

## FOURTH SCHEDULE

(r.9)



### NATIONAL BIOSAFETY AUTHORITY

**APPROVAL DOCUMENT OF THE APPLICATION FOR CONFINED FIELD TRIALS (CFT) TO DETERMINE THE PERFORMANCE OF MAIZE WITH EVENT MON 89034 (Bt *Cry1A.105* AND *Cry2Ab2* GENES) AGAINST STEM BORERS AND THE FALL ARMY WORM, AND EVENT MON 87460 (*CspB* GENE) FOR DROUGHT TOLERANCE**

APPROVAL NUMBER:  <b>NBA/GMO/CO9/18/46</b>	DATE OF ISSUE: <b>8<sup>TH</sup> AUGUST, 2023</b>  VALID UP TO: <b>7<sup>TH</sup> AUGUST, 2028</b>
In accordance with regulation 9 of the Biosafety (Contained Use) Regulations, of the Biosafety Act 2009, approval is hereby granted 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	<b>Kenya Agricultural and Livestock Research Organization (KALRO)</b>
Specification of the genetically modified organism	<b>Insect resistant and drought tolerant maize (<i>Zea mays</i>)</b>
Quantity approved	<b>3.0 Hectare of CFT site at KALRO, Kiboko, Makueni County</b>  <b>3.0 Hectare of CFT site at KALRO, Kitale, Trans-Nzoia County</b>
Specification of the genetic modification	<b>MON 89034 and MON 87460 were individually transformed through Agrobacterium-mediated transformation, then stacked through conventional breeding (Breeding stack of insect resistance and drought tolerance).</b>
Risk category	<b>Low</b>
Purpose of the use	<b>To conduct Confined Field Trials (CFTs) is to assess the efficacy of transgenic maize with stacked events of MON 87460 and MON 89034 containing <i>Cry1A.105</i>, <i>Cry2Ab2</i> and <i>CspB</i> genes against stemborers, Fall Army Worms (FAW) and drought stress respectively, under field conditions.</b>

This approval is granted subject to the following conditions:

1. **The Applicant shall seek import permit from the Kenya Plant Health Inspectorate Service (KEPHIS) and the National Biosafety Authority (NBA) for the importation of genetically modified maize seeds from South Africa;**
2. **The imported GM maize seeds shall be escorted by NBA Biosafety Officers from the Point of Entry to an approved Biosafety Level two Facility (BSL II) at KALRO and the two CFT sites in Kitale and Kiboko;**
3. **The Applicant shall ensure all personnel working in this project, including those on permanent, contracted and/or casuals are trained or sensitized on biosafety matters and records maintained for regular audits by NBA;**
4. **Before commencement of the Project, the Applicant shall avail a detailed work plan of the project for the next five (5) years including expected milestones. This is to aid the Regulators to plan for project monitoring;**
5. **An isolation distance of 400 meters shall be maintained between the CFT sites and conventional maize fields throughout the trial period.**
6. **All experimental materials shall be disposed-off on site through milling of grains, burning or chopping of all maize stovers and plant debris and burying on site, followed by six (6) months of post-harvest monitoring. No experimental material should leave the CFTs, except samples for analytical tests, which shall be stored in an approved BSL II Facility;**
7. **In the event of any accidental or intentional release of GM maize from the CFT sites, NBA and KEPHIS shall be notified immediately in writing, and the applicant shall be responsible for the restoration of the environment;**
8. **Biosafety data including possible interactions of the two Events (MON 89034\*MON 87460) shall be generated in accordance with the Food/Feed Safety Assessment and the Environmental Risk Assessment Guidelines published by the National Biosafety Authority; and**
9. **The Applicant shall provide quarterly and annual progress reports to the NBA in the prescribed format through the Institutional Biosafety Committee (KALRO IBC).**

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

Place : **NAIROBI**

DATE : **8<sup>TH</sup> AUGUST 2023**

Name: **DR. ROY B. MUGIIRA, Ph.D, MRSB**

Signature: 

**CHIEF EXECUTIVE OFFICER,  
NATIONAL BIOSAFETY AUTHORITY**