Objection to Application for Confined Field Testing of AMY3 RNAi Transgenic Lines (transgenic Cassava Clones) by International Institute for Tropical Agriculture (IITA) and ETHZ Biotechnology Lab in Zurich

Submitted to National Biosafety Management Agency (NBMA)
By Health of Mother Earth Foundation(HOMEF)

August 2017

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Partner organisations supporting this objection

This memorandum is supported by the following organizations:

1. All Nigeria Consumers Movement Union (ANCOMU)
2. Committee on Vital Environmental Resources (COVER)
3. Community Research and Development Centre (CRDC)
4. Ijaw Mothers of Warri
5. Host Communities Network of Nigeria (HoCoN)
6. OilWatch Nigeria
7. Green Alliance, Nigeria (GAN)
8. African Centre for Leadership, Strategy & Development
9. Institute of Human Rights and Humanitarian Law (IHRHL)
10. Women Environmental Programme (WEP)
11. Persons with Disabilities Action Network (PEDANET)
12. Students Environmental Assembly of Nigeria (SEAN)
13. Centre for Environment, Human Rights and Development (CEHRD)
14. Ogoni Solidarity Forum (OSF)
15. KebetKache Women Development and Resource Centre
16. Federation of Urban Poor (FEDUP)
17. Community Forest Watch (CFW)
18. The Young Environmentalist Network (TYEN)
19. Women' s Rights to Education Program (WREP)
20. Community Action for Public Action (CAPA)
21. Peoples Advancement Centre (ADC) Bori
22. Social Action
23. SPEAK Nigeria
24. Urban Rural Environmental Defenders (U-RED)
25. Gender and Environmental Risk Reduction Initiative (GERI)
26. Women' s Right to Education Programme (WREP)
27. Foundation for Rural/Urban Integration (FRUIT)
28. Community Action for Popular Participation
29. Torjir-Agber Foundation (TAF)
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31. Jireh Doo foundation
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33. Initiative for empowerment for Vulnerable (IEV)
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35. Kwaswdoo Foundation Initiative (KFI)
36. Environment and Climate Change Amelioration Initiative (ECCAI)
37. Manna Love and care Foundation (MLC)
38. Okaha Women and children development Organisation (OWCDO)
39. JODEF-F
40. Glorious Things Ministry (GTM)
41. Daughters of Love Foundation
42. Community Links and Empowerment Initiative (CLHEI)

43. Gender and Environmental Risk Reduction Initiative (GERI)
44. Nigerian Women in Agriculture (NAWIA)
45. Osa foundation
46. Initiative for Improved Health and Wealth Creation (IIHWC)
47. Peace Health Care Initiative (PHCI)
48. Ochilla Daughters Foundation (ODF)
49. African Health Project (AHP)
50. Artists in Development
51. Ramberg Child Survival Initiative (RACSI)
52. Global Health and Development initiative
53. First Step Initiative (FIP)
54. Ruhujukan Environment Development Initiative (REDI)
55. The Centre for Environment, Human Rights and Development (CEHRD), Nigeria
56. Centre for Children' s Health Education, Orientation and Protection (CEEHOPE)
57. Next Generation Youth Initiative (NGI)
58. AIRGO
59. Rural Action for Green Environment (RAGE)
60. United Action for Democracy
61. Campaign for Democracy
62. Yasuni Association
63. Egi Joint Action Congress
64. Green Concern for Development (Greencode)
65. Kebetkache Women Development & Resource Centre
66. Kebetkache Ahoada Women Farmers Cooperative
67. Ahoada Uzutam Women Farmers Cooperative
68. Ogboaku Ahoada Farmers Cooperative
69. Gbobia Feefeelo Women
70. Ovelle Nyakovia Women Cooperative
71. Rumuekpe Women Prayer Warriors
72. League of Queens
73. Emem Iban Oku Iboku
74. Uchio Mpani Ibeno
75. Rural Health and Women Development
76. Women Initiative on Climate Change
77. Peoples' Centre
78. Citizens Trust Advocacy and Development Centre
79. Initiative for Peace, Empowerment and Tolerance
80. Climate Transformation and Energy Remediation Society (CLIMATTERS)
81. Gender and Community Empowerment Initiative (GECOME)
82. Community Links Initiative
83. Pearls Care Initiative (PCI)
84. Angel Support
85. Climate Change and Amelioration Initiative (ECCAI)
86. Consumer Campaign Foundation

1. ABOUT US

Health of Mother Earth foundation (HOMEF) is an environmental/ecological think-tank and advocacy organisation. HOMEF works to bridge the yawning gap between policy/decisions made by governments and the actual needs at the grassroots. HOMEF recognises that policies are often top down and actions based on such can distort the possibilities of meeting actual needs.

We recognise that the global crises the world is experiencing have impacts on our nation and that these manifestations have systemic roots. Pressures on nations manifest in pressures on the environment and the current paradigm of development and growth based on competition will lead to the critical destruction of biodiversity and continued destructive extraction of natural resources, disrespect for Mother Earth as well as dependency on risky technologies.

More about HOMEF at www.homef.org
Contact person: Nnimmo Bassey. nnimmo@homef.org
Telephone: +234 817 370 6095

2. BACKGROUND INFORMATION

Cassava: Major Food Security Crop for Nigerians

Cassava constitutes the staple for millions of our peoples. Nigeria is one of the top producers in the world, followed by Brazil and Thailand[1]. The crop is both versatile and valuable. It also has the ability for high yield and its leaves and tubers (roots) are used for food while the stems are the main planting material. Because of its hardy nature and ability to survive in harsh weather and soil conditions[2]. Because cassava does well even in poor soils, the economic pressure imposed on poor farmers to purchase artificial fertilizer is greatly reduced. Cassava is a major food security crop not just for Nigerians but for Africa and in the past, where grains had failed, local affected people in Angola and Zambia resorted to cassava to fill in the gaps[3].

Research in the genetic manipulation of cassava has been ongoing since the mid 1990s. Some of the objectives of the manipulation concerned the cyanogens content[4], the storage potential, the mosaic virus, and the increase of its yield of starch. Another reason advanced by the proponents is that genetically modified (GM) cassava would "potentially help improve the nourishment of millions[5]"As in other claims of this nature, the potential of GM cassava to be practically more nutritious is highly debatable. Equally, the cyanogens content of cassava was not really the problem because even the "bitterness" of cassava is a form of natural protection against insects, rats, monkeys and the poisonous varieties have the advantage of producing higher yields because they are less susceptible to pests. In addition, suitable processing methods that take care of perceived problems have been traditionally developed already[6]. The proponents of GM cassava must have seen this classic southern crop as a major frontier for the control of the food supply of a vast number of poor countries and as an inroad for the legitimization of biotech crops in such countries.

