NATIONAL BIOSAFETY AUTHORITY

APPROVAL TO CONDUCT CONTAINED USE ACTITIVITY INVOLVING CONFINED FIELD TRIALS OF TRANSGENIC SORGHUM CONTAINING PRO-VITAMIN A AND ENHANCED IRON AND ZINC BIO-AVAILABILITY AT KALRO KIBOKO

APPROVAL NUMBER: **NBA/GMO/CO9/18/20**	DATE OF ISSUE : **4TH MARCH 2015** VALID UP TO : **4TH MARCH 2020**
In accordance with regulation 9 of the Biosafety (Contained Use) Regulations, of the Biosafety Act 2009, I hereby grant the approval to undertake contained use activity of the genetically modified organism herein stated in the research institution mentioned in this approval.	
Name of the Applicant/ Research Institution	Kenya Agricultural and Livestock Research Organization (KALRO)
Specification of the genetically modified organism	**Sorghum (*Sorghum bicolor*)**
Quantity approved	**i. 2,000 ABS 203 sorghum seeds approved for importation from DuPont Pioneer, USA. Subsequent imports, if needed, to be approved upon notification to NBA. PIP is needed for all imports.** **ii. ABS 188 sorghum seeds to be obtained from harvest of previous CFT crop.** **iii. Total acreage approved is 1.0 Ha (2.5 acres) at CFT site located at KALRO, Kiboko**
Specification of the genetic modification	**The ABS188 and ABS 203 traits were introduced into sorghum lines via *Agrobacterium*-mediated transformation of immature sorghum embryos using plasmids pABS 188 and pABS 203 respectively. The plasmid vectors were disarmed by removing the oncogenes from the vector to eliminate any effects of pathogenicity. Molecular techniques (Quantitative PCR, southern and western blots) will be used for detection of the GMO.**
Risk category	**Low**
Purpose of the use:	**The overall objective of this project is to assess the nutritionally enhanced ABS188 containing increased pro-vitamin A, enhanced iron and zinc bioavailability, and ABS 203 (containing pro-vitamin A alone) and their hybrids under confined field conditions at KALRO Kiboko, Kenya. The specific objectives include;**

	a) **To backcross/introgress ABS traits (iron, zinc and pro-vitamin A) from ABS 188, ABS 203 (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 ABS 203 and wild relatives of sorghum (*S. bicolor* subspecies *arundinaceum* and *S. bicolor* subspecies *drummondii*)**

This approval is granted subject to 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.**

This approval is not transferrable and is valid for: **Five (5) years**

Place: **NAIROBI** Date: **4th MARCH 2015**	Name: **WILLY K. TONUI, PhD, RBP** Signature: **CHIEF EXECUTIVE OFFICER** **NATIONAL BIOSAFETY AUTHORITY**