to the National Root Crops Research Institute (NRCRI) as part of permit in accordance with the National Biosafety Management Agency Act 2015 (as amended).

The advice of National Biosafety Committee, National Biosafety Technical Sub-committee and risk assessment and risk management report guided the decision of the National Biosafety Management Agency.

The Permit authorises the Permit holder and persons covered by the permit to conduct specified dealings, including importation of the approved genetically modified organism referred to in this decision document.

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

Information about where the GMOs have been planted pursuant to this Permit is that they were previously tested only in screen house at ETH Plant Biotechnology Laboratory in Zurich, Switzerland.

Section 1 Interpretations and definitions

- 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 (as amended);
- (b) word gender includes any other gender;
- (c) words in the singular include the plural and words in the plural include the singular;
- (d) words importing persons include partners 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.

2. **In this Permit:**

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

'Clean' (or 'Cleaned') means, as the case requires:

- (a) in relation to an area specified in this Permit as requiring Cleaning, the destruction of the GMOs in that area, to the reasonable satisfaction of the National Biosafety Management Agency; or
- (b) in relation to Equipment, the removal and Destruction of the GMOs from the equipment, to the reasonable satisfaction of the National Biosafety Management Agency.

Contingency Plan' means a written plan, detailing measures to be taken in the event of the unintended presence of the GMOs outside an area that shall be inspected. A Contingency Plan shall include procedures to:

- (a) ensure the National Biosafety Management Agency is notified immediately if the Permit holder becomes aware of the event,
- (b) recover and/or destroy the GMOs; and
- (c) inspect for and destroy any Volunteers that may exist as a result of the event.
- 'Potato' means plants of the species Solanium tuberosum

'Cultivate' means:

- (a) till the soil in a manner which will promote the germination of potato stems; and
- (b) provide adequate soil moisture to promote the germination of potato stems.

'Destroy' (or **'destroyed'** or **'destruction'**) means, as the case requires, killed by one or more of the following methods:

- (a) stalk pulling; or
- (b) root cutting and mulching/slashing; or
- (c) ploughing; or
- (d) burning/incineration; or
- (e) treatment with herbicide; or
- (f) hand weeding; or
- (g) autoclaving; or
- (h) burial under at least one (1) metre of soil; or
- (i) a method approved in writing by the National Biosafety Management Agency.

- **Note:** 'As the case requires' has the effect that, depending on the circumstances, one or more of these techniques may not be appropriate. For example, in the case of killing the remains of harvest of the GMOs, treatment of post-harvest remains by incineration may not be a sufficient mechanism.
- **'Equipment'** includes, but is not limited to, harvesters, seeders, storage equipment, transport equipment (e.g. bags, containers, trucks, etc.), clothing and tools.
- **Exclusion Zone'** means an area extending at least 1.5 kilometres outwards from the outer edge of a Planting Area, which shall be kept free of deliberately planted (GM and non-GM) potato while the GMOs are growing in the Planting Area.
- 'GM' means genetically modified.
- 'GMOs' means the genetically modified organisms that are the subject of the dealings authorised by this Permit. GMOs include live plants, root stock that is able to grow into live plants, and viable materials.
- **'Logbook'** means a written or electronic record containing information required to be maintained by this Permit holder and which is able to be presented to the NBMA on request.
- 'Monitoring Zone' means an area of land extending at least 100 metres in all directions from the outer edge of a Planting Area.
- '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.
- 'Planting Area' means an area of land where the GMOs are intentionally planted and grown pursuant to this Permit.
- 'Plant Material' means any part of the potato plants grown in a Planting Area in respect to a Planting Area, whether viable or not.
- 'Agency' means the National Biosafety Management Agency.
- 'Sign-off' means a notice in writing from the National Biosafety Management Agency, in respect of an area, that post-harvest obligations no longer apply in respect of that area.
- **'Volunteers'** means GM or non-GM potato plants, which have not been intentionally grown.
- **'Waterways'** means all permanent natural waterways and man-made waterways that flow into natural waterways.

