

**REPORT OF THE NATIONAL BIOSAFETY COMMITTEE (NBC) ON
ASSESSMENT OF THE APPLICATION BY THE NATIONAL ROOT CROPS
RESEARCH INSTITUTE (NRCRI) UMUDIKE FOR CONFINED FIELD TRIAL
(CFT) OF CASSAVA WITH ELEVATED LEVELS OF IRON AND ZINC IN
THE STORAGE ROOTS EXPRESSING HIGH RESISTANCE TO CASSAVA
BROWN STREAK DISEASE (CBSD) AT DENIS HOTEL ABUJA ON 4-5TH
JULY, 2019**

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 B. E. Ubi, with the following under-listed members.

The Committee was mandated to review the submission of the National Biosafety technical Sub-committee (NBTS) with the aim of advising 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/N		Observations	Remarks/Recommendations
1.	Administrative Information		
	Purpose of Application	To perform event selection and characterization based on assessing a combination of agronomic performance, phenotypic characteristics, and trait efficacy (e.g. measurements of iron and zinc concentrations in storage roots), as well as high resistance to Cassava Brown Streak Disease (CBSD).	Cassava varieties preferred by Nigerian farmers were used for the genetic transformation.
	Previous applications or	No previous application has been submitted in Nigeria. However, CFTs of these	It may be noted that the institution had received approval for CFT on GM

	approvals	cassava transgenic events have been conducted Uganda and gene efficacy proven	events in the past
	Applicant	National Roots Crops Research Institute (NRCRI), Umudike	
	Contact Details of Principal Investigator	Name of Lead Scientist: Dr. Ihuoma Okwuonu Address: Km 8 Ikot Ekpene Road, PMB 7006, Umuahia 440001, Abia State, Nigeria Telephone(s): +2349035068714 E-mail: ihuomaumezurumba@yahoo.com	The Curriculum Vitae of the Principal Investigator(PI) and the Trial Manager should be provided
	Proposed Location and Size of Trial	Block N3, NRCRI, Ikot Ekpene Road, PMB 7006, Umuahia 440001 GPS Coordinates: N 05 29.0081', E 007 31.929; elevation - 118 m	
	Proposed duration of Trial	Two and half years (or 36 months). Expected starting date is August 1 st 2019 and expected termination date being July 31 st 2022	There is a discrepancy in the duration of the trial years (i.e. two and half years) and the months in bracket (i.e. 36 months). This should be clarified
2	Plant Information		
	Toxicity and Allergenicity	Observations were made that there is substantial equivalence between transgenic and non-transgenic cassava varieties in relation toxicity and	

		allergenicity as verified by several studies	
	Describe the Intended Phenotypic Changes to the Plant.	Apart from the aforementioned micronutrient enhancement traits and virus resistance, there are no other intended changes to plant phenotype.	
	Intended Reproductive Effects	<p>The genetic modifications resulting in the cassava events described herein were not intended to alter the reproductive or survival biology of the cassava varieties.</p> <p>Furthermore, the possibility of wind pollination is ruled out due to the relatively large cassava pollen which does not favour wind pollination. Cassava is almost exclusively propagated vegetatively and the short viability period of the pollen does not favour the chance of unintended viable pollen transfer for cross pollination. Moreover, wild relatives of cassava are not commonly found in Nigeria.</p>	An isolation distance of 100m maintained in this trial is adequate
	What is the source of genetic material? Is the source of genetic material	<p>The three sources of genetic materials are plant viruses, <i>E. coli</i> and <i>Arabidopsis thaliana</i>.</p> <p>The plant viruses are two viruses known to cause CBSD (CBSV and UCBSV),</p>	

