



NATIONAL BIOSAFETY AUTHORITY

Summary risk assessment report on the application to introduce transgenic cassava containing cassava brown streak disease resistance genes for confined field trials (CFT) in Kenya

Background information

The National Biosafety Authority (NBA) received an application on 8th February 2013 from Kenya Agricultural Research Institute (KARI) titled "Application to introduce transgenic cassava containing Cassava Brown Streak Disease resistance genes for confined field trials in Kenya". The application was administratively screened for completeness and acknowledged. The overall objective of the proposed CFT is to develop, obtain regulatory approval for transgenic cassava variety TME204 with superior resistance to Cassava Brown Streak Disease (CBSD). The specific objectives include;

- i. To test the efficacy of candidate lines in different ecological zones to identify and select the best suited individual line for further advancement, regulatory approval and later deployment;
- ii. To conduct safety assessments and collect data needed for submission to Kenyan Regulatory Authorities for approval during environmental release;
- iii. Collect comparative data required for variety release of the new line to farmers;
- iv. To carry out line bulk up activities for efficient delivery of Variety TME204 to farmers.

Cassava, *Manihot esculenta* is susceptible to Cassava Brown Steak Disease (CBSD) that is caused by two different single strand RNA viruses namely; Cassava Brown Streak Virus (CBSV) and Uganda Cassava Brown Streak Virus (UCBSV) which are both monopartite ssRNA viruses which are transmitted by whitefly vectors. There are no known natural sources of resistance to CBSD that can be incorporated into cassava through conventional breeding; hence the introduction of the resistance using RNAi technology by use of *Agrobacterium tumefaciens* based vectors. This technology has been successfully used to confer virus resistance in other transgenic crops such as papaya and plums. The genetic modification is intended to introduce CBSD resistance to cassava variety TME204 through RNAi technology by expressing viral sequences derived from truncated full length coat protein of both cassava brown streak virus (CBSV) and Uganda cassava brown streak virus (UCBSV).

Summary details of the application

Title of application: Application to introduce transgenic cassava containing cassava brown streak disease resistance genes for confined field trials in Kenya.

Applicant: Kenya Agricultural Research Institute (KARI)

Collaborating Institutions: Donald Danforth Plant Science Centre, USA

Type of Application: Confined Field Trial (CFT)

Locations of Research: Two sites namely; KARI Alupe Research Sub- Centre (Busia County) GPS coordinates: 0°29'52.2"N 34°07'30.3"E and

KARI Mtwapa Research Centre (Kilifi County) GPS coordinates: 3°56'12.9"S 39°44'33.4"E

Parental Organism: Cassava (*Manihot esculenta*)

Trait being modified: Disease resistance (Cassava Brown Streak Disease)

Genetic modification method used: RNAi technology by use of *Agrobacterium tumefaciens* based vectors

Risk Assessment Summary Table

No.	Issues of concern	Potential adverse effects (Hazard)	Estimation of likelihood	Consequences if the adverse effect were to happen	Estimation of risk (Likelihood x consequence)	Risk management measures	Conclusion (Acceptable or Manageable)
1	Gene flow	Possibility of out-crossing with the African wild type sorghum relative (<i>Manihot glaziovii</i>) or other cultivated sorghum varieties in the neighborhood	Unlikely	Severity of crossing with neighboring plants is minor	Low risk	<ul style="list-style-type: none">• <i>M. glaziovii</i> plants are not known to be within the vicinity of the trial sites.• Continuous monitoring of isolation zone for 1 year will ensure continued absence of any cassava or <i>M. glaziovii</i>• All flower buds to be removed before maturity• Recommended isolation distance of 100 metres between the trial sites and other cassava plants to be maintained.• Rows of non-transgenic cassava surrounding entire experimental plots will act as guard rows	Acceptable
2	GMO handling	Inadvertent loss of propagative material	Unlikely	Severity of unintended dispersal or movement of vegetative material is intermediate	Moderate risk	<ul style="list-style-type: none">• Material is under confinement and chances of escape are low.• Staff involved in the trial including security personnel will be trained on biosafety containment measures before project commencement	Acceptable
3	Dispersal mechanisms	Persistence and invasiveness	Unlikely	Severity of wild uncontrolled growth is	Low risk	<ul style="list-style-type: none">• Cassava is not considered to be a weed nor invasive in an agricultural setting; however, one characteristic of weed i.e.	Acceptable

