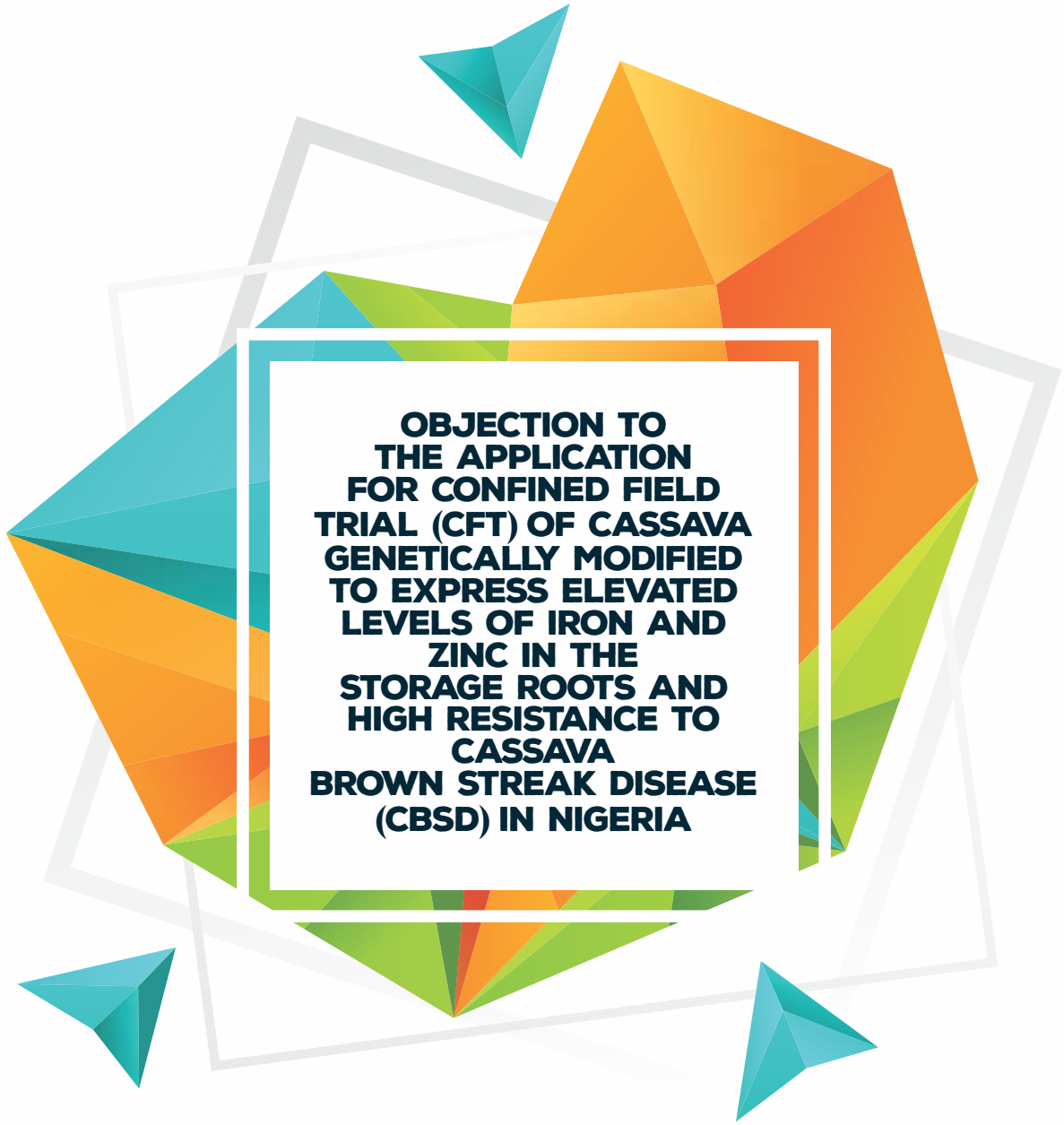
OBJECTION TO THE APPLICATION FOR CONFINED FIELD TRIAL (CFT) OF CASSAVA GENETICALLY MODIFIED TO EXPRESS ELEVATED LEVELS OF IRON AND ZINC IN THE STORAGE ROOTS AND HIGH RESISTANCE TO CASSAVA BROWN STREAK DISEASE (CBSD) IN NIGERIA



HOMEF

OBJECTION TO THE APPLICATION FOR CONFINED FIELD TRIAL (CFT) OF CASSAVA GENETICALLY MODIFIED TO EXPRESS ELEVATED LEVELS OF IRON AND ZINC IN THE STORAGE ROOTS AND HIGH RESISTANCE TO CASSAVA BROWN STREAK DISEASE (CBSD) IN NIGERIA

SUBMITTED TO THE
NATIONAL BIOSAFETY MANAGEMENT
AGENCY (NBMA)

BY

HEALTH OF MOTHER EARTH FOUNDATION (HOMEF)

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1. ABOUT HOMEF

HOMEF is the ecological think tank and an advocacy organization promoting environmental/climate justice and food sovereignty in Nigeria and Africa.

Our main thrust is examining the roots of exploitation of resources, peoples and nations. We nurture movements for the recovery of memory, dignity and harmonious living with Mother Earth.

HOMEF believes in the rights of Mother Earth, the need to equip communities to push back oppression and the need for justice for the environment, our food systems and natural cycles at every level of policy engagement.

HOMEF believes in contextual solutions over externally generated and imposed ideas and is firmly rooted in the ideals of solidarity and dignity.

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2. BACKGROUND INFORMATION

Nigeria is one of the largest producers of cassava in the world,with an annual output of over 34 million tonnes of tuberous roots. Cassava is largely consumed in many processed forms and its production has been increasing for the past two decades in area cultivated and in yield per hectare (Federal Ministry of Agriculture). This important root crop forms a major staple food, both for Nigerians and for millions of other peoples. It is a highly economic crop, owing to it resilience to harsh weather, its ability to reproduce even in poor soil conditions, and its availability all year round. In terms of food security, it is preferred to grains, peas and beans which are more seasonal.

Genetic modification of cassava has been premised on the need to improve its nutritious content and/or yield, reduce starch breakdown, reduce cyanide content and confer resistance to the cassava mosaic disease. However, none of these has been achieved since the almost two decades of research on the crop. The genetically modified crop,for example, the virus resistant varieties, has met with technical failures,while the conventional breeding (non-GMO) have recorded success in combating disease.

The International Institute of Tropical Agriculture (IITA), the Donald Danforth Plant Science Centre, the National Biotechnology Development Agency and National Root Crops Research Institute in Nigeria made an application, in 2004, to the Federal Ministry of Environment to carry out field trials of genetically modified cassava in Nigeria. That same year, IITA wrote to the Ministry to discontinue the application as tests carried out in the USA showed failure of the cassava at conferring resistance to the cassava mosaic disease. We note that same IITA had several naturally bred varieties of cassava that was resistant the mosaic disease.It is needful to add here that the results of these field trials conducted on genetically modified food crops in Nigeria are not in the public domain.

Modification of cassava to confer increased mineral content presents serious concerns (De Steuret al., 2015) and experts have maintained that the cultural ways in which cassava is consumed in Nigeria-with nutrient rich soups and vegetables sufficiently supply needed nourishment.

Health of Mother Earth Foundation wrote to the IITA in 2011 when the institute announced that it had developed three new varieties of vitamin A cassava that would put an end to vitamin A deficiency and improve livelihood of farmers. We advised that it would have the same result as the Golden Rice which encountered fundamental hitches that prevented its commercial release.

We object to this application by the National Root Crops Research Institute, Umudike,for confined field trial (CFT) of cassava genetically modified to express elevated levels of Iron and Zinc in the storage roots and high resistance to cassava brown streak disease (CBSD) in Nigeria.

Our objection is based,mainly on the fact thatthe stability of the traits involved in the modification process is not confirmed, the potential for gene flow to wild varieties of the crop and impact on non-target organisms poses serious threat to biodiversity, and such risks posed by this genetically modified cassava to consumers, farmers, the environment and our economy are not made known in the application.Also, genetic engineering of mineral content in staple crops poses serious concern and has the inherent disadvantage of over-expression of multiple genes. We strongly reject this application and demand that approval should not be granted.