	<p>likely to affect the safe conduct of a confined field trial? If yes, how?</p>	<p>which were used as the source of sequences derived from the respective coat protein (CP) coding regions.</p> <p><i>E. coli</i> strain K12, a non-pathogenic strain, was the source of the neomycin phosphotransferase II (NPTII) encoding <i>nptII</i> gene.</p> <p><i>Arabidopsis thaliana</i> was the source of the iron-regulated transporter (IRT) and ferritin encoding genes introduced into cassava events.</p> <p>The source of the genetic material indicated above is not likely to affect the safe conduct of the CFT.</p>	
	<p>Changes in Toxicity and Plant Composition</p>	<p>The genetic modifications resulting from these cassava events were not intended to result in any changes to the potential toxicity or allergenicity of cassava.</p> <p>Cassava events produced using transformation plasmids p9001 and p8023 were intended to express a change in micronutrient composition, namely elevated concentrations of iron and zinc in the storage roots, as well as high resistance to CBSD.</p>	
	<p>Describe the</p>	<p>The detailed information provided on the genetic</p>	

	features of the genetic construct?	construct (plasmid p9001, p5001 and p8023) is adequate. Restriction maps of the plasmid and their detailed description in tabular form were provided.	
3	Trial Description		
	Experimental Design	Information provided on experimental design is adequate	
	Are there wild plant species in the vicinity of the trial site that could be fertilized by pollen from the trial plants, resulting to viable seeds?	Observations were made to the fact that there are no wild species of cassava that could be fertilized by cassava pollen in the vicinity of the CFT	
	Describe mechanisms in place to prevent pollen-mediated gene flow from the plants in the trial sites.	An isolation distance of 100 meters will be maintained between the CFT site and any other sexually compatible species in accordance with the reported standard for separation used in cassava breeding programs. The experimental plants will be surrounded by a 2 meter wide set of guard rows inside the fenced area. The two outermost guard rows will be wild type (TME 117) cassava plants that will be	NBC recommends that the aperture of the wire mesh that will be laid 2m subterranean and 2m high should be specified (and should preferably be not more than 1 cm to prevent entry of rodents into the trial site)

		treated as pollentrap rows. All of these cassava guard rows will be destroyed with the test plants at the end of the field test.	
	Describe measures in place to control trial plant volunteers after termination of the trial.	Measures put in place were deemed appropriate in controlling plant volunteers after the termination of the trial.	
5.	Material confinement		
	Packaging	Packaging description is adequate and in accordance with standard procedures	
	Harvesting, Transport and Storage	The applicant showed evidence of envisaged use of NBMA guidelines for harvesting, transport and storage	All relevant regulatory Agencies concerned with transfer of plant materials should be involved
	Disposal and Clean-up	The applicant showed evidence of envisaged use of NBMA guidelines for disposal and clean up of harvested materials and crop residues	
	Site Security	The application indicated envisaged compliance with Biosafety guidelines for the security of the CFTs.	As stated above, the NBC recommends that the aperture of the wire mesh that will be laid 2 m subterranean and 2 m

			high should be specified (preferably not more than 1 cm to prevent entry of rodents into the trial site)
6.	Records, Personnel and Planning		
	Other reports	Adequate arrangements are being put in place to ensure proper record keeping and documentation.	
	Contingency Plans	The outlined contingency plans are adequate.	
	Recovery of materials	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 provided.	In the unlikely event of material loss, stringent recovery measures should be deployed

RECOMMENDATION

1. There is a discrepancy in the duration of the trial years (two and a half years) and the months in brackets (36 months). This should be clarified.
2. The curriculum vitae of the Principal Investigator (PI) and the Trial Manager should be provided.
3. Sketch Map of the trial site is provided and the experimental design is adequate. NBC recommends that the aperture of the wire mesh that will be laid 2 m subterranean and 2 m high should be specified (and should preferably be not more than 1 cm to prevent entry of rodents into the trial site)
4. All relevant regulatory Agencies (e.g. NBMA, Plant Quarantine Service, Nigerian Customs) concerned with materials transfer should be involved.
5. The NBC having gone through the document submitted by the applicant and the assessment and recommendation by the NBTC do hereby recommend to NBMA to approve the application subject to addressing the observations.

NBC members

NAME	SIGNATURE	DATE
Prof. Benjamin E. Ubi (Chairman)		
Prof. P. C. Onyenekwe		
Dr. Rose Gidado		
R.A. Usman		
Kadiri Haleemat		
Mrs Mopelola Akeju		
Azosiri Chioma		
Dr. Solomon Sunday		
Abah Anthony		
Oyewunmi Adeola		
Dr. Nkechi Mba		
Raheem Rasheed A.		
Dr. Egbere O. John		
Jamila Abubakar Maina		

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