IITA's massive focus and long quest for the Control of Cassava In Nigeria

In 2004, IITA, the Donald Danforth Plant Science Centre, National Agency for Biotechnology Development Agency and The Nigerian National Root Crops Research Institute of Nigeria applied to the Federal Ministry of Environment, for an application for a "contained" field trial of GM cassava." It was reportedly being processed until early that year when IITA wrote to the Ministry to stop the application because the test (carried out by them in USA) failed to confer resistance against the Cassava Mosaic Disease. In 2006, Friends of the Earth Nigeria wrote to the Federal

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1. *IFAD. A cassava industrial revolution in Nigeria. The potential for a new industrial crop. Rome 2004.* http://www.fao.org/documents/show_cdr.asp?url_file=/docrep/007/y5548e
2. *FAO (2013) Save and Grow: Cassava – A guide to sustainable production and intensification.* http://www.fao.org/3/a-i3278e.pdf
3. *FoEI (2013) Playing With Hunger – the Reality Behind the Shipment of GMOs as Food Aid.* http://www.foei.org/wp-content/uploads/2015/08/playing_with_hunger2.pdf
4. http://researchnews.osu.edu/archive/cassava.htm
5. http://www.fao.org/documents/show_cdr.asp?url_file=/docrep/v4510e/v4510e00.htm , *FAO document about on post storage capacities of cassava.*
6. *Zweifel, H. Cassava: a symbol of controversial approaches to food security*

Minister of Environment for clarification on the status of the applications reportedly received by the ministry for GMO cassava.[7]

On December 14th 2011, IITA announced that it had developed three new varieties of vitamin A cassava that could improve the livelihoods of millions of farmers in Africa and help put an end to malnutrition due to vitamin A deficiency on the continent. Drs. Peter Kulakow and Norbert Maroya, IITA Cassava Breeders, said, "The development of these varieties is a major breakthrough that will change the nutritional status of people living on cassava-based food.[8]" The IITA team said the release of this first set of vitamin A cassava varieties in Nigeria was "a victory for women and children."

We had responded then to IITA to leave this classic Southern Crop alone. We enumerated why we do not need this so called "biofortified"cassava. This is basically a replay of the Golden Rice hoax: The infamous Golden Rice was first developed in 1999, and was offered as the panacea for Vitamin A deficiency (VAD). The transgenic rice however had fundamental problems and to date has not been commercialised. An adult would need to eat up kilogrammes of that rice variety a day for the required intake of vitamin A, whereas eating just a couple of carrots would suffice.

We hereby place on record our objections to the application made by the International Institute for Tropical Agriculture (IITA) and ETHZ Plant Biotechnology Lab Zurich to the Nigerian Biosafety Management Agency (NBMA) for a Confined Field Trial (CFT) to test transgenic cassava events developed by EWTHZ Plant Biotechnology Lab based in Switzerland.

This is an application by the joint collaboration of IITA-ETHZ plant Biotechnology Lab to NBMA for a CFT to test transgenic cassava events developed by ETHZ Plant Biotechnology Lab Zurich. We note that this is the first application for field-testing of the AMY3 RNAi transgenic lines. The Applicant clearly affirmed they have been previously tested only in a screen house at ETH Zurich. NO APPLICATION HAS BEEN PREVIOUSLY MADE FOR THE CFT AND COMMERCIAL RELEASE OF THESE TRANSGENIC CASSAVA CLONES BEFORE IN ANY JURISDICTION.

It is unsettling that an experiment carried in a laboratory in far away Switzerland that has not be tested in any other country is to be carried out here in Nigeria. If this is the first time to test this sort of transgenic cassava, why Nigeria? Why not in Switzerland? We object to foreign laboratories and entities using Nigerians as laboratory rats. Using Nigeria has a testing ground for this technology, and thereby exposing the nation to associated risks, is one of the bases for our objecting to this application.

7.Open Letter dated 24 May 2006

8. IITA (19 December 2011) "IITA-led team develops Vitamin A cassava to tackle malnutrition in Africa." http://www.iita.org/news-item/iita-led-team-develops-vitamin-cassava-tackle-malnutrition-africa/

3. SUMMARY OF CONCERNS

The IITA has been a respected institution in Nigeria and Africa on whom farmers depend for good quality and safe crops. We see their collaboration with the Swiss laboratory to introduce genetically modified cassava into Nigeria as a betrayal of trust and a mortal danger for Nigerian and African food and agricultural systems. This application for a completely needless crop variety modification instructs that Africans should be wary of products and claims from the IITA. We strongly object to this untested GM cassava and if NBMA approves this application, we can as well say good bye to food safety in Nigeria.

Based on previous research and statements by IITA, we believe that the application may actually be aimed at producing the genetically modified cassava for the production of biofuels. We are concerned that this GM variety will inevitably contaminate our cassava species and foods with an admittedly untested technology. Considering our seed and stems planting systems, there is no way our farmers would be stopped from planting the IITA cassava for food.

IITA, Ibadan , in a statement[9] released to the press in December, 2006 unambiguously stated that the ambition by Nigerian Government to achieve 10 percent ethanol for fuel can only be attained when production of cassava grows to about 7 billion kilograms annually, according to their research. IITA, Ibadan which revealed the outcome of the research said then, the 10 percent attainment of ethanol in fuel would require massive production of cassava and sugarcane[10]. How does IITA intend to produce this massive biofuel without taking farmers off the food production line to start producing food for machines? How would this sort of egregious non-food production be carried out without land grabbing and displacement of poor farmers.

On the website of the developer of this cassava technology, Prof Zeeman, we see that he works on starch metabolism and biochemistry which has now been tried with Cassava. We note that this professor usually works with Arabidopsis. See more at http://www.impb.ethz.ch/research/research-pbc/research/research-and-thesis-projects.html. Interestingly, there is no mentioning of this specific project/application of his technology with Cassava on the website of the developer of the technology. From a related website, http://www.impb.ethz.ch/research/reseach-pb/research-pb.html, it is seen that it is another group that typically works on genetically engineered of cassava or all kinds of plants focusing on nutritional compounds such as iron and Vitamin A.

It does appear that the cassava variety being applied to be tested in Nigeria is a continuation of a PhD project under the supervision of Profs Zeeman and Gruissem.[11] Part of that PhD research was to develop first transgenic lines of starch-altered cassava and they did all the work with one line of Cassava they got from IITA (cv60444) which they grew over the years in climate chambers/greenhouses at ETH.

Transferring these products to Nigerian soil and environment is a gamble that highlights the risk of turning Nigeria into the dumping ground of risky, needless and untested technologies.
The presentation of the variety under the narrative of "food" and "hunger alleviation" may well be a means of gaining acceptance though the aim appears to be about "fuel" and industrial global exports is misleading and dangerous.

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9. Muhammed, Hamisu (19 December 2006). Nigeria: Biofuel – Nigeria Needs 7bn KG of Cassava Annually, Daily Trust, http://allafrica.com/stories/200612190564.html
10. Daily Trust: Nigeria: Biofuel - Nigeria Needs 7bn KG of Cassava Annually. http://allafrica.com/stories/200612190564.html
11. https://www.research collection.ethz.ch/bitstream/handle/20.500.11850/154780/eth-46938-02.pdf

While a presentation[12] by one of the professors developing GE cassava at ETH shows work done on GE cassava research within the "food" narrative - what is now submitted to the NBMA is a starch-altered GE cassava solely for "fuel."

Promoting GM crops for biofuels demonstrates the hypocrisy of the biotech giants, who are always quick to summit that GE crops are necessary to produce more food for the growing world population. They make the case that relying only on natural crop varieties would create food deficits and lead to forests being cleared for cultivation, to meet rising food demand. Yet, the same companies think nothing of diverting large areas of arable land for cultivation of crops to develop ethanol for fuel, to feed the voracious machines of the North.

The applicant claims there are "no expected changes in toxicity or allergenicity of transgenic cassava clones," but cites no research to back up the claim. The toxicity or allergenicity or any significant change in composition intended by the genetic modification has to be in relation to something and in this case, it is not clear what the applicant is referring to. Would it be toxicity to humans, animals, the soil or the general environment? This is highly presumptuous as other scientists have said all methods of crop improvement have potential to cause unintended compositional changes.[13] What makes IITA's GM cassava different? We are confounded how claims such as these with no evidence to support them can be 'scientifically' acceptable. But that is very typical and this application is no exception.