3. SUMMARY OF OBJECTIONS

Although we had limited time, we have carried out rigorous independent scientific assessment of this application and here is a summary of our concerns.

Section 1- Administrative Information

We note that genetic engineering of mineral content in staple crops poses serious concern and has the inherent disadvantage of over-expression of multiple genes (De Steuret al., 2015).The applicant did not provide information relating to the several gene orchestrated processes from mineral uptake by the roots to transport throughout the plant to accumulation in edible tissues (cassava storage roots). The unintended outcome and hence potential harm of these complex genetic interplay remain unknown.

It has been recognised by the UN's International Conference on Nutrition that there is need to move from over-emphasis on food fortification strategies, including biofortification, toward a permanent solution, i.e. diet diversification through locally available foods.
Nigeria should shift towards developing and implementing key strategies for food and dietary diversification at the community and household levels. Agroecology is an important and viable alternative which addresses this need.

Previous Applications or Approvals

The fact that the commercial release of thisGM cassava has not been authorised before in any jurisdiction, raises much concern.
The lack of relevant scientific information and knowledge regarding the extent of potential adverse effects, call for the Precautionary Principle referenced in theCartagena Protocolto be triggered. Addressing uncertainty is a key element of that Protocol.

The National Biosafety Management Agency should note that recently in Africa, many countries such as Zimbabwe also conducted CFTs on GM cassava as orphan crops but such research in these countries has been discontinued and abandoned at laboratory stage for being futile.

Section 2-Plant Information

There is a high possibility of gene flow from the genetically modified cassava and this portends great threat to biodiversity and loss of the indigenous varieties of the crop.

Although cassava cultivars are propagated exclusively by stem cuttings, there could be movement of material from the site throughflooding, animal feeding,several species of wasp (mainly polistesspp) and honey bees (Apismelfera) pollinators of cassava,ant dispersal of cassava seeds or unlawful harvest.
Tendency and Weediness: we note that the ability of cassava to establish and maintain volunteer growth can be a veritable feature that can further cause contamination.

Toxicity and Allergenicity: The possibility that the cassava plant from the experimental field trial will be consumed is very high. It will be almost impossible to rule out surreptitious acquisition of the stem-cutting and the likelihood of unlawful harvest by locals who had always accessed improved cassava varieties from NRCRI, Umudike the CFT site. This is a serious concern as the transgenic cassava is said to have some allergen properties.

Section 2.2-Modified Plant Information

Intended Phenotypic Changes to the Plant: The adopted modification technology is undeclared. All commonly used genetic transformation systems in cassava rely on the induction of somatic embryogenesis (Beyene et al., 2016).

The culture of rapidly dividing, highly disorganized callus tissues, such as the Friable embryogenic callus (FEC) used in cassava transformation systems, is known to induce changes at the genetic and epigenetic levels (Kaeppleret al., 2000; Ma et al.,2015; Miguel and Marum, 2011).

Obviously, there will be significant alteration and /or loss of nutrient following this modification and this application has not substantiated anything to the contrary.

Source of Genetic Material: No molecular information is provided by the applicant.
Has the applicant checked to see if the introduced genes or sequences are as they say?Have they checked for possibility of unintended effects?

Changes in Toxicity or Plant Composition: There is no data on outcomes and experience with the proposed transgenic cassava candidate. Crucially, the claim by the applicant that "There are no expected changes in toxicity or allergenicity of transgenic cassava clones" lacks credibility and is quite deceptive.
Plants, including cassava, face challenges in maintaining homeostasis of these two metals - Iron and Zinc, as they may generate highly reactive hydroxyl radicals. The hydroxyl radicals can harm most cell parts, for example, DNA, proteins, lipids and sugars (Alagarasanet al., 2017).

NBMA, should note the fate of the popular Golden rice, which was genetically modified to achieve biofortification supposedly tocombat vitamin A deficiency considered a pandemic in South and South-East Asian countries and Africa. Interestingly, more than twenty years after (1996-2018), the FDA has eventually affirmed that the Golden rice offers No Nutritional Benefits (U.S FDA, 2018 A and B).

Features of the Genetic Construct:

Over-abundance of Zn and Fe might cause significant toxicity to some biological systems (Pahlsson, 1989; Price and Hendry, 1991).
Genetic engineering of mineral content in staple crops is challenging and has the inherent drawback of over-expression of multiple genes (De Steuret al., 2015).

The designers of this construct failed to take into consideration the gene-environment interaction (GEI) which underlines individual response to dietary Iron. Put another way, genetic variation produces observable phenotypic differences under specific conditions (Miranda and Lawson, 2018)
The stability of the traits involved, as well as the potential for gene flow, and the risks posed by this GM cassava to farmers, consumers, the economy, and environment remain unknown.

Section 3-Trial Description

The experiment design provides no details on how all the anticipated cassava diseases will be diagnosed either on the field or in the laboratory. Meaning that many of the findings may be by subjective deductions and not scientifically.

The experimental design does not show any parameter / variables that will measure the anticipated impact of the herbicides (Primextra Gold and Touchdown Forte) to be used, and /or its event outcomes on organisms (including microorganisms) and biodiversity. Although the agronomic data may reveal some potential environmental harm, informal observations are likely to miss many potential environmental impacts.

The application is lacking in the standard operating of procedures (SOP) / protocols for collecting environmental impact data from the field trials. Obviously, the CFT's impacts on non-target organisms would not be evaluated and measured.

Section 4-General Confinement

Flood and pollinators such as honeybees (Apis mellifera) will most likely cause adventitious contamination. Again, the honeybees (Apis mellifera) population in this region may suffer some sort of adversity as a result the undue exposure to this novel genetic construct.

Section 5- Material Confinement

The procedure stated for the packaging and labelling for transport of the experimental plant to the trial site are not referenced to any standard biosafety protocol.

Tables and charts referred to in many sections are not available for review.

4. DETAILED COMMENTS/OBJECTIONS

1. Administrative Information

Purpose of Application: Application for a confined field trial (CFT) for transgenic Cassava (Manihot esculentaCrantz) events with two Nigeria cultivars TMS 98/0505 and TMS 91/02324 to be evaluated in confined field trial (CFT) testing were developed to express elevated levels of iron and zinc in the storage roots and express high resistance to cassava brown streak disease (CBSD) as a pre-emptive strategy for the disease arriving Nigeria.

Query/Applicant Response

Micronutrient deficiency, particularly iron and zinc, is of major public health concern in Nigeria. For example; iron and zinc deficiency is estimated at 80% and 83 % respectively in pre-school children (Abah et al., 2015; Ibeawuchi et al., 2017; Abubakr et al., 2017).

Cassava consumed as the second staple for over 180 million people in Nigeria is highly deficient in these minerals, consequently resulting to hidden hunger amongst consumers across the country. Supplementation for these micronutrients has been attempted but with limited coverage especially in rural communities. As an alternative food-based approaches involving dietary diversification, nutrient education and biofortification are being emphasized in order to reach more people (Thompson et al., 2011). Breeding for these traits conventionally is constrained due to limited genetic variability in natural germplasm, necessitating the use of transgenic approaches (Zhu et al., 2017).

Genetically engineered cassava (Manihot esculenta Crantz) events with two Nigeria cultivars TMS98/0505 and TMS91/02324 to be evaluated in confined field trial (CFT) testing were developed to express elevated levels of iron and zinc in the storage roots and express high resistance to cassava brown streak disease (CBSD) as a pre-emptive strategy for the disease arriving Nigeria.

The purpose of the CFT testing is to perform event selection and characterization based on assessing a combination of agronomic, phenotypic characteristics and trait efficiency (e.g measurement of Iron and Zinc concentrations in storage roots).

OBJECTIONS

1. There is absolutely no scientific evidence that the deficiency of Iron and Zinc in cassava consumed by Nigerians result to "hidden hunger". Such claim by the applicant not premised on empirical data is preposterous.
2. The interest of the proponents of this GM cassava is self-serving and contradicts the tenets of food safety, food security, food sovereignty and economic interests of Nigeria. Nigeria and Nigerians must not allow them accomplish their untoward interest at the detriment of our food chain.
3. This is because the current GM cassava was not designed to solve significant food related challenge, rather it is in furtherance of reductionist solutions proposed by the biotech machinery for a myriad of agronomic and nutritional diversity challenges.