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 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 the Permit.
- 2. This Permit does not authorise dealings with GMOs that are otherwise prohibited for marketing 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*).
- 4. The holder of this permit ('the permit holder') is **National Root Crops Research Institute**, **Umudike**, *Nigeria*
- 5. 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.
- 6. The dealings authorised by this Permit are to conduct experiments with the GMOs, breed, propagate, grow, import, transport, and dispose of the GMOs and the possession, supply or use of the GMOs in the course of any of these dealings.
- 7. The Permit Holder shall notify the Agency as soon as practicable if any of the contact details of the project supervisor (Principal Investigator) changes.
- 8. 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.
 - 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 planting 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
 - 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.
- 9. The Permit Holder shall be able to access all Exclusion Zones (if any) and to access and control all Planting Areas, Pollen Traps (if any), Monitoring Zones (if any) and 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.

- 10. 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 'trial manager', 'site labourer' 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 Exclusion Zones (if any), and access and control Planting Areas, Pollen Traps (if any), Monitoring Zones (if any) and approved facilities for the duration of the Permit; and
 - **Note:** this may include a description of any contracts, agreements, or other enforceable arrangements.
 - (d) written methodology to reliably detect the GMOs or the presence of the genetic modifications in a recipient organism, and to distinguish between categories of GMOs approved for release; and
 - (e) a Contingency Plan to respond to inadvertent presence of the GMOs outside an area that shall be inspected.
- 11. 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.
- 12. The confined field trial site shall be inspected and approved by the Agency before commencing the trial.
- 13. 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
- 14. 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.
 - iii. Would not embark on strike
- 15. 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.

- 16. 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: It 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 The Permit holder shall inform the Agency if the Permit holder becomes aware of:(a) if he or she was reckless as to whether such information existed; and
- ii. the Permit Holder will be taken to have become aware of contraventions, or unintended effects, of a kind mentioned in paragraph The Permit holder shall inform the Agency if the Permit holder becomes aware of:any contraventions of the Permit by a person covered by the Permit; or or The Permit holder shall inform the Agency if the Permit holder becomes aware of:(c) 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. For example, if it is a condition of the Permit that volunteers are destroyed prior to reaching maturity and a volunteer reaches maturity, then the person responsible for controlling volunteers will have contravened that Permit condition.

17. 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 (+2348180805451), which provides emergency number 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.

18. 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

- 19. Persons covered by this Permit shall not deal with the GMOs except as expressly permitted by this Permit.
- 20. 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

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 grown, and on other activities that can be undertaken.

- 21. The only plants that may be grown at a Planting Area are:
 - (a) the GMOs covered by this Permit as described in Attachment A of the Permit;
 - (b) plants approved in writing by the Agency.
- 22. Planting and growing of the GMOs may only occur within the following limits:

Area and duration

Maximum size of any Planting Area	Duration
As indicated in the application	As indicated in the approval

State and location in which Planting Areas may be located

Jos, Plateau state.

- 23. Plant Material shall not be used, sold/Commercialized or otherwise disposed of for any purpose which would involve or result in its use as food for humans or feed for animals.
- 24. If experimentation or analysis with the GMOs is not conducted in accordance with requirements, experimentation or analysis with the GMOs may only be undertaken within:
 - (a) a Planting Area prior to post-harvest Cleaning; or
 - (b) a facility approved by the Agency.

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. Incinerators

should be located in Confined Field Trial sites for the purpose of burning of all waste GMOs materials and volunteers.

Physical confinement and site security

- 25. The trial site shall be adequately secured with:
 - (a) perimeter fence of wire mesh/gauze;
 - (b) 24-hour security personnel;
 - (c) clearly written sign posts at the four corners of the perimeter fence indicating CFT site of the GMOs and contact phone No.