				minor		<p>“discontinuous germination and long-lived seeds” appears to apply unreservedly for cassava.</p> <ul style="list-style-type: none"> In unmanaged habitats, the viability of cassava is limited and the plant does not have a tendency for weediness and is unlikely to persist in the environment unless it is maintained No flowers or seeds will be allowed to form in the CFT site. Cassava plants do not propagate from storage roots, and the role of these organs in persistence is not of concern 	
4	Gene safety	Adverse effects on human and animal health (Allergenicity, Toxicity)	Unlikely	Minor	Low risk	<ul style="list-style-type: none"> The protein derived from CP gene of CBSV and UCBSV is not an allergenic to humans or animals. The vector is not naturally pathogenic The source of genetic material including selectable marker gene nptII used for the constructs are safe and have been used successfully in other transformation work without any reported risks 	Acceptable
5	Stability of inserted gene	Gene disintegration leading to cassava lines being exposed to CBSD disease	Likely	Severity of gene disintegration in subsequent generations is minor	Low risk	<ul style="list-style-type: none"> The coat protein is constitutively expressed and stably integrated. Agrobacterium provides clean insert with low copy numbers. Only lines with low copy numbers (1 or 2 copies) will be selected thus reducing the possibility of losing resistance expression. 	Acceptable
6	Non target organisms	Effect on other organisms	Unlikely	Mortality and/or effect growth characteristics is minor	Low risk	<ul style="list-style-type: none"> No new proteins are produced by use of RNAi technology. The products arising from this technology are not known to be toxic when ingested by native fauna populations including mammals, birds, reptiles and insects 	Acceptable
7	Environmental issues	Loss of biodiversity	Unlikely	Intermediate	Moderate risk	<ul style="list-style-type: none"> The products from gene silencing are not toxic when ingested by native fauna populations including mammals, birds, reptiles and insects. CFT sites are sufficiently isolated and confined. All materials in site to be destroyed at the end of the trial. Cassava is not indigenous in East Africa (Linked to Brazil and Mexico). Therefore the risk of loss of biodiversity is low. 	Acceptable
8	Resistance	Development	Likely	Minor	Low risk	<ul style="list-style-type: none"> RNAi has been used in other 	Acceptable

		of more virulent strains of cassava				transgenic crops and more virulent strains have not been reported.	
--	--	--	--	--	--	--	--

Overall conclusion on risk and risk management

RNAi technology used in developing the transgenic cassava lines for the proposed CFT has been applied successfully to protect other crops from RNA viruses and has led to the development of virus resistant crops. The possibilities that the protein from the coat protein gene as an allergen/toxin are remote considering that the RNAi technology has been commercially adopted for crops like papaya and plums that are consumed by humans in China and USA without any known human/animal health implications. The proposed CFT work is an experiment and no materials will enter the food/feed chain. The facilities involved in the conduct of the CFT activities and the proposed contingency measures are adequate to prevent exposure of humans, animals and the environment to unnecessary risks.

Decision

The application is approved with the following conditions;

1. Applicant to obtain a plant import permit from KEPHIS and since the transgenic cassava lines are to be imported from USA, a schedule of importation should be prepared and availed to NBA and KEPHIS for monitoring purposes.
2. Ensure both CFT facilities at Mtwapa and Alupe are re-inspected to assess adequacy to handle the current trials.
3. Strict adherence to the set operation and regulatory guidelines for cassava
4. Staff to be involved in the trial to be trained on handling transgenic plants and overall biosafety matters.
5. A schedule of activities to be provided to NBA and KEPHIS before commencement of the trial.
6. Put and implement measures to ensure that no plant material from the confined field trials may enter the human food or animal feed chain.
7. Provide quarterly and annual progress reports to NBA.

Approval details

Approval number: NBA/GMO/C09/18/8

Approval Date: 26th September 2013

Duration of approval: 5 years (Renewable)

Approved by,



Prof. Dorington O. Ogoyi
Chief Executive Officer
National Biosafety Authority - Kenya

Date: 18th April 2020