The Applicant claims that '...there are no plants of wild species near the confine field that could be fertilized by cassava pollen. The only wild Manihot species in Nigeria is M. glaziovii (Bock 1984)...'

It would be good to produce the environmental impact assessment including baseline surveys to support their claims rather than promote a CFT application to be carried out in 2017 by citing a reference work done in 1984, a whopping 33 years ago! Another archaic citation is Kawano et al of 1978, an embarrassing 39 years old work for an health related scientific work.
These are totally unacceptable and it is alarming that IITA has not done any study on this sensitive subject but is content to present a writing based on obsolete books or rather relying on their partners abroad for information and expertise.

The Applicant said the trial personnel have relevant skills in biotechnology and "will be appropriately trained in biosafety to cope with the requirement of the study." This assertion suggests that IITA does not already have the requisite personnel to handle the biosafety aspect of this application. Again, this shows that Nigerian is chosen as the platform to roll out this risky experiment probably because they believe that any sort of application would be endorsed by the NBMA.The Applicants are testing AMY3 RNAi lines RNAi, a technique that is novel – and although there is no experience with such GE plants in Nigeria as of yet, it is known that there are separate risk issues associated with this technology and only few RNAi based plants have been commercialized - typically in the US in commodity crops that serve primarily as animal feed

12. Wilhelm Gruissem. "Metabolic engineering of carbon pathways to enhance yield of root and tuber crops "CAssava Source-Sink", ETH Z. http://www.gcp21.org/wcrtc/ppt/S17presentation/S17-07.WilhelmGruissem.SIGNED.ID1112.4230.pdf

13. See, for example, Rijssen, Fredrika et a. (2013) ***Food Safety: Importance of Composition for Assessing Genetically Modified Cassava (Manihot esculenta Crantz).*** http://pubs.acs.org/doi/full/10.1021/jf401153x?src=recsys&

GE cassava for biofuel is a very 'northern' idea. It will not work in Nigerian context with little to no oversight over production chains and certainly not for small-scale farmers. It hasn't even worked in industrial countries as all previous dual-use GE crops have utterly failed to this point, with the worst case being with Cry9C maize in the US which was also meant primarily as feed and explicitly NOT as food. Within weeks after the first harvest, even in a country like the US, it was shown to have ended up in all kinds of food products like cornflakes, tacos etc. They took the product off the market within a year but it was still around - and may still be around - for years.[14]

Cassava is almost exclusively a food crop in many communities in Nigeria. We consider it futile to believe that, once released commercially, this would NOT go immediately and straightaway into the food chain. Altered starch composition would make this a very different plant for food purposes. The whole idea of "biofuel cassava" or "herbicide-tolerant cassava" is a classic idea of G20 and AGRA[15] folks pushing for industrial or GMO crops into Nigeria and Africa as a pathway to entering the industrial commodity crop production for export markets. This is the undeclared and "official" narrative of "food" and "hunger alleviation." In the case of this application, Nigerians need to know who is funding this project and the application should unveil the funder(s).

We also note that the applicant's email l.stavvolone@cgiar.org in the application has Consultative Group for International Agricultural Research (CGIAR) and not the IITA. We expect that an applicant from IITA should at least us an IITA email address.
Also the Applicant's Fax number is +44 2087113786, a foreign number and not a Nigerian number. This whole application is neocolonial and unacceptable. It reminds us of the Biblical story of the "the hand of Jacob, but the voice of Esau."

The proposed duration of the trial is 12 Months. The time frame certainly cannot be adequate to carry out this kind of test. It is instructive to note that according to the Applicants that worked on the transgenic lines of the starch-altered cassava they got from IITA (cv60444) at ETH lab in Zurich, the research was to develop first transgenic lines of starch-altered cassava and it took them several years. Let us be reminded they grew these transgenic lines in climate chambers/greenhouses at ETH. Why do the Researchers in Nigeria think they can do this CFT in one year?

There is no clarity about the starting date of this field testing as the applicants wrote: "Expected-starting date: May, 2017." Is it that this application had already commenced before NBMA asked Nigerians to comment and that this exercise is just window dressing? Is the NBMA taking Nigerians for a ride? Could this application simply not have been rejected and shelved and spare Nigerians the time to examine it?

14. Wikipedia. StarLink corn recall. https://en.wikipedia.org/wiki/StarLink_corn_recall
15. Alliance for Green Revolution in Africa

4. SUMMARY OF OBJECTIONS

A summary of our opposition to the field trial of IITA's GM cassava variety:

Section 1: Purpose of application

The use of AMY3 RNAi lines – Whilst RNAi technology has advantages such as conferring resistance to transgenic plants, it has disadvantages which are very worrying. RNAi has 'off-target' effects which can create unintended consequences resulting in unexpected mutant phenotypes. RNAi has several drawbacks including phenotypic instability in later generations. The proposed trial does not include plans to prevent these from happening nor did it highlight solutions if such incidences occur. This is important because this is a field trial. (This section also applies to the intended reproductive effects in section 2.2)

Section 2.2

The purpose of the trial is to reduce starch breakdown in Cassava. The argument for the genetic modification of Cassava has generally been about increasing vitamin content and yield to help the poor people of Africa. We cannot see how preventing starch breakdown does this. Proponents in fact have highlighted that high starch concentration of Cassava is one of the reasons for modification, by addition of vitamins to solve malnutrition. Cassava is an excellent energy source and the aim of this project makes it very difficult to reject the idea that the purpose could possibly be to find a valuable source of renewable bio-energy such as ethanol and biofuels. The project aim is not convincing.

Section 3

Trial description

Use of imidacloprid: Based on its high water solubility (0.5-0.6 g/L) and persistence, both the U.S. Environmental Protection Agency and the Pest Management Regulatory Agency in Canada consider imidacloprid to have a high potential to run off into surface water and to leach into ground water especially in areas where soils are permeable, particularly where the water table is shallow. The application did not include how it proposes to prevent this from occurring and from the image on Annex C, it is clear there is a water body not far from the trial site.

A 2012 water monitoring study by the state of California, performed by collecting agricultural runoff during the growing seasons of 2010 and 2011, found imidacloprid in 89% of samples, with levels ranging from 0.1-3.2 µg/L. 19% of the samples exceeded the EPA threshold for chronic toxicity for aquatic invertebrates of 1.05 µg/L. The authors also point out that Canadian and European guidelines are much lower (0.23 µg/L and 0.067 µg/L, respectively) and were exceeded in 73% and 88% of the samples, respectively. The authors concluded that "imidacloprid commonly moves offsite and contaminates surface waters at concentrations that could harm aquatic invertebrates".

Imidacloprid is listed on EPA's Tier 1 Screening Order for chemicals to be tested under the Endocrine Disruptor Screening Program (EDSP). Dave Goulson[16] of the University of Stirling showed that trivial effects of imidacloprid in lab and greenhouse experiments can translate into large effects in the field. The research found that bees consuming the pesticide suffered an 85% loss in the number of queens their hives produced, and a doubling of the number of bees who failed to return from food foraging trips.

