REPORT OF THE NATIONAL BIOSAFETY COMMITTEE (NBC) ON AN APPLICATION BY NATIONAL ROOT CROPS RESEARCH INSTITUTE, UMUDIKE, TO CONDUCT A CONFINED FIELD TRIAL ON LATE BLIGHT RESISTANT TRANSGENIC POTATO HELD AT DENIS HOTEL, ABUJA

25-26TH MAY, 2022

INTRODUCTION

In line with the National Biosafety Management Agency (NBMA) regulations, an ad-hoc National Biosafety Committee (NBC) was constituted by the DG/CEO, NBMA under the Chairmanship of Professor Celestine Aguoru, with the list of NBC members attached.

The Committee in expressing her opinion relied on the dossier submitted by applicants, the expertise of the members and other relevant documents to advise the Agency on the merits and demerits of the application.

Mode of Assessment

The application was assessed through an in-depth review of the submitted dossier.

S/No		OBSERVATIONS	REMARKS/RECOMMENDATIONS
1.	**Administrative Information**		
	Purpose of Application	The applicants propose a confined field trial to test transgenic potato for resistance to late blight disease	This transformation was done through pCIP99 and pSIM4392 transgenic events
	Previous applications or approvals	No previous application has been made on this combination. The application is new.	
	Applicant	National Root Crops Research Institute, Umudike	
	Contact Details of Principal Investigator	a. Name of Contact Person: Dr Charles Amadi b. Postal Address: National Root Crops Research Institute, Umudike, PMB 7006 Umuahia, Abia State c. Email: okeyamadi2003@yahoo.com d. Telephone: +234 (0) 803 565 0556	The Curriculum Vitae of the Principal Investigator and the Trial Manager should be provided
	Proposed Location and Size of Trial	Potato Research Programme, NRCRI Sub-Station, Kuru, PMB 04 Vom, Plateau State. GPS information on location of the Confined Field Trial (CFT);	

		Geographical coordinates: 09°44' N – 08°48' E. Trial Manager: Mr Kahya Shuaibu Email: kahyass91@gmail.com Phone number: +2348166939131	
	Proposed duration of Trial	Starting Date: 1st June 2022 Date of Termination: 31st May 2024	Expected starting date to be determined by the NBMA after approval
2	**Plant Information**		
	Toxicity and Allergenicity	**Toxicity:** Potatoes naturally contain glycoalkaloids (GA) which are not fully degraded during cooking and frying. Available information suggests that the susceptibility of humans to glycoalkaloid poisoning is high and very variable: oral doses in the range of 1 - 5 mg/kg body weight are marginally to severely toxic to humans whereas 3 - 6 mg/kg body weight can be lethal (OECD, 2015). There is no reason to expect a change in glycoalkaloid levels in the genetically modified (GM) late blight resistant	Before commercialization, food safety assessment tests must be carried out to ensure that the glycoalkaloids levels do not exceed the safety limits as those in its conventional counterpart

		potatoes compared to its non-GM near-isogenic variety. However, glycoalkaloid levels will be measured as part of the food safety assessment before the GM potatoes are commercialized.	
		Allergenicity: Potatoes are not considered a common source of allergens when cooked or fried. Two studies have revealed potential allergenicity of patatin when tubers are eaten raw and other proteins belonging to the family of soybean trypsin inhibitors. However, a recent study reported the absence of severe allergy to potatoes in a large population suggestive of a good profile of tolerance. There is no reason to expect a change in levels of patatin in the genetically modified (GM) late blight resistant potatoes compared to the non-GM varieties.	Allergenicity tests should be carried out to ensure the absence of allergens compared to its conventional counterparts

	Describe the Intended Phenotypic Changes to the Plant.	Apart from being resistant to late blight disease compared to its unmodified counterpart, no other phenotypic changes are expected	
	Intended Reproductive Effects	The genetic modification that led to the events were not intended to affect the reproductive biology and has not done so in the past	
	What is the source of genetic material? Is the source of genetic material likely to affect the safe conduct of a Confined Field Trial? If yes, how?	The transgenic potato varieties are Diamant, Desiree, Victoria, Tigoni, and Jalene. All of them are currently cultivated by farmers in Africa with Diamant being grown in Nigeria. The donor organism for all of the genetic material included in the DNA insert are: Genes: The R genes have been isolated from Solanum wild species including their native promoter and terminator sequences: ***RB* gene** *(Rpi-blb1* syn.) isolated from So*lanum bulbocastanum* (ornamental nightshade) which is a	

