



NATIONAL BIOSAFETY AUTHORITY

Summary risk assessment report on the application to conduct Confined Field Trials of transgenic Sorghum containing pro-vitamin A and enhanced Iron and Zinc bio-availability

Background information

The National Biosafety Authority received an application on 24th September, 2014, from Kenya Agricultural and Livestock Research Organization (KALRO) to conduct a confined field trial of transgenic sorghum containing pro-vitamin A and enhanced iron and zinc bio-availability. The primary aim of the proposed trial is to evaluate the nutritionally enhanced African Bio-fortified sorghum (ABS) i.e. ABS 188 containing increased pro-vitamin A, enhanced iron and zinc bio-availability and ABS 203 (containing Pro-vitamin A alone and their hybrids under confined field conditions. Specific objectives of the project include;

- a) To backcross ABS traits (iron, zinc and pro-vitamin A) from ABS188, ABS203 (with pro-vitamin A alone) into African sorghum varieties (KARI Mtama1, Macia, Tegemeo and Gadam).
- b) To evaluate the agronomic performance of hybrids of ABS with selected African sorghum varieties (KARI Mtama1, Macia, Tegemeo and Gadam) under CFT.
- c) To evaluate ABS (188 and 203) traits stability in the hybrids for at least 4 generations.
- d) To assess the effect of nutritional genes on fitness of hybrids between ABS203 and wild relatives of sorghum (*S. bicolor* sub species *arundinaceum* and *S. bicolor* sub species *drummondii*).

The transgenic sorghum has been generated firstly for expression of pro-vitamin A in the seed and the endosperm. This is achieved through the insertion of the phytoene synthase gene (*psy*) and carotenoid desaturase (*crtI*) which are involved in the carotenoid biosynthetic pathway. PSY enzyme catalyzes the formation of phytoene from geranyl geranyl diphosphate while CRTI catalyze a series of desaturation steps leading to the formation of Lycopene, which is further, converted to β -carotene (pro-vitamin A). The second improvement involves improvement of Fe and Zn Bioavailability. This is achieved through the introduction of the *lpa* (low phytic acid) gene, a membrane transporter gene which is thought to inhibit the transport of *phytic* acid in embryos hence leading to more free Fe and Zn minerals and thus rendering them available for absorption by the body.

Summary details of the application

Title of application: Application to conduct Confined Field Trials of transgenic Sorghum containing pro-vitamin A and enhanced Iron and Zinc bio-availability

Applicant: Kenya Agricultural and Livestock Research Organization (KALRO)

Collaborating Institutions: DuPont Pioneer (USA)

Type of Application: Confined Field Trial

Location of Research: KALRO Research Centre, Kiboko, Makueni County, 2°12'42.7"S 37°43'01.6"E

Parental Organism: Sorghum (*Sorghum bicolor subspecies bicolor Moench*)

Modified Trait: Nutritional enhancement (Pro-vitamin A, Enhanced Iron and Zinc Bioavailability)

Genetic modification method used: *Agrobacterium tumefaciens* transformation method

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	Vertical gene flow leading to increased fitness and competitive advantage	Unlikely	Severity of harm from outcrossing with conventional cassava and wild relatives of sorghum is minor	Low risk	Africa is the center of origin of sorghum with many sexually compatible weeds and wild relatives; Sorghum is largely self-pollinated; Imposition of isolation distance of 400m; Cover sorghum panicles with bags to limit seed / pollen movement; Postharvest monitoring for 6 months, volunteer plants to be destroyed	Acceptable
2	GMO handling	Inadvertent loss of propagative material	Unlikely	Severity of harm of unintended	Low risk	Low chances of escape, material under	Acceptable