Pollen dispersal

- 26. A Planting Area shall be:
 - (a) surrounded by a Pollen Trap; or
 - (b) surrounded by a Monitoring Zone and an Exclusion Zone.
- 27. If a Pollen Trap is used in accordance with the previous condition, Pollen Trap Plants shall:
 - (a) have a reasonably dense and vigorous growth; and
 - (b) be Flowering at the same time as the GMOs; and
 - (c) form a continuous barrier at least 20 m wide around the Planting Area while the GMOs are flowering, although one path of up to 2.5 m in width is allowed in order to access the Planting Area.
- 28. If a Monitoring Zone and an Exclusion Zone are used in accordance with condition A Planting Area shall be::
 - (a) while the GMOs are being grown in the Planting Area, the Monitoring Zone shall be maintained in a manner appropriate to allow the identification and Destruction of potato plants; and
 - (b) the GMOs shall not be planted in a Planting Area if any potato plant, other than a crop planted pursuant to this permit is present in the Exclusion Zone; and
 - (c) the Monitoring Zone and Exclusion Zones shall be inspected by people trained to recognise Volunteers, and actions taken as follows:

Area	Period of inspection	Inspection frequency	Inspect for	Action
Monitoring Zone	From 14 days prior to the expected commencement of Flowering of any GMOs* until all GMOs have been harvested or Destroyed	At least once every 30 days	Volunteers	Destroy before Flowering

Area	Period of inspection	Inspection frequency	Inspect for	Action
Exclusion Zone	From 7 days prior to the expected commencement of Flowering of any GMOs* until all GMOs have finished Flowering	At least once every 30 days	Intentionally planted soybean	Destroy before Flowering; alternatively, Destroy the GMOs before Flowering

^{*} Permit holder is required to provide information to the Agency on the expected flowering period, however the inspection period should be based on the observed development of the GMOs, so that inspections commence prior to any GMOs flowering.

Note: Details of any inspection activity shall be recorded in a Logbook as detailed.

Dispersal of GMOs

- 29. The outer edge of a Planting Area, and of a Pollen Trap if used, shall be at least 50 m away from Waterways.
- 30. Isolation distance from related non-GMO species should not be less than 100meters.
- 31. All potato plants grown at a Planting Area or Pollen Trap are considered the GMOs for the purposes of this permit.

Note: All conditions applying to the GMOs also apply to potato plants grown in a Planting Area or Pollen Trap.

- 32. The GMOs shall be harvested separately from any other crop.
- 33. If GMOs are destroyed, they are taken to have been harvested for the purposes of this permit and all conditions applying to post-harvest apply equally to post-destruction.
- 34. Roots from the GMOs shall be dealt with separately from any other root.
- 35. Areas of land used in connection with the GMOs shall be Cleaned as follows:

Area	as to be Cleaned	When
(a) (b)	Planting Area Pollen Trap	Within 30 days of harvest of the GMOs or within 9 months of planting the GMOs, whichever occurs first
(c)	any area where GMOs may have dispersed during planting, growing or harvesting, including irrigation channels and drains	As soon as practicable and before use for any other purpose
(d)	any area used to Clean any Equipment used in connection with the GMOs	
(e)	any area used to Destroy GMOs	
(f)	any area used to peel, store or experiment with GMOs	

Note: Areas of land that have been cleaned, or from which the GMOs have been harvested, are also subject to Inspections. Cleaning activities shall be recorded and notified to the Agency.

- 36. Any Equipment used in connection with the GMOs shall be cleaned as soon as practicable and before use for any other purpose.
- 37. Any extreme weather event that is expected to affect or has already affected a Planting Area or Pollen Trap, while the GMOs are growing or while the areas are subject to inspection requirements, shall be notified in writing to the *Agency* as soon as practically and reasonably possible.

Note: The Contingency Plan shall be implemented if the GMOs are detected outside areas under inspection.

Dispersal of the GMOs during transport or storage

- 38. Transport and storage of GMOs outside the Planting Area shall:
 - (a) only occur to the extent necessary to conduct the dealings permitted by this Permit or other valid authorisation; and
 - (b) be in accordance with the *National Biosafety Regulations/Guidelines on Identification, Transport, Storage and Disposal of GMOs* or
 - (c) if harvested Plant Material 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.

Transport of GMOs for the purpose of export is permitted on notification to the Agency as the permit holder would have authorisation to export the GMOs to the destination country.

39. Methods and procedures used to transport GMOs shall be recorded, and shall be provided to the *Agency*, if requested.