		plant in the Solanaceae family, native to Mexico and parts of the U.S. Southwest. ***Rpi-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. ***Rpi-vnt1.1*** *(Rpi-vnt1* syn.) gene isolated from *Solanum venturii* 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. ***Rpi-mcq1*** gene *(Rpi-moc1* syn.) isolated from *SoIanum mochiquense* which is a Peruvian tuber- bearing wild species. The selectable marker gene is: The *nptII* gene occurs naturally in *Escherichia coli* and confers resistance to kanamycin, neomycin	

		and some aminoglycoside analogues (i.e., paromomycin, geniticin and butirosin which are not in clinical use). None of these sources is expected to affect the safe conduct of the CFT.	
	Changes in Toxicity and Plant Compositi on	Changes in toxicity or composition are not expected, nor were they observed based on compositional analyses on tubers from CFTs of the 3 R-gene Victoria event Vic. 172 in Uganda (Ghislain, in prep.).	The safety of products from this CFT should be confirmed by appropriate regulatory authorities such as NAFDAC
	Describe the features of the genetic construct?	*The detailed information provided in the dossier on the genetic construct* **i.** *pCIP99 (GenBank IN 164628.1) plasmid is a binary vector of 24,819 bp including a T-DNA of 18,585 bp bearing from left border to right border the following genes: nptf7,*	

		Rpi-vnt1.1, GB, and Rpi-blb2. **ii.** The **pSIN4392** plasmid is a binary vector of 30,176 bp including a T-DNA of 21,316 bp bearing from left border to right border the following genes: nptf7, Rpi-vnt1, Rpi-mcq1, and Ppi-bIb2. The plasmid maps and the tables describing the gene constructs are provided in the dossier	
3	**Trial Description**		
	Experimental Design	The planting of the transgenic events will be conducted using a randomized complete block design (RCBD) with 4 replications comprising at least a row of 10 plantlets/tubers per genotype with a spacing of 30 cm and 75 cm between rows. Each plot size will be 3 m by 3.75 m separated from the next one by 1 m. Plants will be exposed to natural infection without using any	The experimental design is adequate

		measure to control late blight disease.	
	Are there wild plant species in the vicinity of the trial site that could be fertilized by pollen from the trial plants, resulting in viable seeds?	No wild relatives of the potato are present in Nigeria while potato varieties grown by farmers are out of reach of the pollen from the transgenic varieties. In addition, true seeds from potatoes are not used by farmers for planting and do not persist in their natural habitat.	
	Describe mechanisms in place to prevent pollen-mediated gene flow from the plants in the trial sites.	The physical distance to the nearest potato variety grown by farmers exceeds 30 times the recommended physical distance of 20 m for gene flow in potatoes. A periodic inspection (monthly) around the trial site will ensure no potato fields are planted or volunteer potatoes might occur within the reach of pollen.	
	Describe measures in place to control trial plant volunteers after the terminatio	After harvest, data on volunteer emergence are collected for 6 months. After this period, the trial activities are considered terminated. New planting of transgenic potatoes can	

	n of the trial.	take place in the previously used plots. If a new crop, not potato, is to be planted, it is recommended to leave fallow the plots for 2 years after harvest. All experimental plant foliage in the trial will be destroyed and incinerated after harvesting in a pit included in the fenced trial site. The plots will be monitored regularly for volunteers. All volunteer potatoes will be uprooted and incinerated following the relevant SOP.	
5.	**Material confinement**		
	Packaging	Late blight resistant transgenic events from Diamant, Desiree, Victoria, Tigoni, and Jalene with the 3R-gene stack and their near-isogenic lines will be transferred from CIP-BecA and MSU-PBG to NRCRI Potato Research Sub-station at Kuru in Jos South LGA of Plateau State as tuber seeds and in-vitro plantlets. During transportation, the transgenic plants will be packaged in 3 tier, secure packaging system and transported	