				dispersal or movement of propagative material is minor		containment; Staff training on biosafety matters; Operational manuals available at CFT; Supervision of material during transport and appropriate packaging, remnant material destroyed under supervision of biosafety officer	
3	Dispersal mechanisms	Persistence and invasiveness leading to wild uncontrolled growth	Unlikely	Marginal	Negligible	Isolation distances of 400m to be maintained; Covering of sorghum panicles with bags to prevent seed / pollen escape; postharvest monitoring for 6 months to identify and destroy volunteer plants on CFT site	Acceptable
4	Gene safety	Adverse effect on human and animal health (Allergenicity and Toxicity)	Unlikely	Minor	Low risk	Extensive toxicity and allergenicity performed via bioinformatics revealed they are neither toxic nor allergenic; Vector not naturally pathogenic, <i>Agrobacterium</i> to be disarmed to eliminate risks; Source of genetic materials and genetic marker, <i>pmi</i> , have a history of safe use Experimental material to be destroyed after end of study and no consumption at this stage	Acceptable

5	Stability of inserted gene	Possibility of gene disintegration in subsequent periods	Unlikely	Marginal	Negligible risk	Agrobacterium provides clean inserts with low copy numbers, selection of only lines with low copy numbers to eliminate possibility of losing resistance expression	Acceptable
6	Non-target organisms	Adverse effects on other useful organisms in the surroundings	Unlikely	Marginal	Negligible risk	Products arising from this activity on ingestion aren't known to be toxic to native fauna like birds, mammals, and insects. The study is a nutritional enhancement experiment	Acceptable
7	Environmental issues	Possible loss of biodiversity	Unlikely	Minor	Negligible risk	All experimental materials including volunteer plants to be destroyed on site at the end of trial Maintenance of isolation distance between experiment and other sorghum fields	Acceptable

Overall conclusion on risk and risk management

Chances of risk emanating from this project are low. *Agrobacterium*-mediated transformation, a naturally occurring soil bacterium, has a history of safe use. Genes used for this project have negligible hazards to the environment. The inserted genes were isolated from naturally occurring organisms that are already widespread and prevalent in the environment and they have been constituents of food and feed (maize, sorghum, and peas). The other genes, *crt* and *pmi* have been isolated from the soil bacterium *Erwinia uredovora* and a non-pathogenic strain of *E. coli* respectively. The applicant has also met minimum isolation distances, training of staff on the rationale behind CFT trials, secured the facility by establishing appropriate fencing and having security staff present in a 24/7 manner among others.

Decision

The application is approved with the following conditions;

1. Applicant to obtain a plant import permit (PIP) from KEPHIS. On importation, the transgenic material must be escorted by officers from NBA from the port of entry to the experimental site who shall ensure proper packaging during transport.
2. A detailed schedule of activities covering 5 years from the date of approval to be provided both to NBA and KEPHIS before commencement of the trial.
3. Staff to be involved in the trial to be trained on biosafety matters and evidence availed to NBA.
4. Develop and avail operational manual and/or SOPS at Confined trials site and associated laboratory.
5. Ensure that the trial site is re-inspected by the regulators to assess its adequacy to handle this project. This should be done before trial commencement.
6. Put and implement measures to ensure that no plant material from the trial may enter the human food or animal feed chain. Records of internal movement of transgenic sorghum material should be maintained and availed for inspection to regulators on request.
7. Provide quarterly and annual progress reports to NBA in the prescribed format.
8. Considering that food/feed safety data for GM sorghum is limited/scarce, if the project proceeds to environmental release stage, a comprehensive food/feed safety study of nutritionally enhanced GM sorghum shall be undertaken prior to such application.
9. An Environmental Impact Assessment (EIA) shall be required in the event that the project proceeds to environmental release. Modalities of this requirement shall be provided by the NBA when this stage is reached.

Approval details

Approval number: NBA/GMO/C09/18/20

Approval Date: 4th March 2015

Duration of approval: 5 years (Renewable)

Approved by,

A handwritten signature in black ink, appearing to read 'D. Ogoyi', with a long, sweeping underline that extends to the right.

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

Date: 18th April 2020