16. https://en.wikipedia.org/wiki/Dave_Goulson

Health impact

Imidacloprid and its nitrosoimine metabolite (WAK 3839) have been well studied in rats, mice and dogs. In mammals, the primary effects following acute high-dose oral exposure to imidacloprid are mortality, transient cholinergic effects (dizziness, apathy, locomotor effects, labored breathing) and transient growth retardation. Exposure to high doses may be associated with degenerative changes in the testes, thymus, bone marrow and pancreas. Cardiovascular and hematological effects have also been observed at higher doses. The primary effects of longer term, lower-dose exposure to imidacloprid are on the liver, thyroid, and body weight (reduction). Low- to mid-dose oral exposures have been associated with reproductive toxicity, developmental retardation and neurobehavioral deficits in rats and rabbits. Imidacloprid is neither carcinogenic in laboratory animals nor mutagenic in standard laboratory assays.

No studies have been published involving human subjects chronically exposed to imidacloprid. Effects of imidacloprid on human health and the environment depend on how much imidacloprid is present and the length and frequency of exposure. Effects also depend on the health of a person and/or certain environmental factors.

A study conducted in tissue culture[17] of neurons[18] harvested from newborn rats showed that Imidacloprid and acetamiprid, another neonicotinoid, excited the neurons in a way similar to nicotine[19], so the effects of neonicotinoids on developing mammalian brains might be similar to the adverse effects of nicotine.

Section 4:

Genetic confinement: The study proposes an isolation distance of 100m between the genetically modified cassava and any other plants capable of hybridizing with cassava. This is insufficient. Research carried out on planting practices to minimize GMO pollen contamination suggests an isolation distance of over 200m.

17. https://en.wikipedia.org/wiki/Tissue_culture
18. https://en.wikipedia.org/wiki/Neuron
19. https://en.wikipedia.org/wiki/Nicotine

5. DETAILED COMMENTS AND OBJECTIONS

1. ADMINSTRATIVE INFORMATION

Purpose of Application: Application for a confined field trial for Cassava (Manihot esculenta Crantz).

Query/Applicant Response	The aim of the production of these transgenic lines (AMY3 RNAi lines) is to reduce starch breakdown in the storage roots of cassava after pruning the shoots, prior to harvest of the crop.
Objection	Postharvest physiological deterioration (P PD) of cassava (Manihot esculenta) storage roots is a complex physiological and biochemical process. It is poorly understood regarding biological regulation, and the interactions among protein groups and signals that determine PPD syndrome in cassava stora ge roots. Many regulatory networks linked with specific proteins modulation and signaling transduction pathways are involved in post -harvest physiological deterioration (PPD) of cassava (Djabou et al ., 2017). The genetic modification of RNAi transcriptional gene silencing targeting is not the sina qua non that will not take care of the implication of Ca $^{2+}$-CaM, ROS and PCD pathways interact to fine-tune the PPD response. The aim of the proponents of this GM cassava contradicts the food security interests of Nigeria. It may have untoward interest detriment to our food chain. This is because the current GM cassava was not designed to solve yield or any food related challenge.
Query/Applicant Response	The Objective is to obtain storage roots with lower post–harvest physiological degradation after harvest <u>without any loss of the nutritious starch</u>.
Objection	This applicant has not provided any data or evidence supporting the claim: ...without any loss of the nutritious starch. Note that α-Amylase (E.C.3.2.1. 1) is a calcium metalloenzyme and a hydrolase enzyme that catalyses the hydrolysis of internal α-1, 4 - glycosidic linkages in starch to yield products like glucose and maltose. These breakdown products hydrolysis catalysed by α-Amylase constitute the substr ates for starch biosynthesis and therefore the nutritious elements.
Query/Applicant Response	The construct expressing an RNA hairpin homologous to the first 210 base pairs of the Manes. 05G097100 gene (Phytozome) encoding α-amylase targeting it for transc riptional gene silencing. This hairpin is driven by the solanum tuberosum patatin promoter that confines silencing to the storage tissues (root-specific promoter).

Objection	The parallel drawn between the solanum tuberosum patatin promoter and the genetically modified cultivars to be field-tested (cv.604444) is a cause for great concern. Not only are these two completely different plant species, but differences may exist in: I. The gene insertion site in the chromosomes of the plant in each event (which are random), II. Rearrangements of the inserted gene and interactions between the transgenic protein and the plant (which will differ in different plant species).

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 first -time application by the joint collaboration of IITA-ETHZ plant Biotechnology Lab to the Nigerian regulatory authorities for a CFT to test transgenic cassava events developed by EWTHZ Plant Biotechnology Lab. This the first application for field -testing of the AMY3 RNAi transgenic lines. They have b een previously tested only in screen house at ETH Zurich. No application has been previously made for the CFT and commercial release of these transgenic cassava clones before in any jurisdiction.
Objection	We are very s keptical about the status of this t ransgenic cassava clones because it is lacks PEER REVIEW having not been evaluated in any other part of the world. Uncertainty is a key element as to why the Biosafety Protocol (Cartagena Protocol on Biosafety to the Convention on Biological Diversity) was put in place. 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 and in the NBMA Act 2015 to be triggered. It has only be en evaluated in a screen house which is an integral part of ETHZ Plant Biotechnology Laboratory. Not even the originating country has evaluated it in the field. The National Biosafety Management Agency should note that many of their related agencies in South Africa recently denied/ declined approval for an application for the release GM cassava into their country environment.

	Nigeria can therefore not argue that GM cassava is needed to feed the hungry or for biofuels 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 is originally from South America. The unmodified cassava cultivar 60444 included in this study has been selected in the IITA from West African Landraces.
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 cv 60444 was developed at the National Root Crops Research Institute (NRCRI) in the 1960s in Ibadan and it was later transferred to IITA for improvement through breeding. Then, it was being cultivated by Nigerian farmers but later it was abandoned due to susceptibility to the diseases . T he cv 60444 germplasm grown in Nigeria is susceptible to cassava mosaic disease (CMD) regardless of whether it is GM cassava or non GM cassava. The problem with this cultivar cv 60444 germplasm is susceptibility to the diseases and not Postharvest physiolo gical deterioration (PPD) (Adenle et al.,2012) Even the study cultivar 60444 selected from IITA has been cultivated for many decades by smallholder farmers in Nigeria. Therefore, this transgenic GM cassava with its accompanying patents claims of ownership by the owners of the foreign genes ahead of the farmers and indigenous people in the communities in Nigeria will be unjust and socially and ethically unacceptable.

Query/Applicant Response	Cassava is monoecious and bears separate male and female flowers on the same plant. Male and female flowers are borne on the same branch panicle, with female flower at the base and the male flower towards the tip. In a given inflorescence, female flower open from one to a few weeks earlier than the male flowers. By the time male flower opens, the female flower on the same branch have been fertilized or have aborted. However, because flowering on a single plant may last for more than 2 months, pollen from a flower may fertilize other flowers on the same plant or flowers on surrounding plants, with the proportion of each dependent on the genotype, the environment, and the presence of pollinating insects. The pollen grains of cassava are relatively large in size, and are sticky. Therefore, wind pollination appears to be of little consequence whereas several species of honeybees (Apis mellifera) are considered the main pollinators in Africa. Cassava pollen loses viability rapidly after it is shed. Pollen viability seems to decline substantially after this time. In practice, breeders take care to perform pollination with 1 h after collection of pollen to help successful fertilization. Cassava seeds develop with small fruits, usually three per fruit, with 1-3 seeds being fertile (Jennings and Iglesias, 2002). Developing seeds ar e viable 2 months after pollination, and the fruit becomes mature about 1 month after that or about 3 months after pollination. Fruit dehiscence is explosive; the seed initially falls close to the mother plant but may be further dispersed by ants. Newly ha rvested seeds exhibit physiological dormancy and require 3 to 6 months of storage at ambient temperature before they will germinate. Seed germination is favoured by dry heat and complete darkness. To conserve the positive attributes of known genotypes, cas sava is normally vegetatively propagated by means of stem cuttings, which are known horticulturally as ' stakes'. Stakes are typically at least 20 cm long, and have 4 to 5 nodes each with a viable bud.
Objection	The biology of the cassava plant as briefly outlined by the applicant lends credence to our objection as there is likely to be transgene flow. In addition, there could be movement of material from the site through: I. flooding, II. animal feeding or III. unlawful harvest