4. The true intent is to pry open Nigeria's food and farming systems to GM based agriculture, by giving the highly contested and failed technology to the country.

5. Genetic engineering of mineral content in staple crops is challenging and has the inherent drawback of over-expression of multiple genes (De Steuret al., 2015). The applicants made no disclosures pertaining to the many gene orchestrated processes from mineral uptake by the roots, to transport throughout the plant, to accumulation in edible tissues (cassava storage roots). The unintended outcome and hence potential harm of these complex genetic interplay remain unknown.

6. An important dimension of the candidate GM cassava pertains to nutritional enhancement (biofortification) to express elevated levels of Iron and Zinc in the storage roots. The dearth of literature that critically addresses the biosafety and the socio economic aspects relevant to the biofortification of indigenous cassava cultivars through GE, to improve nutrition for poor people and nutrient deficient populations, is of grave concern, and calls for extreme caution (ACBIO, 2016).

7. The present strong focus on biofortification (particularly cassava) through GE is remarkably horrendous, given the need to move from over-emphasis on food fortification strategies, including biofortification, toward a permanent solution, i.e. diet diversification through locally available foods, which was recognised as early as 1992 by the UN's International Conference on Nutrition (ACBIO, 2016). In this regard, agroecology and, in particular, diet diversification, including through home gardens have been singled out as the most successful strategies to combat micronutrient deficiencies in developing countries (Lopez Villar, 2015).

8. There are also viable alternatives that address the biotic and abiotic (i.e. the living and non-living components, respectively, of an ecosystem) stresses and challenges, which confront some of these crops.

9. The time is long overdue for Nigeria as a country to shift to developing and implementing key strategies for food and dietary diversification at the community and household levels.

10. More than 24 years ago, the Food and Agriculture Organisation (FAO) supported this approach, including the promotion of under-exploited traditional foods and home gardens and the raising of small livestock; improved preservation processes and storage facilities for fruits and vegetables, to reduce waste, post-harvest losses and effects on seasonality; the strengthening of small-scale agro-processing and food industries; and nutrition and education to encourage the consumption of a healthy and nutritious diet (FAO, 1997; Lopez Villar, 2015).

11. A shift inAgriculture paradigm to Agroecology, which can provide enough food for all in a sustainable manner (De Schutter, 2010; De Schutter, 2014), by building on traditional agriculture, which is extremely rich in biodiversity and the diversity of ecosystems is the golden option.

12. Though using staple crops for transgenic biofortification is an apparent strategy to reach poor, malnourished populations, these crops remain a meagre source of various other untargeted micronutrients.

13. Ebuehi (2005) reported significant losses in various minerals including calcium, magnesium, phosphorus, iron, sodium and chloride ions identified in the roots and raw leaves of cassava as a result of boiling. Boiling and frying has also been implicated in losses of certain micronutrient in plantain including iron, copper and zinc (Ahenkora, et al., 1996).

14. Above all, transgenic biofortification is certainly not a panacea for eliminating malnutrition (Ruel and Alderman, 2013).

Previous Applications or Approvals

[Information on the status of this crop and trait, including pending, approved, or denied applications for filed trails and commercial release here or in other jurisdictions. Indicate also if this is a new application or a renewal.]

Query/Applicant Response

This is a new application. No application for CFTs of the cassava events described herein have been previously submitted in Nigeria. The cassava events described herein have not been authorized for commercial release in any jurisdiction, nor have any applications for CFTs been denied in any jurisdiction.

OBJECTION

1. The fact that the commercial release of these cassava events has not been authorised before in any jurisdiction, raises many concerns for us.
2. It lacks peer review, having not been evaluated in any other part of the world.
3. There is no data on outcomes and experience with the proposed transgenic cassava candidate. What are the results from contained use of the cassava?. Has the applicant measured Iron and Zinc levels in the GM cassava?
4. The objective for this GM cassava is detrimental to the food safety, food security and economic interests of Nigeria.
5. This GM cassava is an integral part of the reductionist solutions proposed by the biotech machinery for a myriad of agronomic and nutritional diversity challenges.

The lack of relevant scientific information and knowledge regarding the extent of potential adverse effects, call for the Precautionary Principle referenced in the Biosafety Protocol-Cartagena Protocol- to be triggered. Addressing uncertainty is a key element of that Protocol.

The National Biosafety Management Agency should note that Recently in Africa, many countries such as Zimbabwe also conducted CFTs on GM cassava as orphan crops but such research in these countries, to date, has been discontinued and abandoned at laboratory stage for being futile.

Precisely, similar transformation of the Ugandan farmer-preferred cassava cultivar TME with a virus-derived inverted repeat construct, apparently effective against both brown streak viruses (Ogwok et al., 2012; Odipio et al., 2014), inadvertently resulted in somatic embryo genesis and invariably, the loss of resistance to the Cassava Mosaic Virus Disease (CMD) by the CMD2 gene. Implicitly, this is just one of the numerous unexpected, and unknown consequences of experimenting with transgenic plants (Cassava) (Beyeneet al., 2016).

We urge NBMA to decline approval for this application. Nigerians have no need for it.

2. PLANT INFORMATION

2.1 Unmodified Plant Information

Query/Applicant Response

Cassava originated from South-Central American regions of the Amazon, where the largest diversity of progenitor species exists (Olsen and Schale 1999).

OBJECTION

Cassava is one of the oldest cultivated crops in Nigeria. It can be said to have been grown by communities in Nigeria for well over 5000 years.

This particular germplasm, cultivars TMS98/0505 and TMS91/02324 are of the high-yielding Tropical Manioc Selection (TMS) and was developed at the National Root Crops Research Institute (NRCRI) in the 1970s in Ibadan and it was later transferred to IITA for improvement through breeding. Since the late 1980s, the TMS cultivars form more than 60% of cassava cultivars grown in Nigeria.

The TMS varieties are renowned for boosting cassava yield by 40 percent without fertilizer application and for being ideal for garri preparation, the main staple form of cassava consumed in Nigeria (Nweke, 2004).

Cassava cultivar, TMS 91/02324, produce more ethanol, has more starch and protein content than other TMS cultivars (Ademiluyi and Mepba, 2013).

No single cassava variety best suits all end-user preferences and environments. Target specific genotypes for specific environments, end uses/defined markets and stability of crop performance across environments are more relevant issues in the 21st century as greater emphasis is placed on sustainable agricultural systems (Dixon, 2010).

Therefore, this transgenic GM cassava with unknown and undisclosed unexpected genetic outcome portend grave danger for smallholder farmers in Nigeria.

The intent is to pry open our precious cassava germ plasm, farming systems and food chain to failed GM based agriculture.
This is unjust, socially and is ethically unacceptable.

Reproductive Mechanism of the Plant:

[Describe the generative biology of the plant: This information may be obtained from Organization for Economic C-operation and Development (OCED), biology consensus documents or similar sources, and should include relevant information on: inter- or intra –specific breeding; pollen product, dispersal and viabilit

Query/Applicant Response

The biology of cassava has been described in details in OECD(2014) and is only summarized here.

Cassava flowers are produced on monoecious inflorescence bearing separate female and male flowers on the same panicle. Flowering is highly influenced by environmental conditions and the branching nature of the plant. Flower buds typically forms where the plant branches so that highly ranching genotypes flower more. The number of flowers is genotype dependent and some cultivars have never been observed to flower, which has posed a considerable challenge to conventional breeding with these usually elite genotypes. Individual cassava inflorescence display protogymy, the female flowers open one to two weeks before the male flowers on the same on the same inflorescence therefore preventing self-fertilization on the same inflorescence. Plants with more than one inflorescence, male and female flowers on the same plant may open at the same time and can fertilize. Cassava is generally an out crossing species and highly heterozygous.

The general stages of flowering in cassava are as follows:

- **Branch begins from 2-6 months after vegetative planting.**
- **A flower bud is produced at the branching point within 1 week of branching.**
- **Female flowers are receptive to pollination about 15 days after floral initiation.**
- **Male flowers on the same branch open about 20-30 days later.**
- **Fruits mature and are ready to dehisce (open) within 2-3 months of fertilization.**

Pollen Production, Dispersal and Viability

Cassava pollen grains are large and sticky, and rapidly lose their viability after pollen shed. Due to the large size of cassava pollen, wind pollination is unlikely to occur, several species of wasp (mainly polistesspp) and honey bees (Apismelfera) are considered the main pollinators of cassava in Africa. In practice, cassava breeder perform pollination within one hour after collecting pollen, since cassava pollen viability declines rapidly after this time (Hasleyet al., 2008). Cassava can cross to some of its wild relative e.gM. glaziovil, M.dicothoma, M.oligantha subsp.Nestil which are not commonly found outside of South America.