Persistence of the GMOs or Volunteers post-cleaning

40. 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) Planting Area (b) Pollen Trap (c) Other areas of land that have been cleaned and where the GMOs may be able to establish*.	From the day of Cleaning until: i. the area is replanted with the GMO; or ii. the <i>Agency</i> has issued a Sign-off for the area.	At least once every 30 days	Volunteers	Destroy before Flowering

This excludes, for instance, areas with hard floors used to peel, store or experiment on GMOs.

- 41. 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 post-harvest rainfall events including measurements at or near the area, or any irrigation events;
 - (f) details of any Volunteers observed including number, developmental stage and approximate position of the Volunteers within each area inspected and
 - (g) date(s) and method(s) of Destruction of any Volunteer plants.

Examples of acceptable ways to record the positional information for Volunteers and Related species in the Logbook include:

- descriptiv<mark>e text</mark>
- marking on a diagram
- indicating grid references on corresponding map/sketch.

Note: Details of Inspection activities shall be provided to the Agency.

- 42. While post-Cleaning inspection requirements apply to an area:
 - (a) the area shall be maintained in a manner appropriate to allow identification of Volunteers; and
 - (b) no plants may intentionally be grown in the area unless the plants are:
 - i. the GMOs and non-GM potato planted in accordance with the conditions of this permit; or
 - ii. listed as post-harvest crops permitted for the GM potato field trial site by the Agency; or

iii. agreed to in writing by the *Agency*.

Contingency plan

- 43. If any unintentional presence of the GMOs is detected outside the areas requiring inspection, the Contingency Plan shall be implemented, which include:
 - i. Notification of the Agency
 - ii. incident and corrective action forms shall be completed for each case of accidental release.
 - iii. The incorporation of the completed incident and corrective action forms into the compliance binder maintained at the CFT site.
 - iv. 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.
 - v. if GM plants are accidentally removed from the trial site after planting, 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.
 - vi. In the unlikely event of civil unrest or natural disaster that affects the integrity of the CFT beyond recovery, the NBMA should be notified by the Permit holder and the entire experiment will be destroyed.

Section 4 Sign off

- 44. The Permit Holder may make written application to the *Agency* that planting restrictions and inspection conditions no longer apply to an area if:
 - (a) all post-Cleaning inspection activities have been conducted for at least 12 months on the area and all associated areas of land; and
 - (b) no Volunteers have occurred on these areas in the most recent six-month inspection period.

Note: Associated areas refer to a Planting Area and the aggregate of all other areas of land requiring post-Cleaning inspections in respect of that Planting Area. Associated areas will be signed-off as a group rather than individually. Permit conditions require Cultivation for each Planting Area and Pollen Trap prior to a Sign-off application. The Agency will take into account the management and inspection history for all associated areas, including tillage, irrigation, rainfall and occurrence of Volunteers, in deciding whether or not further inspections are required to manage persistence of the GMOs.

Section 5 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.

45. Notifications shall be sent to the *Agency* as follows:

Notice	Contents	Timeframe
(a) Intention		At least 7 days prior to each planting (to

to Plant	coordinates, a street address and any other directions ii. Identity of the GMOs to be planted at the Planting Area iii. Date on which the GMOs will be planted iv. Period when the GMOs are expected to Flower v. Period when harvesting is expected to commence vi. How the Planting Area is intended to be used during the first year following harvest vii. A history indicating whether the Planting Area and Pollen Trap have previously been subject to flooding (if known); and viii. Whether the Planting Area will be surrounded by a Pollen Trap or by a Monitoring Zone and isolation distance	be updated immediately if the notified intended planting dates change)
(b) Planting	i. Actual date(s) of planting the GMOsii. Any changes to the details provided under part Intention to Plant	Within 7 days of any planting
(c) Harvest	i. Actual date(s) of harvesting the GMOs	Within 7 days of commencement of any harvesting
(d) Cleaning	 i. Actual date(s) on which any areas needing Cleaning were Cleaned ii. Method of Cleaning 	Within 7 days of completion of any Cleaning
(e) Inspection activities	i. Information recorded in a Logbook	Within 30 days of inspection