		in enclosed vehicles. A label identifying the material, its nature and numbers per transformed event will be included. The trial manager is in charge of monitoring the movement of all material (non-living and living) to and from the trial site. All movements are registered in the logbook. For activity materials, permits will be obtained from the NBMA and NAQS. The handling of transgenic events will follow established SOPs by the GBPP team in compliance with NBMA.	
	Harvesting, Transport and Storage	Following the relevant SOP, transgenic potato will be harvested as follows. Two weeks before harvest, potato plants will be dehaulmed (removal of the above part of potato plants) with all plant debris taken to the designated area for destruction. Using hoes, tubers will be dogged out from one plant at a time; ensuring that there is no tuber mixing between adjacent plants. For each plot,	Applicants should provide information on how to move harvested materials out of the CFT site, including their storage

		missing plant and tuber in each plot will be counted. Harvested tubers will be separated into the three categories (small tubers = < 30 mm; medium tubers = 30 mm > and < 45 mm; and large tubers = > 45 mm. Tubers will be then counted, weighted, and checked for tuber skin and flesh color, morphology, and damages. Tuber samples for compositional and genetic analyses will be separated, packaged, and stored within the premises following relevant SOPs and permits granted by NBMA. All data will be recorded by the trial manager in the logbook and the experimental data sheets to be shared eventually to the Pls as a duplicated copy.	
	Disposal and Clean-up	All plants, tubers, and debris are deposited into the designated pit present within the CFT site. The discarded material is then burnt in the incineration pit on site. Accurate	

		records will be taken during the whole process, kept on site and maintained by the trial manager. Hoes and other tools used during the trial will be cleaned and kept within the premises.	
	Site Security	The CFT is fully fenced (2m) with an entrance locked and guarded 24 h / 7 days/ week. It is located within the NRCRI Potato Research Sub-station compound which is also guarded and fenced. The trial site, plots will have a visible sign describing the trial at the entrance. Within the fenced area, all plots will be labelled with water-proof barcoded labels.	Information provided on site security is adequate following its compliance with NBMA guidelines on site security
6.	**Records, Personnel and Planning**		
	Other reports		In addition to the records the applicants have stated will be provided, the applicant will need to provide any other record as may be required by the NBMA
	Contingency Plans	Because all transgenic plant material will be handled exclusively within the CFT site, which is fenced and guarded at all times, accidental release can only happen during	Information on contingency plan is adequate

		transportation of the material before or after the trial, or through unexpected destruction or vandalism of the CFT site, or unanticipated extreme weather events. If for any reason there is a breach of confinement or a hazard becomes evident, the trial manager and the principal investigator (who will be on call 24 hrs.) will be notified immediately. Efforts will be undertaken to recover the material in coordination with the regulatory authorities (NBMA). Local administration will assist in the recovery of materials, if necessary. A record of the corrective action will be filled out for each occurrence. The record of corrective action forms will be incorporated into the compliance binder maintained in the CFT site. National authorities (NBMA) will be immediately notified following relevant SOPs.	

		If the integrity of the CFT is completely disrupted, for example by civil unrest or natural disaster, NBMA will be notified, and all the experimental plants will be destroyed.	
	Recovery of materials	If for any reason there is a breach of confinement or a hazard becomes evident, the trial manager and the principal investigator (who will be on call 24 hrs.) will be notified immediately. Efforts will be undertaken to recover the material in coordination with the regulatory authorities (NBMA). Local administration will assist in the recovery of materials, if necessary.	In addition to the security measures and contingency plans put in place, measures for the recovery of materials that may be inadvertently lost should be put in place

RECOMMENDATIONS

1. The Curriculum Vitae of the Principal Investigator and the Trial Manager should be provided.
2. Expected date of commencement and termination should be determined after approval by the NBMA.
3. All relevant regulatory agencies (NAQS, NCS, NASC, etc.) concerned with material transfer should be involved.
4. Applicants should provide information on how to move harvested materials out of the CFT site, including their storage
5. The NBC having gone through the document submitted by the applicant and the assessment, hereby recommend to the NBMA to approve the application subject to correction of all the observations.

MEMBERS OF THE NATIONAL BIOSAFETY COMMITTEE

S/NO	NAME	ORGANISATION	SIGNATURE	DATE
1.	PROF. CELESTINE AGUORU			
2.	MRS. KADIRI HALEEMAT	NAFDAC		
3.	DR. GABRIEL A. MALOMO	ARCN		
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8.	DR. SAB EBIRIEKWE	RMRDC		
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