Seed Production, Dispersal, and Dormancy

Developing seeds become viable about two months after pollination, and the fruit becomes mature one month after that.

Dehiscence is explosive and the seed fall close to the mother plant. Cassava seeds are adapted to ant dispersal and ants may transport the seed up to several meters from its place of origin. Newly harvested seed exhibits physical dormancy and requires 3-6 months storage before it will germinate. Seeds remain viable for up to one year when stored at ambient temperature; however, germination percentage declines after six months.

Cassava cultivars are propagated exclusively by stem cuttings, referred to as stakes. Vegetative propagation is preferred by cassava farmers because it is the only way to maintain the desirable trait combinations present in the farmer-preferredcultivar and ensures a larger amount of planting materials. When cassava plants are harvested, nodal cuttings derived from the stem are cut for production of the next crop. The stakes are typically about 25cm in length (Hasleyet al .,2008) y; and seed production an

OBJECTION

The biology of the cassava plant as briefly outlined by the applicant lends credence to our objection. There is a high possibility of gene flow and this portends great threat to biodiversity and loss of the indigenous varieties of the crop.

There could also be movement of material from the site throughflooding, animal feeding,several species of wasp (mainly polistesspp) and honey bees (Apismelfera) pollinators of cassava,ant dispersal of cassava seeds or unlawful harvest.d dispersal, seed dormancy, capacity for vegetative propagation.]

Query/Applicant Response

Tendency and Weediness:

[Is the unmodified plant regarded by agricultural experts as weed in the regions where it is cultivated? If so, are controls methods available that may be used to effectively limit the dispersal and establishment of the unmodified plants? NOTE: The information on the confined field trail location and how the genetically modified plant will be managed are described elsewhere in this application]

Cassava does not survive in abandoned fields or as an escape from cultivation. It is propagated almost exclusively by stem cuttings. Low fecundity and physiological seed dormancy limit the spread and establishment of the crop into unmanaged habitats.

OBJECTION

Cassava plant is renowned for its resilience and ability to cope with a wide range of environmental stresses and continues to produce tubers under poor growing conditions (Gleadow, Pegg and Blomstedt, 2016).

This ability of cassava to establish and maintain volunteer growth can be a veritable feature that can further cause contamination.

This tendency of cassava that the applicant did gloss over have incalculable implication for biodiversity.

Query/applicant response

Toxicity and Allergenicity:
[Is the plant species known to be a source of substances that are toxic or allergenic to human or animals? if yes, identify the substances and levels that induce toxicity or allergenicity and the affected species.]

Cassava is one of 3,000 plant species that produce cyanogenic compounds that upon breakdown release hydrogen cyanide (hcn) and can therefore be toxic to humans. the main cyanogenic glucoside are linamarin (>90%) and lostraulin (<10%). Cassava cultivars have been classified into groups according to their cyanogenic glucoside content, measured as hcn equivalents, or tastes of their roots (mcmahon et al 1995). Cultivars producing less than 100mg hcn equivalent per kg root tissue are classified as low in cyanogenic glycosides.

Cassava is not a commonly allergenic food. However, there has been reports describing latex (Hevesbrasiliensis) allergic individuals exhibiting allergy to plant-derived foods (latex-fruit syndrome), including cassava (Gaspar et al., 2003; Iberoet al., 2007). Santos et al., 2011 recently described a glutamic acid –rich protein (Mane 5) with similarity to Hev b 5 as an allergen in cassava tuber. IgE cross-reactivity between Hev b5 and Mane 5 suggest that Hev b 5 might act as primary sensitizer and could therefore lead to allergic manifestations upon cassava consumption without prior exposition (Santos et al., 2013). Thus, cassava can be added to of fruits and vegetables to which latex allergy positive subjects potentially cross-react (OECD, 2009).

OBJECTION

The cultivars to be field-tested (TMS 91/02324) averages up to 110 mg HCN eq Kg-1 and therefore its roots are classified as "slightly bitter" and high in HCN. The HCN of the cultivars to be field-tested (TMS 91/02324) exceeds the upper limit threshold and may be very unsafe for human consumption.

In Nigeria, between the years 2016-2017 alone, reported mortality (death) after a meal of poisonous cassava has been relatively high. All such deaths are due to intolerable levels of HCN.

The possibility that cassava plant from the experimental field trail will be consumed is very high.It will be almost impossible to rule out surreptitious acquisition of the stem-cutting and the likelihood of unlawful harvest by locals who had always accessed improved cassava varieties from NRCRI, Umudike the CFT site.

This is a serious concern as the transgenic cassava has not been evaluated for allergenicity.

2.2 Modified Plant Information

Query/Applicant Response

Describe the Intended Phenotypic Changes to the Plant

The cassava events described herein are intended to express elevated levels of iron and zinc in the storage roots and to exhibit resistance to cassava brown streak disease (CBSD) caused by cassava brown streak virus (CBSV) and Uganda Cassava brown streak virus (UCBSV). Apart from the aforementioned micronutrient enhancement traits and disease resistance, there are no other intended changes to the plant

OBJECTION

The candidate GMO cassava is a transgene (adopted modification technologyis undeclared).

All commonly used genetic transformation systems in cassava rely on the induction of somatic embryogenesis (Beyene et al., 2016).

Lately,Friable embryogenic callus (FEC) - based methods are the most commonly employed to produce transgenic cassava plants (Chauhan et al., 2015).

The culture of rapidly dividing, highly disorganized callus tissues, such as the FEC used in cassava transformation systems, is known to induce changes at the genetic and epigenetic levels (Kaeppleret al., 2000; Ma et al., 2015; Miguel and Marum, 2011).

Obviously there will be significant alteration and /or loss of nutrient following this modification but this application have not substantiated anything to the contrary.
The claim is very superfluous and misleading and the application should be rejected.

Query/Applicant ResponseIntended

Reproductive Effects:

The genetic modifications resulting in the cassava events described herein [Tables 2, 4, 8, 6] (-provided by the applicant) were not intended to alter the reproductive or survival biology of cassava. The standard conditions for ensuring reproductive isolation of cassava apply to all genetically modified cassava proposed for evaluation in the CFT.

OBJECTION

Tables 2,4,8,6 not available for review

All commonly used genetic transformation systems in cassava rely on the induction of somatic embryogenesis (Beyeneet al., 2016).

Such modification which results in changes at the genetic and epigenetic levels (Kaeppleret al., 2000; Ma et al., 2015; Miguel and Marum, 2011).

Regenerated plants and their progenies are expected to be identical clones, but often display heritable molecular and phenotypic variation. This will doubtlessly impair and grossly alters the plant biology.

Also, no data to the contrary was provided by the applicant. In the circumstance therefore, the unexpected outcome of transgene modification of the cultivars remain unknown and worrisome. This CFT may after all not worth the troubles.

Query/Applicant Response

What is the source of the genetic material? Is the source of the genetic material likely to affect the safe conduct of a confined field trial? If yes, how?

The following donor organisms were used as a source of introduced genes or siRNA sequences:

Plant Viruses: Two viruses known to cause CBSD, CBSV UCBSV, were used as the source of sequences derived from the respective coat protein (CP) coding regions. Both CBSV and UCBSV are (+) sense, single-stranded, RNA viruses belonging to the genus Ipomovirus in the family Potyviridae Potyviruses, and indeed a great many plant viruses, are common constituents in food and feed, and to date there are no examples of plant viruses known to be pathogenic to animals or humans (Mandal and Jain, 2010). The CBSV-CP and UCBSV-CP derived sequences were introduced as an inverted repeat fused tandem, separated by the pyruvate orhtophospahtediknase (PDK) intro-3 and do not result in the expression of any new proteins.

