

FOURTH SCHEDULE

(r.9)



NATIONAL BIOSAFETY AUTHORITY

**APPROVAL TO CONDUCT CONFINED FIELD TRIALS OF TRANSGENIC BANANA FOR
RESISTANCE TO BANANA XANTHOMONAS WILT (BXW) DISEASE IN KENYA**

APPROVAL NUMBER: NBA/GMO/C09/18/25	DATE OF ISSUE : 7 TH NOVEMBER 2016 VALID UP TO : 7 TH NOVEMBER 2021
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	Genetically engineered bananas (<i>Musa spp.</i>) with bacteria resistance against Banana Xanthomonas Wilt (BXW) disease.
Quantity approved	30 transgenic lines, 4 non-transgenic controls all totaling 408 experimental parent plants; including their future suckers (34 lines, 3 plots, 4 replications as per Annex II of Application Document). Two banana varieties approved for this study namely; 'Gros Michel' and 'Cavendish Williams'. Total acreage approved is 0.2 hectares of CFT at KALRO Alupe which must be inspected and authorized by NBA and KEPHIS before use.
Specification of the genetic modification	Embryogenic cell suspensions of banana cultivars 'Gros Michel' and 'Cavendish Williams' were transformed using <i>Agrobacterium</i> -mediated transformation system with plasmid constructs having either <i>Hrap</i> or <i>Pflp</i> gene (all from sweet pepper) or stacked (<i>Hrap-Pflp</i>) for bacterial wilt resistance. The <i>Agrobacterium</i> strain used was EHA105. Neomycin phosphotransferase gene II (<i>nptII</i> gene) was used as the selectable marker in this transformation, molecular characterization using PCR and southern blots were used to confirm presence and integration of the transgenes.

Risk category	Low
Purpose of the use:	The purpose of this confined field trials is to evaluate transgenic banana ('Gros Michel' and 'Cavendish Williams') expressing <i>ES-Pflp</i> or stacked (<i>Hrap-Pflp</i>) genes for resistance against Banana Xanthomonas wilt (BXW) caused by the bacterium <i>Xanthomonas campestris</i> under confined field conditions. These plants will also be assessed for agronomic performance, trait durability and collection of relevant biosafety data.

This approval is granted subject to the following conditions:-

1. At the commencement of the trial, transportation of the transgenic banana suckers must be escorted by Officers from NBA and KEPHIS from the BeCA BSL II green house to the experimental CFT site, to ensure proper packaging during transport.
2. A detailed schedule of activities for a period not exceeding five (5) years from the date of approval of the project must be provided both to NBA and KEPHIS before commencement of the trial to aid in monitoring purposes.
3. Avail evidence of staff to be involved in the trial having been trained by regulators (NBA and KEPHIS) on biosafety matters before commencement of experiment.
4. The proposed CFT at KALRO-Alupe must be jointly inspected and approved first for use by NBA and KEPHIS before start of experiment.
5. Avail operational manual and/or SOPS at all points of use in the CFT.
6. Put and implement measures to ensure that no transgenic banana material from the laboratory, glasshouse and the CFT enters the human food or animal feed chain.
7. Adequate containment measures to eliminate incidences of accidental escape of transgenic banana into the environment must be put in place. No volunteer banana plants should be allowed to flower at the CFT.
8. All the transgenic plant material must be rendered biologically inactive through burning and deep burial within the CFT. Strictly adhere to the proposed waste management plan and records must be maintained and availed to biosafety inspectors on request. Any material retained for further analysis shall be counted and accounted for at all times.
9. Provide quarterly and annual progress reports to NBA in the prescribed format. The reports should be discussed by and forwarded through the IBC.

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

Place: **NAIROBI**

Date: 7TH NOVEMBER 2016

Name: **WILLY K. TONUI, PhD, RBP,EBS**

Signature:



**CHIEF EXECUTIVE OFFICER,
NATIONAL BIOSAFETY AUTHORITY**