Query/Applicant Response	Tendency and weediness No, cassava is not invasive or weedy
Objection	Cassava plant is renowned for its ability to establish and maintain volunteer growth which can be a veritable source of escape and contamination. This tendency of cassava that the applicant glo ssed over has incalculable implication for biodiversity.
Query/Applicant Response	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 (McMahon et al 1995). Cyanogenic glucosides in cassava are linamarin (>90%) and lostraulin (<10%) and cassava varieties have been classified into various groups based on the content of the cyanogenic glucosides, measured in HCN equivalents, or tastes of their roots (Mc Mahon et al 1995). In the cassava breeding program at the IITA, 100mg HCN eq Kg -1 is used as the upper limit for cassava classified as low in cyanogenic glucoside content. The cultivars to be field -tested (cv.604444) averages up to 110 mg HCN eq Kg -1 and t herefore its roots are classified as "slightly bitter" and it requires processing to remove the cyanogen prior to consumption. Such practice is common in Nigeria where households and village-level commercial processing removes the risk of cyanide poisoning and increases the shelf life of cassava based food products. However, no cassava plant from the experimental field trail will be consumed. These will be incinerated within the CFT site.
Objection	The cultivars to be field -tested (cv.604444) averages up t o 110 mg HCN eq Kg-1 and therefore its roots are classified as "slightly bitter". The HCN of the cultivars to be field -tested (cv.604444) 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 claim that no cassava plant from the experimental field trail will be consumed is very deceptive. It will be almost impossible as you rule out surreptitious acquisition of the stem-cutting and the likelihood of unlawful harvest by locals who had always accessed improved cassava varieties from IITA in the CFT site.

2.2Modified Plant Information

Query/Applicant Response	Describe the Intended Phenotypic Changes to the Plant The intended phenotypic change is reduction of starch breakdown in the storage roots of cassava after pruning the shoots, prior to harvest of the crop. The objective is to obtain storage roots with lower post - harvest physiological degradation after harvest (thanks to the pruning) without any loss of the nutritious starch (thanks to transgene).
Objection	The candidate GMO cassava is a transgene (Source undeclared) which adopts RNAi [20] transcriptional gene silencing of α-amylase. Gene silencing (either transcriptional or translational) is the regulation of gene expression in cells to prevent the expression of certain genes and hence traits and gene dependent activities. It is related to gene knock down (Complete elimination) except that when genes are silenced over 70% of its expression are lost. The α-amylase (α-1,4-glucan-4-glucanohydrolase) present in the cassava cultivar currently being grown in Nigeria belong to the family of endo -amylases that catalyses the initial hydrolysis of starch into shorter oligosaccharides through the cleavage of α-D-(1–4) glycosidic bonds. The end products of α-amylase action are oligosaccharides with varying length with an α-configuration and α-limit dextri ns, which constitute a mixture of maltose, maltotriose, and branched oligosaccharides of 6–8 glucose units that contain both α-1,4 and α-1,6 linkages. These biochemical process underline the processing of cassava for use as staple food largely consumed in Nigeria, other Africa countries and many parts of the tropics. Complete or partial knock down (gene silencing 7u0%) of gene encoding for the expression of α-amylase will greatly compromise the staple food value of cassava. Both the aim and objective of t his candidate GM cassava contradicts the food security and economic interests of Nigeria because the candidate GM cassava is not designed to solve yield or food related challenge. Obviously there will be significant alteration and /or loss of nutrient following this modification but this application have not substantiated

[20] *See Sirinathsinhji, Eva (November 2016) Risks of GM crops engineered to utilise RNA interference. TWN Biosafety Briefing note.*

	anything to the contrary. The claim is very superfluous and misleading and the application should be reject. The GM Cassava is genetically modified to reduce starch breakdown in storage roots of cassava. Hence the focus is to enhance its starch content to provide a feedstock for a burgeoning biofuels market. Primarily, cassava is grown in Nigeria as staple food driven largely by the demand for food for her nearly 200 million people and no t for industrial starch production. Cultivars that meet industrial starch production like the candidate GM cassava may not be very suitable for other food uses of cassava. It therefore poses a threat to food security. There is lack of solid experimental evidence to suggest that: I. High starch accumulation in starch storage roots is associated with strong transport capacity of the stems; II. High starch accumulation in the starch storage roots is related to lower efficiency of starch degradation. Increased Starc h Production is known to associate with many problems and high resource consumption. More so, it impacts negatively on the environment, especially the containment of sulphur, cyanide, solid and liquid waste (Sririth, et.al. 2000).
Query/Applicant Response	Intended Reproductive effects: The genetic modification may result in slower regrowth from stem cuttings (stakes), compared to the wild type. The genetic modification does not intend to alter the reproductive biology of the plants; therefore, it does not interfere with the strategies for confinement.
Objection	Modification that results in slower regrowth from the stem cuttings (stakes), will doubtless both impair and grossly alters the plant biology. Also, no data was provided on the effect of the slo wer regrowth from stem cutting (stakes) on stem flow rate (SFR). In the circumstance therefore, the expected pruning and transgene modification of the characters related to the formation of high starch content in the storage roots is very doubtful. The CFT may after all not be worth the troubles.

Objection	Modification that results in slower regrowth from the stem cuttings (stakes), will doubtless both impair and grossly alters the plant biology. Also, no data was provided on the effect of the slo wer regrowth from stem cutting (stakes) on stem flow rate (SFR). In the circumstance therefore, the expected pruning and transgene modification of the characters related to the formation of high starch content in the storage roots is very doubtful. The CFT may after all not be 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 cultivar 60444 originatin g from Nigeria was used for genetic transformation. The genetic materials exogenous to 06444 are derived from: i)Partial DNA sequence from Solanum tuberosum ; a class I patatin promoter (Positon 6-999 bp of the Gen bank GQ352473.1) ii) Partial DNA sequenc e from Manihot esculenta; Manes. 05G097100 gene(position 1 to 210 of the phytozome Manes.05G097100 coding sequence) iii) Synthetic plant intron sequence (57-165 bp of the Genbank M27 939 sequence) The source of the transgenic material will not affect the safe conduct of a confined field trail.
Objection	This application is for a confined field trial release of genetically modified cassava plants containing a gene isolated from cassava and inserted to result in the reduces α-amylase activity in the stor age roots of the transgenic cassava. Limiting the safe conduct of confined filed trails exclusively on the source of the transgenic material is unrealistic and scientifically unsound. The exogenous material included will invariably result elicit extrinsic. Besides this is the first ever evaluation of this construct, so, there are knowledge gaps regarding composition and functional outcome of the genome.