Escherichia coli: E.coli (formerly Enterobacteriaceae) strain K1, a non-pathogenic strain, was the source of the neomycin phosphotransferase II (NPTII) encoding nptii gene (Beck et al., 1982) and is gram negative, motile, facultatively anaerobic rod-shaped bacterium. E.coli is a normal inhabitant of the intestinal flora of humans and animals, where it generally does not cause disease.

Arabidopsis thaliana: The thale cress (A. thaliana) was the source of the iron-regulated transporter (IRT) and ferritin encoding genes introduced into the cassava events listed in Table 6. Arabidosis is a small flowering plant native of Eurasia and Africa, and is a popular model organism in plant biology and genetics. Arabidopsis thaliana, is ubiquitous in the environment and is not commonly known for human and animal pathogenicity or allergenicity.

None of the donor organisms used as sources of introduced genes or siRNA sequences will affect the safe conduct of the CFT.

OBJECTION

No molecular information is provided by the applicant. Has the applicant checked to see if the introduced genes or sequences are as they say?Have there been unintended effects?

The dogmatic concept that plant viruses are safe to human health has been re-evaluated (Mandal and Jain, 2010), and is untrue.
A case-control study, provide evidence that plant viruses may cause disease in humans. Abdominal pain, diverticulosis or diverticulitis, and fever were significantly associated with the presence of some viral RNAs (Colson et al., 2010).
Some group of plant viruses have potential for host-switching to humans or higher animals ((Mandal and Jain, 2010).
The claim that E.coli is a normal inhabitant of the intestinal flora of humans and animals generally,and does not cause disease is untrue.

Diarrhoeagenic E.coli(examples; EHEC/VTEC, ETEC etc)cause many types of diseases and debilitations in humans and animals and non-pathogenic E.colisuch as used in this genetic modification has been incriminated in mutation-derived antimicrobial resistance (Arunasri et al.,2013; Madhan et al., 2019).

The use of Arabidopsis thaliana,a weed, as a source of nutritionally important genes for improvement of staple food crops call for scrutiny. Not being an edible plant, the release of genetically modified cassava plants containing a gene isolated from a non-edible plant Arabidopsis thalianaand inserted into cassava mayoccasionallergic reaction in humans.

Limiting the safe conduct of confined filed trails exclusively on the source of the transgenic material is unrealistic and scientifically unsound.

Query/Applicant Response

Changes in Toxicity or Plant Composition:

The genetic modifications resulting in cassava events listed in Tables 2, 4, and 6 (Annexes 1, 2, and 3, respectively) were not intended to result in any changes to the potential toxicity or allergenicity of cassava. Cassava produced using transformation plasmids p9001 (Annex 1, Table 2) and p8023 (Annex 3, Table 6) were intended to express a change in micronutrient composition, namely elevated concentrations of Iron and Zinc in the storage roots.

There are no expected changes in toxicity or allergenicity of transgenic cassava clones.

OBJECTION

Tables 2, 4,and 6; Annex 1, Table 2 and p8023 Described in Annex 3, Table 6 are not available for review.

An important dimension of the candidate GM cassava pertains to nutritional enhancement (biofortification) to express elevated levels of Iron and Zinc in the storage roots. The dearth of literature that critically addresses the biosafety and the socio-economic aspects relevant to the biofortification of indigenous cassava cultivars through GE, to improve nutrition for poor people and nutrient deficient populations, is of grave concern, and calls for extreme caution (ACBIO, 2016).

There is no data on outcomes and experience with the proposed transgenic cassava candidate. Crucially, the claim by the applicant that "There are no expected changes in toxicity or allergenicity of transgenic cassava clones" lacks credibility and is quite deceptive.

There isalso no data on impacts on non-target organisms. This is a field trial where there will be exposure of insects, animals etc. to the cassava – any tests done to look at this? Did the applicant do any feeding trials with the whole food?

The form of Iron introduced by biofortification;- transformed plasmids (plasmids p9001 and p8023); foods (cassava) with added Iron may taste metallic, turn brown, or spoil faster(IFIC, 2014).

Plants, including cassava, face challenges in maintaining homeostasis of these two metals - Iron and Zinc, as they may generate highly reactive hydroxyl radicals. The hydroxyl radicals can harm most cell parts, for example, DNA, proteins, lipids and sugars (Alagarasanet al., 2017).

GM crops will not address these multiple nutritional challenges/nutritional deficiencies including zinc, vitamin C and D, folate, riboflavin, selenium and calcium (ACBIO, 2016).

In 2011, HarvestPLus said that "by the middle of 2014, more than 150 000 households in Nigeria are expected to be eating vitamin A fortified yellow cassava" (IITA, 2011). We are all aware that there is no such GM biofortified cassava in sight.

NBMA, shouldnote the fate of the popular Golden rice, which wasgenetically modified to achieve biofortification supposedly tocombat vitamin A deficiency considered a pandemic in South and South-East Asian countriesand Africa.Interestingly, more than twenty years after (1996-2018), the FDA has eventually affirmed that the Golden rice offers No Nutritional Benefits (U.S FDA, 2018 A and B).

Query/Applicant Response

Describe the features of the Genetic Construct

Maps of the transformation plasmids, including the tables describing the genetic elements contained within each respective plasmid T-DNA region, are provided in Annexes 1, 2 and 3 for plasmid 9001, p5001, and p8023, respectively.

Plasmid p9001: Agrobacterium –mediated transformation (Taylor et al., 2012; Chauhan et al., 2015) using plasmid p9001 (Annex1; Figure 1 and Table 1) was used to produce cassava events (Table 2) expressing resistance to CBSD and elevated levels of iron and zinc.

Plasmid p5001: The cassava events listed in Table 4 were produced via Agrobacterium –mediated transformation using plasmid p5001 (Annex 2; Figure 2 and Table 3) to express resistance to CBSD.

Plasmid p8023: Cassava events expressing elevated levels of iron and zinc(Table 6) were produced viaAgrobacterium–mediated transformation using plasmid p8023 (Annex 3; Figure 3 and Table 5).

OBJECTION

Is genome editing a valid alternative to transgenesis to develop the long-awaited, biotechnology-derived, non-GM products in cassava? NO

Agrobacterium-mediated plant transformation is a highly complex and evolved process involving genetic determinants of both the bacterium and the host plant cell. There still remain, however, many challenges such as predictable and stable expression of transgenes (Gelvin, 2003).

It should be noted that the transgenic plasmid, p5001 has been reported to exhibit varying expressions, likely due to T-DNA integration position effects, common for Agrobacterium-mediated plant transformation that affects transgene expression through epigenetic mechanisms such as DNA methylation (Kohli et al., 2010).

The cassava events were said to have been produced via Agrobacterium-mediated transformation of friable embryogenic callus (FEC), regeneration of transgenic Plasmid p5001.

The production of transgenic cassava plants through friable embryogenic callus (FEC) are known to result in loss of the most important trait for Africa and Asia: resistance to CMD (Chavarriaga-Aguirre et a., 2016).
Cassava engineered to retain more Iron and Zinc, faces challenges before moving into fields and onto forks (Ghislain, Muzhingi and Low, 2019).
Over-abundance of Zn and Fe might cause significant toxicity to some biological systems (Pahlsson, 1989; Price and Hendry, 1991).

Genetic engineering of mineral content in staple crops is challenging and has the inherent drawback of over-expression of multiple genes (De Steuret al., 2015).

Over-expression of the Arabidopsis thaliana Iron transporter in cassava accumulated three- to seven-times-higher levels of Iron in transgenic storage roots than in non-transgenics in confined field trials (Narayanan et al., 2019). Plants engineered to co-express a mutated A. thaliana Iron transporter (IRT1) and A. thaliana ferritin (FER1) accumulated Iron levels 7-18 times higher and Zinc levels 3-10 times higher than those in non-transgenics in the field (Narayanan et al., 2019).

However, over-expression of Iron-specific, assimilatory gene, has been associated with altered expression of multiple genes involved in Iron homeostasis in a variety of tissues consistent with increased Iron sink strength in transgenic roots (Ihemere, Narayanan, and Sayre, (2012).

Plants including cassava, face challenges in maintaining homeostasis of these two metals - Iron and Zinc, as they may generate highly reactive hydroxyl radicals. The hydroxyl radicals can harm most cell parts, for example, DNA, proteins, lipids and sugars (Alagarasanet al., 2017).