Section 6
Authorization:
After a thorough analysis of the application dossier, risk mitigation and contingency options
available, a permit is hereby granted to the National Root Crops Research Institute (NRCRI),
Umudike, with Ref. No: NBMA/CFT/012.
Section 7
Authorization Period:
This permit is with effect from 3 rd of June 2022 to the 31 st May 2024
Section 8
Signature and Date:
Date: 3 rd June 2022
Director-General/CEO

ATTACHMENT A

DIR No: REF CODE NBMA/CFT/002

Full Title: Limited and controlled release of potato genetically modified for resistance to late blight

Organisation Details

Institution Details: National Root Crops Research Institute, KM 8 Umahia-Ikot Ekpene Road, PMB 7006 Umahia, Abia State

Phone No: +234 8187620664

GMO Description

GMOs covered by this Permit:

Solanium tuberosum containing only the events and genes listed below.

Parent Organism:

Common Name: Potato

Scientific Name: Solanium tuberosum

Modified traits:

Categories – NptII

Description: The potato was genetically modified for resistance to late blight

Purpose of the dealings with the GMOs: CFT on potato genetically modified for resistance to late blight

Genes and events responsible for conferring the modified traits:

Genes: The *R* genes have been isolated from Solanum wild species including their native promoter and terminator sequences:

-RB gene (Rpi-bIb1 syn.) isolated from 50lanum bufb0CastanUm (ornamental nightshade) rich is a plant in the Solanaceae family, native to Mexico and parts of the U.S. Southwest (Song et a/., 2003).

Genes and events responsible for conferring the modified traits:

Genes: *cp4 epsps* gene

-Jtpi-blb2 gene isolated from *Solanum bulbocastanum* (ornamental nightshade) which is a plant in the Solanaceae family, native to Mexico and parts of the U.S. Southwest (Van der Vossen *et* /., 2005).

-Rpi-vnt1.J (*Rpi-vntJ* syn.) gene isolated from *Solanum ventur*// which is a tuberous species of the Solanaceae family, originated in Argentina (South America). It is a species of wild potato classified in the "Petota" section of the genus Solanum (Foster *et al.*, 2009).

-Rpi-mega gene (Ppi-moc1 syn.) isolated from :fiolanum mochiquense which is a Peruvian tuber-bearing wild species (Smilde et al., 2005).



ATTACHMENT B

Checklist of documents that shall be sent to the Agency:

When	What	Timeframe
Prior to	Details of persons covered	14 days prior to any planting
conducting any dealings	Preparation of Standard Operating Procedure (SOP)	14 days before commencement of the CFT
	Location of and approval CFT site	At least 30 days after issuance of permit and before planting
	Plan to inform people covered by the permit	14 days prior to any planting
	Plan to ensure control and access to all the Sites	14 days prior to any planting
	Detection methodology	14 days prior to any planting
	Contingency plan	14 days prior to any planting
Prior to planting	Intention to plant	At least 7 days prior to any planting
During	Planting	Within 7 days of any planting
growing	Pruning	From 7 months to allow for proper bulking and subsequent analysis
	Harvest	Within 7 days of commencement
Post-Cleaning	Cleaning	Within 7 days of completion
	Inspection	Within 30 days of each inspection
	Fallowing	At least one year
Any time after issue of the licence	Any changes of the project supervisor contact details	As soon as practically possible
the ficence	Any relevant conviction, revocation, suspension or cancellation of any relevant permit or circumstances that may affect compliance to licence conditions	Immediately, if occurs
	Any information relevant to on-going suitability	If and when requested
	Any changes to details provided under conditions Prior to conducting any dealings with the GMOs, the Permit	Within 14 days of the changes

When	What	Timeframe
	Holder shall provide to the 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 - Prior to conducting any dealings with the GMOs, the Permit Holder shall provide to the a Contingency Plan to respond to inadvertent presence of the GMOs outside an area that shall be inspected.	
A Section Section	Signed statements from persons covered under the licence	If and when requested
	Any additional information regarding health and safety of the people and the environment, contraventions of this licence or any unintended effects of the dealings authorized by the licence	As soon as practically and reasonably possible, after becoming aware
	Extreme weather conditions	As soon as practically and reasonably possible, if expected or occurs
	Methods and procedures for transport	If and when requested

