NATIONAL BIOSAFETY AUTHORITY

APPLICATION TO INTRODUCE TRANSGENIC MAIZE WITH STACKED EVENTS MON 810 CONTAING cry1Ab GENE AND MON 87460 CONTAINING *csp*B GENE UNDER CONFINED FIELD TRIALS FOR EFFICACY AGAINST STEM BORERS PESTS AND DROUGHT TOLERANCE IN KENYA

APPROVAL NUMBER: **NBA/GMO/CO9/18/21**	DATE OF ISSUE : **30TH JUNE 2015** VALID UP TO : **30TH JUNE 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	**Maize (*Zea mays*)**
Quantity approved	**i. Total acreage not exceeding 3.0 Ha for CFT site at KALRO Kiboko and 3.0 Ha for CFT site at KALRO Kitale (subject to site approval by NBA and KEPHIS).** **ii. Quantity of GM maize seeds to be imported shall be indicated in notifications for imports to NBA and KEPHIS plant import permits**
Specification of the genetic modification	**Insect protected maize line MON810 was generated using the particle acceleration transformation method to transfer the *cry*1Ab gene to maize. The transformation plasmids used to produce MON810 line were PV-ZMBK07 and PV-ZMGT10.** **MON87460 was generated using Agrobacterium –mediated transformation to transfer the *csp*B gene to maize. The plasmid vector used PV-ZMAP595 was the binary plasmid type and was disarmed.** **The stack event MON810 X MON87460 was generated by crossing the inbred lines of MON810 and MON87460 though conventional breeding.**
Risk category	**Low**

Purpose of the use:	**The main objective of the proposed project is to assess the efficacy of transgenic maize with stacked event MON810xMON87460 obtained by crossing MON810 and MON87460 containing cry1Ab and *csp*B respectively against stem borer pests and drought stress under confined field conditions. The project will be carried out in two CFT sites namely; KALRO Kiboko representing lowlands and KALRO Kitale representing highlands.**

This approval is granted subject to the following conditions:-

1. **Applicant to obtain a plant import permit (PIP) from KEPHIS. On importation, the transgenic seed maize must be escorted by officers from NBA and KEPHIS from the port of entry to the experimental or storage site.**

2. **Ensure that the trial site at KALRO Kitale is inspected and approved by NBA and KEPHIS before issuance of PIP. The trial site in KALRO Kiboko must also be re-inspected to assess its current status before use in the new project.**

3. **A detailed schedule of activities not exceeding 5 years from the date of approval should be provided both to NBA and KEPHIS before commencement of the trial to facilitate monitoring of the project.**

4. **Before commencement of the trial, staff on both Kiboko and Kitale CFT sites must be trained on biosafety matters and evidence availed to NBA.**

5. **Develop and avail operational manual and/or SOPS at both Confined field trial sites.**

6. **Put and implement measures to ensure that no plant material from the trial may enter the human food or animal feed chain.**

7. **All the transgenic plant material including leaves, stovers, grains, seeds and below ground debris must be rendered biologically inactive before disposal.**

8. **Notify NBA and KEPHIS of any changes to the experiment or change of protocol that might alter the risk status of the GM maize plants. Any unusual observation including but not limited to stacked genes interaction should be reported to the regulator immediately.**

9. **Post-harvest monitoring to be done for at least twelve months (if rain fed) or 3 months (for irrigated CFTs). All the volunteer maize plants in the CFT and surrounding 400 metres must be uprooted and destroyed before flowering.**

10. **Considering that there exists limited biosafety data on stacked events of this nature, the authorized party is encouraged to generate critical biosafety data that would support environmental release of the transgenic event in future should it be necessary.**

11. **If the project proceeds to environmental release, appropriate Environmental Impact Assessment (EIA) approval certificate or exemptions must be obtained from National Environmental Management Authority (NEMA) prior to such release.**

12. **Provide quarterly and annual progress reports to NBA in the prescribed format.**

This approval is not transferrable and is valid for: **Five (5) years**	
Place: **NAIROBI** Date: **30TH JUNE 2015**	Name: **WILLY K. TONUI, PhD, RBP** Signature: **CHIEF EXECUTIVE OFFICER** **NATIONAL BIOSAFETY AUTHORITY**