The designers of this construct failed to take into consideration the gene-environment interaction (GEI) which underlines individual response to dietary Iron.Put another way, genetic variation produces observable phenotypic differences under specific conditions (Miranda and Lawson, 2018)
Recently, gene-editing technology to create virus-resistant cassava plants have had serious negative ramifications. The new gene-editing technology designed to cut the DNA of the mosaic virus and make the cassava plants resistant to its damaging effects turned out to be of a huge opposite disaster, resulting in the propagation of mutated viruses (Mehta et al., 2019).

The priority, rather, is the standardization of biotechnology methods applicable to several cassava varieties that guarantee the maintenance of the genotype and production of non-transgenic varieties.

The stability of the traits involved, as well as the potential for gene flow, and the risks posed by this GM cassava to farmers, consumers, the economy, and environment remain unknown.

3. Trial Description

This section describes the purpose of the field trial, experimental designs and data to be collected, including anticipated pesticides use. Include a description of the habitat at the site, and any organisms of conversation concern that may be in the general area.

Query/Applicant ResponseTrial Description:

The purpose of the field trial is to evaluate the performance of transgenic cassava event modified for CBSD resistance and for elevated levels of iron and zinc under field conditions in Nigeria. Tissue culture plantlets will be received from the Donald Danforth Plant Science Centre, St louis Missouri USA through the courier company FeDEX. They will be hardened and then multiplied using the semi autotrophic Hyroponic (SAH) technology in place at NRCRI. This entails the transfer of in vitro derived plantlets into artificial substrate (Klassman) supplemented with solution of Macro and Micro nutrients for a period of 3-4weeks in a controlled growth chamber. Plantlets will be multipliedat 3weeks intervals for a period of 3months and acclimatise for 1 week at the biosafety level II screen house before transplanting to the field.

The trial will be conducted within a secured site in 200x 200m (2 hectare) area enclosed by a 2m high chain-linked fence and 1.5m high block fence inside with a locked gate and 24/7 guard. The trial site is a sandy-loamy soil that has been left to fallow for a period of 1 year. Pre-emergence herbicide (Primextra Gold) at a concentration of 200mg/20l will be applied to the site after land preparation prior to field establishment.

Transgenic cassava events produced using three different transformation plasmids, p9001 (Annex 1, Table 2, 15 events), p5001 (Annex 2, Table 4, 12 events), and p8023 (Annex 3, Table 6, 10 events), and their modified parental cultivar will be evaluated. The trail design will be a randomized complete block design (RCBD) replicated three times. Each block (rep) will comprise 17 test plants for p9001, 13 test plants for p5001 and 12 test plants for p8023 in a single row of 10. Plant spacing will be1m between rows and 1mwithin rows, the entire experiment of the transgenic plant is expected to cover an area of 7025m2 (See Scheme in Annex 4). The non-transgenic controls will be imported alongside the transgenic counterparts and will be multiplied and hardened (using SAH technology) in the PC.II at NRCRI,Umudikebefore transportation to the field. TME 117 (CMD susceptible) will be used as border rows. The trial will be managed agronomically including the application of basic fertilizer (NPK15; 15:15) at the ratio of 600kg/ha with regular manual weeding to eradicate weeds. Post emergency herbicide (Touchdown Forte) at a concentration of 150mg/20l will be applied at the border for weed control.

Data will be collected during the growing season and at harvest. During the growing season the following data will be collected:

1. CMD symptoms scoring
2. Whitefly population scoring
3. Plant height
4. Height at first branching
5. Level of branching
6. Days of first appearance of flowers
7. Plant architecture
8. Overall vigor
9. Scores for cassava bacterial blight, cassava anthracnose and cassava green mite, leaf material will be sampled during data collection.

At harvest, approximately 12 months after planting, the following data will be collected:

1. CMD symptoms scoring
2. Fresh root yield
3. Dry matter content
4. Foliage weight
5. Harvest index
6. Cyanogenic potentials
7. Number of roots

Leaf and root material will be sampled at harvest.

OBJECTION

No Annexes or Tables referred were available for review.

The fact that both the tissue culture plantlets and the non-transgenic controls will be imported is one reason we object to this application. NRCRI lacks indigenous capacity for design, transgenic construct and development. Nigeria is ill prepared for this destructive experimentation with our staple crop.

Why won't their foreign collaborators conduct the CFT in the USA? Why forcibly impose the CFT on Nigerians?
The risk management practices that are proposed by the applicant are not sufficient and lacking in details. Inadvertently, the applicant's field trial design only assess agronomic properties like yield, fruit/root quality and disease susceptibility.

The experiment design provides no details on how all the anticipated cassava diseases will be diagnosed either on the field or in the laboratory. Meaning that many of the findings may be by subjective deductions and not scientifically.

The experimental design is devoid of any parameter / variables that will measure the anticipated impact of the herbicides (Primextra Gold and Touchdown Forte) to be used, and /or its event outcomes on organisms (including microorganisms) and biodiversity. Although the agronomic data may reveal some potential environmental harm, informal observations are likely to miss many potential environmental impacts.

The application is lacking in the standard operating of procedures (SOP) / protocols for collecting environmental impact data from the field trials. Obviously, the CFT'simpacts on non-target organismswould not be evaluated and measured.

Above all, since the field had been fallow for 1 year (which is inadequate), are there no known organisms of conservation concern at the test site? The applicant didn't spare any thought for biodiversity. The study design is carelessly done, very undesirable and unethical.

4. General Confinement

This section describes the measures to be taken to ensure confinement of the genetically modified plants and genes it is based on knowledge of the unmodified crop and the intended genetic modification.y thought for biodiversity. The study design is carelessly done, very undesirable and unethical.

Query/Applicant Response

The trail site is located at the NRCRI headquarters station,about 8km from Umuahia, Capital of Abia State in South –Eastern Nigeria. A spatial distance of 100m will be maintained between the CFT site and any plant capable of hybridizing with cassava. See Annex 4 for 3schematic representation of the site showing location of the trial and surrounding.

OBJECTION

No Annex 4 for schematic representation available for review.

There is the possible threat of contamination that comes because cassava is anallogamous plant, which means there is 100% chance of out-crossing. Insects pollinate cassava.

This transgenic GM cassava will therefore contaminate farmers' varieties and/or other varieties cultivated for other purposes such as animal feed in Umuahia.

As was the case withBt cassava, this transgenic cassava willnegatively impacthuman and animal health.

With herbicide use recommended in cassava, there is a big risk of toxins accumulating in the roots. It also deforms the root and reduces itsproductivity

In addition, several cassava cultivars are massively grown in Ibadan, in areas that are very contiguous to the CFT site. Strictly speaking, the isolation distance of 100m will be equivocal.

Query/Applicant Response

Are there wild plant species in the vicinity of the trial site that could be fertilized by pollen from the trail plants, resulting to viable seeds?

There are no plants of wild species near the trial site that could be fertilized by cassava pollen. The only wild Manihot species in Nigeria is M. glaziovii, which is a non-indigenous, ornamental tree species with no weedy characteristics. There are no M. glazioviiplants within at least 100m metres of the trial site. No specimens of M. glazioviiwere found around the site during field testing in the last ten years

OBJECTION

It is admitted by the applicant that the wild species of cassava, M. glazioviidoexist. The same species worldwide is still being used successfully in breeding program as a source of resistance to cassava mosaic virus, which is a notable challenge to cassava production unlike PPD. It is questionable that a National Root crop Research Centre claims that no specimens of M. glaziovii were found around their centre (site during field testing) in the last ten years.

Beyond the NRCRI collection, the M. glazioviiis known to have escaped and grows wildly in Nigeria. Undoubtedly, this CFT at NRCRI, will contaminate this all-important wild cassava germplasm.

Query/Applicant Response

Describe mechanisms in place to prevent pollen-mediated gene flow from the plants in the trial site;
[Genetic confinement or reproductive isolation measures are based on the biology of the unmodified plant and the introduced genetic modification, and include isolation distance and/or other measures as justified by the reproductive biology of the unmodified plants, and any intended effects of the introduced traits on their reproductive biology.]

An isolation distance of at least 100m will be maintained, between the CFT site and any other sexually compactible species in accordance with the standard for separation used in cassava breeding program (Kawano et al., 1978). This isolation distance is calculated staring form the outermost border row. The isolation zone will bemonitored once per month during the growing season andany prohibited plant found will be removed by rogueing prior to flowering.