Query/Applicant Response	Changes in Toxicity or Plant Composition: There are no expected changes in toxicity or allergenicity of transgenic cassava clones.
Objection	The cultivars to be field -tested (cv.604444) contains 110 mg HCN eq Kg-1 which reasonably exceeds the upper limit threshold for HCN. This is a significant change in toxicity and very much unacceptable. It will endanger the life of Nigerians by causing cyanogenic poisoning.
Query/Applicant Response	Describe the features of the Genetic Construct The transformation vector was developed with pCAMBIA1301 as the base vector (GenBank accession AF234297). pCAMBIA1301 is a binary plant transformation vector for use with Agrobacterium tumefaciens. In addition to the components of the hairpin construct described below, it contains: the hygromycin phospotransferase II (hptII) plant selectable marker gene from Escherichia coli fused to the Nos promoter from A. tuumefacins and to the Cauliflower Mosaic Virus (CaMV) 3' UTR polyadenylation sequence. The transformation plasmid vectors used to create the transgenic cassava lines are referred to as pCAMBIA1301_patatin AMY3 RNAi. Detailed descriptions of these vectors and the genetic elements as well as a description of the method of modification are presented in Annex B. The vector was used to insert into cassava: • The hpt II gene (selectable marker) expressing an enzyme that confers resistance to the antibiotic hygromycin B. • Inverted repeat sequences coding for hairpin double-stranded RNAs homologous to the first 210 base pairs of Manes. 05G097100 sequence (encoding a α-amylase). The structure of this transcribed RNA renders it untranslatable, therefore no exogenous protein is produced.

Objection	
	The event is the transformation of the cassava cultivar cv60444 with pCAMBIA1301 as the base vector (genetically modified) by the insertion of two genes. The first is the hptII gene as the selectable marker that confers resistance to the antibiotic hygromycin B. The second is a double stranded RNAs fused between solanum tuberosum patatin promoter and the CaMV poly A terminator. The insertion orientation target silence encoding of α-amylase in the storage roots of cassava. The promoter sourced from solanum tuberosum patatin and the genetically modified cultivars to be field -tested (cv.604444) are completely different plant species. This is a cause for great concern. Not only are these two completely different plant species, but differences may exist in the gene insertion site in the chromosomes of the plant in each event (which are random), rearrangements of the inserted gene and interactions between the transgenic protein and the plant (which will differ in different plant species). CaMV related DNAs has been used to secure expression of transgenes in a large proportion of commercialised GMOs and it has been found to have a recombination hotspot where it tends to fragment and join with other double stranded DNA in a very non -specific manner. Studies indicate that these hotspots are flanked by multiple motifs involved in recombination and functions efficiently in all plants, green algae, yeast and Escherichia coli. The potential therefore exists for the viral genes to recombine with other viruses to generate new infectious viruses (Gurian-Sherman, 2006), carcinogens and mutagens as well as to reactivate dormant viruses. Several, demands has been made that the use of the CaMV DNAs in transgenic plants be phased out due to the structural instability arising out of its use. Our objection is premised on the fact that : 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, economy, environment and lots more remain unknown.

3. *Trail 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 Response	Trial Description: The purpose of the field trial is to evaluate the effect of reduced a α-amylase activity in the storage roots of the transgenic cassava under a local field condition in Nigeria to confirm results obtained in greenhouse at ETH Zurich. The field trail will be conducted within the confined filed, under a screen house (see Annex A) to red uce the risk of infestation of Bemisia tabaci, the whitefly vectoring cassava mosaic disease (CMD), to which the parental cv60444 cultivar is susceptible. Plant leaves will be weekly spread with insecticides, alternating Imidacloprid and Lambda–cyhalothrin (active principles) every 4weeks. Ten transgenic lines and the wild-type genotype will be evaluated (see annex B for genetic characterization of AMY3 RNAi lines). Lines to be tested will be planted in a randomized pattern within the screen house, 10 pla nts per line will be analysed. Plants on the edges of the screen -house will be excluded. Disease -free plants will be produced in vitro at ETH Zurich and sipped by courier to IITA, Ibadan in Nigeria. Data will be collected at harvest, 10-30 days after pruning, and 20-40 days after stick re-planting. At harvest, which will be 5 months after planting, the following data will be collected: 1) Plant height 2) Shoot weight 3) Storage root weight Storage roots and stems will be sampled during data collection in order to determine starch content. Half of the plant (5 per line) will be pruned and the roots left in the soil for 10days. The stem of the harvested plants will be cut and replanted (10 sticks per lines).

	Following stick planting, the following data will be collected: 1) Scoring of the shoot regrowth 2) Length of the growing shoot When a suitable stage of regrowth is obtained (est. 20 -40 days), stems will be sampled during data collection in order to determine starch content. The trail site is in the forest agro -ecology of Nigeria (see Annex C). The site was cleared of the native forest several decades ago. Therefore, there is no known organism of conservation concern at the test site. Pockets of the original forest that exist in the area are well separated from the test site.
Objection	The risk management practices that are proposed by the applicant do not go far enough. Inadvertently, the applicant's field trial design only assess agronomic properties like yield, fruit/root quality and pest susceptibility. The expe rimental design is devoid of any parameter / variables to measure the anticipated impact of impact pesticide use and /or 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. There is a lack in the application of any mention of protocols for collecting environmental impact data from the field trials. Impacts on non-target organisms should be evaluated and measured. Above all, the applicant's claim that: "Therefore, there is no known organism of conservation concern at the test site " is careless, 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.

Query/Applicant Response	The trail site is located at the IITA headquarters station in Ibadan, capital of Oyo state in South-Western Nigeria. An isolation distance of 100m will be maintained between the CFT site and any plants capable of hybridizing with cassava. See Annex A for an aerial picture of the confined field trail site, and Annex C for an aerial picture of the location of the trail site, surrounding fields and other geographical features.
Objection	The applicant admits that the wild species M. glaziovii plants are kept in the IITA collection. Undoubtedly, this CFT at IITA, will very likely contaminate this all-important wild cassava germplasm. In addition, several cassava cultivars are massively grown in Ibadan in areas that are very contiguous to the CFT site. Strictly the isolation distance of 100m will be equivocal.
Query/Applicant Response	Are there wild plant species in the vicinity of the trail site that could be fertilized by pollen from the trail plants, resulting to viable seeds? There are no plants of wild species near the confined field that could be fertilized by cassava pollen. The only wild Manihot species in Nigeria is M. glaziovii (Bock 1984), which is a non-indigenous, ornamental tree species with no weedy characteristics. Few M. glaziovii plants are kept in the IITA collection within the IITA campus. However, they are located more than 1000M away from the CF site and therefore are not at risk to be pollinated by trail plants
Objection	The applicant admits that the wild species M. glaziovii plants are kept in the IITA. 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. The M. glaziovii is not only maintaed in IITA but beyond the IITA collection, it is known to have escaped and grows wildly in Nigeria. Undoubtedly, this CFT at IITA, very likely 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 cassava fields in accordance with the standard for separation used in c assava breeding programs (Kawano et al, 1978). This isolation distance is calculated starting from the outermost border row. The isolation zone will be regularly monitored during and after the trial to ensure the continued absence of any cassava. In additi on, pollen dispersal will be prevented by removal of any male or female flowers during the entire duration of the experiment. In cassava, inflorescence production is preceded by three-way branching of the main stem, making it easy to detect early stages of the flowering process. Weekly monitoring for initiation of inflorescence will take place starting from 2 months after planting and any inflorescence will be removed and destroyed before maturation. Therefore, there will be no possibility for pollen production or distribution. Furthermore, inside the fenced area, the experimental plants will be surrounded by a 2 meter wide set of guard rows. These will be made of wild type cassava plants (cv. 60444 and other cassava lines flowering at the same time) that w ill be treated as pollen trap rows. All planta within the cassava guard rows will be incinerated along with the tested plants at the end of the field test. No effects of the introduced traits is intended or expected on the reproductive biology of the tested plants.