The experimental plant will be surrounded by 2 meter wide set of guard rows inside the fence area. The two outermost guard rows will be wild type (TME 117) cassava plant that will be treated as pollen trap row. All these cassava guard row will be destroyed with the test plants at the end of the field test.

OBJECTION

The separation / isolation distance of 100m prescribed by Kawano et al 1978 as buffer zone for GM cassava field trials need scientific interrogation. Having been earlier prescribed for a non-GM cassava breeding, it requires validation before it can be unilaterally considered a standard for GM cassava CFT.

Flood and pollinators such as honeybees (Apis mellifera) will most likely cause adventitious contamination. Again, the honeybees (Apis mellifera) population in this region may suffer some sort of adversity as a result the undue exposure to this novel transgene.

Query/Applicant Response

Describe measures in place to control trial plant volunteers after termination of the trial:

[Describe the crops to be allowed following the confined trial, duration of monitoring or volunteers, frequency of monitoring, methods of destruction and disposal of any identified volunteers, and any other measures needed to ensure that the trial plants do not persist on the trial site.]

This application is for CFTs extending over multiple growing seasons at the same trial site. Following completion of the final trial, the trial site will be subject to a 6 month period of post- harvest land use restriction, during which time no other cassava may be planted, and monitored at least monthly for the presence of cassava volunteers, which if found, shall be removed by rouging prior to flowering and destroyed by incineration on the trial site.

OBJECTION

The fallow period is short.There is the possibility of contamination of cassava cultivar in Umuahia, Abia because of this CFT. Insects pollinate cassava; therefore, this GM cassava will contaminate local farmers' varieties or other varieties cultivated for other purposes in the locality.

5. Material Confinement

This section describes the mechanism by which trial personnel will maintain control of the genetically modified plant material, so that it is not mixed with non-modified plant material, does not escape into the environment, and is not eaten by humans or livestock.

Query/Applicant Response Packaging:

[Describe how the genetically modified plant material will be packaged and labelled for transport to the trial site and measures for cleaning and /or disposing of the packaging material. Note that the chain of custody documentation is required for all genetically modified material being transported.]

The experimental plant will be imported from St. Louis Missouri, USA with individual plantlets contained in a 50ml clear plastic sealed tubes encased in Styrofoam packaging. The styrofoam packing will be enclosed in plastic bags and placed in sealed carton boxes. The labels on the plastic bags will be clearly written to match the description inside. The consignment will be carried by the commercial courier Fedex from the United States to NRCRI Umudike accompanied by the requisite phytosanitary documentation and received at NRCRI PCL II facilities by NRCRI Principal investigators and the NRCRI Institutional Biosafety Committee (IBC). The consignment will be inspected by NBMA personnel and Nigerian Agricultural Quarantine Service inspector. Following inspection, the materials will be placed into temporary storage for 2 weeks in a growth chamber for recovery from the stress and then hardened and multiplied using SAH technology at the weaning chambers of the level II biosafety screen house. After, 3 months of multiplication and hardening, plantlets will be moved out of the weaning chamber into the level II biosafety screen house within the same confinement of 1 week, before transplanting to the field. Packing containers and materials will be disposed of by incineration.

All records , including the import permit , record of shipment, and records of inspection, will be maintained in the compliance document Binder at NRCRI, with copies transmitted to the DDPSC for archival.

OBJECTION

The procedure stated for the packaging and labelling for transport of the experimental plant to the trial site are not referenced to any standard biosafety protocol.

Article 18.3 (c) of the Cartagena Protocol on Biosafety says:
Each Party shall take measures to require that documentation accompanying:Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.
This is the international minimum standard that must be followed.

Query/Applicant Response

Harvesting, Transport and Storage:
[Describe how the plant material will be harvested, including plans for any material to be retained, and how that material will be stored and/or transported.]

Cassava leaves and storage roots will be harvested approximately 12 months after planting (12MAP) and samples collected for shipment to the Danforth Plant Science for related trait analysis using established protocols. Shipment and approval will be obtained from the biosafety regulators before shipment.

OBJECTION

The lack of capacity and competencies by the NRCRI for the Post-harvest analysis of the CFT product and outcome is of grave concern, particularly as the finding will be rechannelled back to Nigeria which has become a dumping ground.

Full disclosure is required for "analysis using established protocols" in public interest.

No SOPs for retention and shipping.

No protocol for occurrence of non-compliance

Also, the applicant failed to state any reference for the standards that all the protocols for the CFT are in conformity to.

Query/Applicant Response

Disposal and Clean-up:
[Describe how surplus planting material will be disposed of at the trial site, how any equipment used during planting or other farm operations will be cleaned, and how harvested materials and crop residues will be disposed.]

Back-up planting material will be retained within the biosafety level II screen house at the NRCRI PCL II in Umudike for replacement of plants that failed to establish in the field to ensure replicate number are maintained for proper field experimentation.

All plant material will be harvested by hand. Cassava stems of non-transgenic and transgenic plants will be collected and used for the establishment of yield selection and agronomic trials. All plant materials will be excavated, chopped up and sun dried for 2 weeks prior toincineration in existing pit within the fenced CFT site at NRCRI prepared for this purpose. All disposals of material will be recorded in the compliance document Binder and tools used in harvesting will be washed, verified free of any plant material and stored at the trail site.

Surplus planting material will be retained with the BL2 screen house at IITA headquarters, Ibadan. These plants will be a source of replacement of plants in case of failure of plant establishment in the CFT at IITA thereby ensuring proper field experimentation.

All plant material will be harvested by hand. Cassava sticks of wild –type and transgenic plants will be collected for analysis and replanted in the field. Once plant sampling is completed and data collected, all plants will be dug up, chopped up and allowed to air dry in the sun for 2-3days after which they will be destroyed by incineration in the existing pit, within the fenced CFT site at IITA, prepared for this purpose. Disposal of all materials will be recorded in the compliance binder. All tools used in the harvest will be washed, cleaned and stored at the trial site itself.

OBJECTION

The period planned for all plants to be dug up, chopped up and allowed to air dry in the sun presents an opportunity for rodents to invade the CFT site and feed freely on the trial materials. The application did not provide for infrastructure /facility for deterrence of rodents which abound in the locality for the CFT.

Surely, escape of the genetic material into animals (especially through rodent) and food chain cannot be AVOIDED. The application should be declined.

Washing and cleaning as proposed by the applicant is an inadequate treatment for tools contaminated with DNA / genetic materials/biologicals.

There is no treatment protocol for residual plant material recovered during the process of cleaning field tools on CFT site.
Acceptable methods of cleaning are not outlined.

Steps for trial personnel verification to ascertain that tools are free of preparative plant material and propagative plant material are not outlined.

Query/Applicant Response

Site Security:

[Describe measures in place to ensure security of the trail site to prevent incursion by humans or animals. Measures may include fencing, security patrols, lockable gates, etc…]

The CFT site is surrounded by two meter high chain-linked fence topped with barbed wire, 1.5m high block wall and a locked gate to prevent unauthorized access by people and animals (See Annex 5). A wire mesh at the base of the chain linkfence (1m subterranean and 1 m above the ground is meant to prevent rodent incursion. The guard house is made available at the gate to ensure 24- hour security at the site. Only personnel and visitors authorized by the IBC are allowed to the trail site and log book will be maintained to keep a record of the names, purpose, dates and time of all entries to the site.

OBJECTION

The chain-like fencing cannot prevent incursion by animals. Intrusion of the CFT site by animals especially rodents which usually feed on cassava is a compromise of both the ecosystems and biodiversity.

This application did not propose pre-trial sites inspection by Biosafety inspectors or other regulatory agents for compliance with this provision site security to prevent incursion by humans, animals, or insects.

6. Records, Personnel, and Planning

Query/Applicant Response

Records and Documentation:
[Describe measure in place to ensure adequate documentation of all confinement measures and data requirements as described herein.]

All records will be placed in a Compliance Document Binder
Maintained at the CFT site and will be available at all times for review by inspectors designated by the NBMA. Duplicate copies of all records shall also be transferred to the DDPSC for archival.

The compliance forms to be completed and maintained will include:

Record of shipment and receipt: To document movement of regulated plant material to the NRCRI containment facility from Danforth Plant Science centre, USA, and to the NRCRI CFT site from the NRCRI PCL II facility. This form is also used to document the movement of harvested plant material from the trail site to NRCRI PCL II facility after harvest.

Record of planting; To document the exact number of transgenic cassava plants of each modified line planted in soil in the CFT site, the exact number and purpose of any plants not planted but retained and the sterilization and/or destruction of any shipping containers.

Record of current season monitoring: To document the monthly monitoring of the 100 m isolation distance as well as to document the devitalization of any prohibited plant found to be within the isolation area.

Fertilizer, pesticide and insecticide usage form, To document all fertilizer, pesticide, and insecticide application during and after the CFT.
Record of Corrective Action: In case of any breach of reproductive isolation, NRCRI IBC and the NBMA will be immediately notified by phone of the incident and record of corrective action will be completed.

Record of Harvest / Destruction: To document the harvest and /or destruction of test plant and spreader rows.
Record of Post-Harvest monitoring: To document the monthly post-harvest inspection of the post-harvest site for living Cassava plants and destruction of volunteers.

The data forms to be completed will include:

Record of Plants in the screen house form: To document and monitor the general health of the plantlets during the hardening period.

CMD Bi-weekly Rating form: CMD will be scored (1-5scale) on each of the individual plant within the plot on a weekly basis, starting one month after planting for the first 6 months, and then on a bi-weekly basis after that.

Whitefly Bi-weekly Rating Form: Whitefly population will be quantified on each of the individual plant within the plot on a weekly basis starting one month after planting for the first 6 months, and the on bi-weekly basis after that.

Monthly Plot Observation form: For each plot, data will be recorded on plant height, branching, and severity of cassava bacteria blight, anthracnose, infestation by green mites, whiteflies and mealybugs, as well as any general comments.

Meteorological Data form: Rainfall, relative humidity and temperature will be recorded daily.

OBJECTION

We have major worries and foresee hindrances on the execution of these rigorous records and documentation requirement which is key to quality management and compliances to standard biosafety protocols.

Query/Applicant Response

Personnel:

[Describe measures in place to ensure that trial personnel will have appropriate education, experience and training to adequately perform assigned duties for confinement and technical requirements of the trail.]

Scientists and Technical staff at NRCRI have carried out several CFTs of transgenic cassava Since 2010. They have also acquired relevant skill through training in biosafety and biotechnology required for the study. The present CFT builds on the expertise acquired at the NRCRI since 2010. Prior to planting, all involved personnel will receive update training in CFT compliance management.

OBJECTION

This application does not indicate the trial personnel.

Query/Applicant Response

Contingency Plans:

[Describe planned response to the loss of control or accidental release of genetically modified plant material, including notification of authorities and the permit holder, recovery and disposal of plant material, and any other measures to be taken to mitigate any potential adverse effects.]

In the highly unlikely event of an accidental release of genetically modified plant material, the NRCRI IBC and the NBMA officials will be notified immediately by telephone and in writing within 24 hours. The accidental release of GM plant material shall be immediately documented in a record of Corrective Action. The trail manager shall retain the original record in the Compliance Document Binder, and copies shall be immediately submitted by facsimile to the IBC and the NBMA.

If an accidental release affects an area outside the perimeter of the trail site, that location shall be marked, monitored and shall be treated in the same manner as the trial site with respect to ensuring that no additional release of material occurs.
Consultation with the NBMA will determine the period of monitoring required and the most appropriate course of action to mitigate any spread of GM plant material following accidental release.

In the unlikely event of unauthorized access to the trail site or a natural disaster that affects the integrity of the CFT, the NBMA shall be notified and any remedial action shall be determined in consultation with the NBMA.

OBJECTION

It is stated by the applicant that "Biosafety Inspectors will accompany the material during each stage of transport". This may not be realistic as it is foreseen that some sections of the transportation of the CFT plant material will be contracted to courier company ant the Biosafety Inspectors may not accompany it at such times.

An element of falsehood noticed in the applicant's response: - facsimile to the IBC and the NBMA. No facsimile services in Nigeria presently.

The application did notstate anticipated threats or potential harmful unintended effects which are specific to the gene, crop and site of growth of any transformation event. Expectedly, the event transgene gene used on TMS 98/0505 and TMS 91/02324 should have some pathological or ecological impact different from those of the cassava cultivar currently grown and consumed in Nigeria.

There is no officialrisk assessment protocol includedto be conducted on this particular event. In particular, no data is given on environmental assessments relevant to cassava and this particular modified cassava.

5 CONCLUSION

Health of Mother Earth Foundation with support from 44 other civil society organisations hereby state their objection to this application by the National Root Crops Research Institute, Umudike,for confined field trail (CFT) of cassava genetically modified to express elevated levels of Iron and Zinc in the storage roots and high resistance to cassava brown streak disease (CBSD) in Nigeria.

We object to this application mainly on the premisethatthe stability of the traits involved in the modification process is not confirmed, the potential for gene flow to wild varieties of the crop and impact on non-target organisms poses serious threat to biodiversity, and such risks posed by this genetically modified cassava to consumers, farmers, the environment and our economy are not made known.

The National Biosafety Management Agency should note that genetic engineering of mineral content in staple crops poses serious concern and has the inherent disadvantage of over-expression of multiple genes.
We reiterate that genetic modification of our food crops is not the solution to food and agriculture challenges. As has been mentioned, nourishment can best be increasedby encouraging diet diversification through locally available foods.

We recommend that Nigeria shouldfocus on developing and implementing key strategies for food and dietary diversification at the community and household levels. We should invest in research on Agroecology which is an important and viable alternative that addresses the issue of nourishment through rich biodiversity and the diversity of ecosystems; increases productivity; nourishes ecosystems; and improves livelihoods of farmers.

Genetic modification of single crops will not address the multiple nutritional challenges/nutritional deficiencies including Zinc, vitamin C and D, folate, riboflavin, selenium and calcium.We urge NBMA to decline approval for this application as Nigerians have no need for it.

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7. PARTNER ORGANIZATIONS WHO ENDORSED THIS OBJECTION

1. GMO-Free Nigeria Alliance
2. Alliance for Food Sovereignty in Africa (AFSA)
3. Nigerians Against GMOs
4. Friends of the Earth Africa (FoEA)
5. Smallholder Women Farmers Organization of Nigeria (SWOFON)
6. Nigeria Women Farmers Association (NIWAAFA)
7. Women in Agriculture
8. Association of Small Scale Agro Producers In Nigeria (ASSAPIN)
9. Cassava Growers Association
10. Civil Society Coalition for Poverty Eradication (CISCOPE)
11. Bio Integrity and Natural Foods Awareness
12. Health Promotion Education and Community Development Initiative (HPECDI)
13. IdamaCoorperative Farm
14. Green Alliance of Nigeria
15. International Climate Change Development Initiative (ICCDI)
16. Community Development Advocacy Foundation (CODAF)
17. Women& Children Life Advancement initiative
18. Women Initiative on Climate Change
19. Rural Alliance for Green Environment (RAGE)
20. Community Forest Watch Nigeria
21. Kebetkache Women Development and Resource Centre
22. Initiative for Peace, Empowerment and Tolerance
23. The Young Environmentalist Network (TYEN)
24. Peace Point Action
25. Policy Alert
26. Centre for Research in Environmental Resource Management (CREMA)
27. Committee on Vital Environmental Resources (COVER)
28. Climate Change and Amelioration Initiative (ECCAI)
29. Gender and Environmental Risk Reduction Initiative (GERI)
30. Pearls Care Initiative (PCI)
31. Gender and Community Empowerment Initiative (GECOME)
32. Good Health Living and Environmental Foundation
33. Initiative for Peace, Environment and Tolerance
34. Eco Defenders Network
35. Urban-Rural Environmental Defenders (U-RED)
36. Climate Transformation and Energy Remediation Society (CLIMATERS)
37. Civil Society Legislative Advocacy Centre (CISLAC)
38. Integrity Conscience Initiative (ICI)
39. SPEAK Nigeria
40. Community Environmental-Watch Committee
41. Youths and Small Holder Farmers (YOSHOFA)
42. Population and Environmental monitoring International
43. EcoActors
44. Eco Assurance and Rural Transformation Center

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