Objection	The applicability of the separation / isolation distance of 100m prescribe by Kawano et al 1978 as buffer zone for GM cassava field trails 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. Research carried out on planting practices to minimize GMO pollen contamination for cassava? suggests an isolation distance of over 200m. Ibadan, is in the ra in forest region of Nigeria, 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.] The trial spot area will be left fallow and kept free of volunteer cassava plants for at least one year after the conclusion of the trial or until a new trial will be started. The presence of volunteers will be monitored on a monthly basis for a period of six months and volunteer plants found will be uprooted left to a ir dry, placed in the incinerator and burnt.
Objection	Fallow or not, the possibility of contamination of cassava cultivar in Ibadan exist because of this CFT. All over Oyo state in Nigeria, cassava is an allogamous plant, which means there is 100% chance of out crossing. 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 trail 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 measure for cleaning and /or disposing of the packaging material. Note that the chain of custody document is required for all genetically m odified material being transported.] The experimental plant will be imported from ETH Zurich, Switzerland. Individual plants will be transported in 50ml clear plastic sealed culture tubes singularly labelled with appropriate identifier unique to this GMO. These tubes will be shipped by express courier from Switzerland to IITA headquarters, Ibadan where they will be received by the IITA principal investigator and transported to the biosafety level 2 (BL20 containment screen house facility. After post -entry inspection and clearance by the regulators, plants will be acclimatized and hardened for 4 -6weeks in sterile soil in individual 15 cm pots. After hardening the plantlets in the pots, they will be packaged in closed cartons lined with plastic film to preven t the spillage of any material. These cartons will be transported within enclosed vehicles from the screen house to the fenced field site within IITA headquarters under the supervision of a representative of IITA institutional biosafety committee (IBC) and the IITA principal investigator. The packaging, including the plastic tubes, the Styrofoam boxes, plastic bags, cartons, pots, will be destroyed by burning with a flammable liquid in the incinerator within the CFT site. A compliance form, material tran sfer form, and import permit will be prepared and maintained to document movement of the plants to the IITA headquarters containment facility from ETH Zurich, Switzerland and within IITA from the containment facility to the CFT site.

Objection	The outlined protocol for the packaging and labeling for transport of the experimental plant to the trial site are not referenced to any standards as set up by the Biosafety Protocol, to which Nigeria is a party. Paragraph (c) of Article 18.2 states: " Living modifie d 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 an d 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." Even in the USA where there are seemingly regulations, the movement and release into the environment of GE crops has been widely criticized as inadequate. As such, the protocol for the packaging and labeling of the experimental plant for transport according to this application are not acceptable.
Query/Applicant Response	Harvesting, Transport and Storage: [Describe how the plant material will be harveste d, including plans for any material to be retained, and how that material will be stored and/or transported.] Destructive data collection and harvesting will be performed in the field. Samples will be stored in sealed plastic bags and transported to the IITA BL2 laboratory, Ibadan for further analysis using established protocols, when and if required.
Objection	Full disclosure is required for "analysis using established protocols" in public interest. Also, the applicant failed to state any reference for the standards that all the protocols for the CFT are in conformity.

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.] 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 f ailure 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. Onc e 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 t his 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 2-3 days proposed for all plants to be dug up, chopped up and allowed to air dry in the sun is a potential window period for rodents to invade the CFT site and feed freely on the trial. The application did not provided 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. "Incineration in the existing pit" this protocol is questionable. Burning of delicate biohazardous / genetic material in a pit is not same as incineration. The pit dug on the ground is not same with design requirements for incinerators. Washing and cleaning as proposed by the applicant is an inadequate treatment for tools contaminated with DNA / genetic materials/biologicals. We would want NBMA to note the following: I. No treatment protocol for residual plant material recovered during the process of cleaning field tools on CFT site. II. Acceptable methods of cleaning are not outlined. III. Steps for trial personnel ver ification to ascertain that tools are free of preparative plant material and propagative plant material. Applicant's containment protocol is seemingly very defective and falls short of standard practice. The application should be declined.
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 is within the IITA campus in Ibadan that is fenced along the entire perimeter and has restricted access to only authorized personnel. The CFT site is surrounded by two -meter high chain -linked fencing buried in the soil, and has a locked gate to prevent unauthorized access by people or animals(see annex A).

	A guardhouse is also made available at the gate to allow for 24 -hour security (see annex A). To ensure that material confinement standards are met, only approved personnel will have access to the area. A logbook will be maintained to keep a record of all visitors to the site and access will be allowed only to authorized personnel.
Objection	Note that chain -liked fencing cannot prevent incursion by animals. Intrusion of the CFT site by animals especially rodents which usually feeds on cass ava is a compromise of both the ecosystems and biodiversity. We equally have observed that this application failed to propose pre - trial sites inspection by Biosafety inspectors or other regulatory agents for compliance with this provision site security t o prevent incursion by humans or animals. We strongly object to this application because the genie will definitely be let out to the environment.

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 completed material transfer agreement forms will be incorporated into the compliance binder maintained at the CFT site and will be available at all times for review by Nigerian Biosafety inspectors and regulators. The compliance forms to be completed and maintained will include:

	Material Transfer forms, to document movement of the plants: To IITA screen house from ETH Zurich, Switzerland. To the IITTA CFT site from the IITA screen house. Confined field trial form , to document the exact number and purpose of Any plants not planted but retained, and the sterilization and / or destruction of any shipping containers. Weekly Flower bud removal form, to document the weekly inspection for flower buds starting from CFT initiation until CFT termination, as well as to document flower bud removal and destruction in the incineration pit. An additional document will be created to summarize the information from the weekly flower bud removal. Monthly Isolation Monitoring form, to document the monthly inspection of the 100m isolation distance, as well as to document the destruction of any prohibited plants 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. Incident and Corrective Action form, in case of any breach of confinement, IITA IBC and National Biosafety office will immediately notified by phone of the incident and the corrective action form will be completed. Isolation distance monitoring form, to document the weekly inspection of the isolation distance and ensure that no cassava plant is established within this area.

	Harvest and Destruction form, to document the harvest and destruction of the test plants and the spreader rows. Post-Harvest volunteer monitoring form , to document the monthly post-harvest inspection of the CFT site for living cassava plants and destruction of volunteers. Transfer to BL2 Screen house and laboratory form , to document the harvested material from the field that will be grown in screen house or moved to the laboratory for further analysis at IITA. 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 infection evaluation form , to document occurrence of CMD infection and severity (1 -5 scale scoring) on each of the individual plants within the plots on bi -weekly basis for the entire duration of the experiment. Monthly Plot Observation form , to record data on plant height, occurrence and severity of cassava bacteria blight, anthracnose, infestation by green mites, w hiteflies and mealybugs, as well as any general comments. Meteorological Data form , to report rainfall, relative humidity and temperature recorded daily by the weather station in IITA.

Objection	This CFT depends largely on foreign expertise and scienti sts. Even the experimental plant will be imported from ETH Zurich, Switzerland. We therefore have major concerns and envisage obstacles on the implementation this rigorous records and documentation requirement which is the cornerstone of quality management and compliances to standard biosafety protocols.
Query/Applicant Response	Personnel: [Describe measures in place to ensure that trail personnel will have appropriate education, experience and training to adequately perform assigned duties for confineme nt and technical requirements of the trail.] Trial personnel have relevant skills in biotechnology and will be appropriately trained in biosafety to cope with the requirement of this study. The principal investigator of this project has long standing experience in biotechnology and compliance with biosafety regulations. A list of authorized personnel for the different activities related to the CFT will be prepared and stored in the compliance binder.
Objection	The trial personnel is unknown to this application. The supposed credentials and would be competencies in biotechnology and biosafety cannot be vouchsafe.

Query/Applicant Response	Contingency Plans: [Describe planned response to the loss of control or accidental release of genetically modified plan t 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 IITA IBC and the Nigerian Biosafety officials will be notified immediately and will receive a written notification within 24 hours of becoming aware of the accident. Biosafety Inspectors will accompany the material during each stage of transport. An accident and corrective form will be completed for each case of accidental release. The completed incident and corrective action form will be incorporated into the compliance binder maintained at the CFT site. In the unlike ly event that transgenic plantlets fall out of its sealed tube packaging material and carrying bag during the transport process, the plantlet will be immediately recovered and returned to its storage tube which will be then marked for subsequent destruction through incineration. Nigeria Biosafety officials will be notified immediately of the occurrence. If any plantlet spills from its pot in the closed carton during transport, it will be similarly recovered and then destroyed. If any plants are accidentally removed from the trial site after planting, the biosafety regulators will be notified immediately of the event and efforts will be undertaken to recover the material under the guidance of the biosafety desk office. The biosafety inspectors will also be notified immediately of any unintended violation of reproductive isolation. If the breach in the reproductive isolation is due to a cassava flowering inside the CFT site, the 100m isolation distances will ensure that genetic confinement is maintained. In the unlikely event of civil unrest or natural disaster that affects integrity of CFT, the biosafety regulators will be notified and all the entire experimental materials will be destroyed.

Objection	The applicant stated that "Biosafety Inspectors will acc ompany the material during each stage of transport". This is impracticable. Some segments of the transportation of the CFT plant material may be contracted to courier company. Would the Biosafety Inspectors still be accompanying it at such times? No formal risk assessment protocol has been included and /or is to be conducted on this particular event. In particular, no data is given on environmental assessments relevant to cassava and this particular modified cassava. The applicant failed to declare antic ipated 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 cv60444 should have same pathological or ecological impact different fr om those of the cassava cultivar currently grown and consumed in Nigeria. Nigeria and Nigerian s are therefore not protected against any vicarious liability that this CFT may cause to their health, environment and food supply chain.

6. CONCLUSION

We believe that the points marshaled out in our objection to the GM Cassava application submitted by IITA and ETHZ Biotechnology Lab in Zurich are sufficient for the application to be rejected. We so urge the NBMA to reject this application outright.

We reiterate that cassava is a major staple crop for Nigerians, Africans and others in the global south. This experimentation designed and packaged from Switzerland does not do any good to the reputation of the IITA whom our farmers have trusted. This poorly packaged application erodes and deletes the basis for the trust built over the years.

We call on the NBMA not to allow our territory to be used for the trial of risky and unnecessary technologies that add no value to our food systems but rather threaten our agriculture, health and survival of our peoples. This application fails on all layers and levels of consideration and IITA will do well to allow ETHZ to retain their speciments in their laboratories in Zurich rather than become a conduit by which our well being is threatened.

REFERENCES

1. Djabou ASM, Carvalho LJCB, Li QX, Niemenak N, Chen S. Cassava postharvest physiological deterioration: a complex phenomenon involving calcium signaling, reactive oxygen species and programmed cell death. Acta Physiologiae Plantarum. 2017;39(4):91. doi:10.1007/s11738-017-2382-0.
2. Adenle AA, Aworh OC, Akromah R, Parayil G. Developing GM super cassava for improved health and food security: future challenges in Africa. Agriculture & Food Security 2012; 1(11): 1–15.
3. Brittan, K. 2006. Methods to Enable the Coexistence of Diverse Corn Production Systems. University of California Cooperative Extension Agricultural Biotechnology in California Series Publication 8192. Online at anrcatalog.ucanr.edu/pdf/8192.pdf [URL verified 3/14/16].
4. Canadian Council of Ministers of the Environment (2007). Canadian water quality guidelines: imidacloprid: scientific supporting document. Winnipeg, Man.: Canadian Council of Ministers of the Environment.
5. Carrington, Damian (March 29, 2012). "Pesticides linked to honeybee decline". The Guardian. Retrieved August 17, 2016.
6. Centre for Science in the Public Interest (CSPI) (2004) Comments to Docket No. 03-031-2 Regarding Federal Register Notice dated January 23, 2004 (69 FR 3271).
7. Endocrine Disruptor Screening Program: Tier 1 Screening Order Issuing Announcement. Federal Register Notice, Oct 21, 2009. Vol. 74, No. 202, pp. 54422-54428
8. Federoff, N.E.; Vaughan, Allen; Barrett, M.R. (13 November 2008). "Environmental Fate and Effects Division Problem Formulation for the Registration Review of Imidacloprid". US EPA. https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0844-0003 Retrieved 18 April 2012.
9. GM Cassava fails in Africa .
10. Gurian-Sherman, Doug. (2006) Senior Scientist, Center for Food Safety, Washington, D.C. personal communication.
11. Gurain-Sherman, Doug (2004) A look at the unintended effects of genetically engineering food plants. Briefing Paper. The Center for Food Safety.
12. IMIDACLOPRID TECHNICAL FACT SHEET . National Pesticide Information Center. Published April 2010, http://npic.orst.edu/factsheets/imidagen.pdf
13. Kimura-Kuroda J, Komuta Y, Kuroda Y, Hayashi M, Kawano H; Komuta; Kuroda; Hayashi; Kawano (2012). Okamoto, Shu-Ichi, ed. "Nicotine-Like Effects of the Neonicotinoid Insecticides Acetamiprid and Imidacloprid on Cerebellar Neurons from Neonatal Rats". PLoS ONE. 7 (2): e32432. PMC 3290564Freely accessible at http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0032432 . PMID 22393406. doi:10.1371/journal.pone.0032432.umble Bee Colony Growth and Queen Production". Science. 336 (6079): 351–2.
14. Riddle, J. 2012. GMO Contamination Prevention—What Does it Take? Univ. of Minnesota SW Research and Outreach Center. Accessed 20 August 2017.
15. Starner, Keith; Goh, Kean S. (2012). "Detections of Imidacloprid in Surface Waters of Three Agricultural Regions of California, USA, 2010-2011". Bulletin of Environmental Contamination and Toxicology. 88 (3): 316–321. PMID 22228315. doi:10.1007/s00128-011-0515-5
16. Sririth,K, et.al. 2000. Cassava Starch Technology: The Thai Experience. Published in Starch/Starke 52; p. 439 – 449.

17. Tonukari, Nyerhovwo John (2004) Cassava and the future of starch. Biotechnology Issues for Developing Countries. Electronic Journal of Biotechnology. 7(1) April 15. http://fpdi.setasign.de/pdfs/a03.pdf#search=%22%2Bcassava%20%2Bstarch%22.
18. Whitehorn, P. R.; O' Connor, S.; Wackers, F. L.; Goulson, D. (2012). "Neonicotinoid Pesticide Reduces B SDA, Forest Service ,Forest Health Protection (December 28, 2005). Imidacloprid - Human Health and Ecological Risk Assessment – Final Report "HUMAN HEALTH RISK ASSESSMENT / Overview. 3-1". United States Forest Service. See at http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.413.2418&rep=rep1&type=pdf

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