



## NATIONAL BIOSAFETY AUTHORITY

### **Summary Risk assessment report for the Application to introduce transgenic maize with water efficiency event MON 87460 to carry out confined field trials under moisture stress at Kiboko in Kenya**

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#### **Background information**

The National Biosafety Authority received an application on 19<sup>th</sup> May 2010, from Kenya Agricultural Research Institute (KARI) to introduce transgenic maize event MON 87460 containing Cold Shock Protein B (*Csp B*) gene coding for drought tolerance under confined field trial (CFT) at KARI Kiboko centre, Makueni County. The application was administratively screened and acknowledged. The main objective of the project is to assess expression of the target trait (water efficiency) in transgenic maize event MON 87460, and to determine its ability to mitigate the effects of moderate drought (moisture stress) under Kenyan conditions. MON 87460 is designed to provide farmers with better yield stability during periods when water supply is limiting by mitigating the effects of drought within the maize plant.

Maize (*Zea mays*) is the primary grain food crop in Sub Saharan Africa (SSA) with more than 300 million people depending on it as their main food source. In Kenya it is a staple food crop. The average yield of maize in SSA is approx 1.5ton/ha while that of farmers in developed world is approximately 5.0ton/ha. The low maize yield is attributed to a number of factors among them drought. Drought tolerance has been recognized as one of the most important targets of crop improvement programs, and biotechnology has been identified as a powerful tool to achieve significant drought tolerance.

The current project proposes to develop genetically modified maize that is drought tolerant suitable for the five agro-ecological zones where the Kenyan farmer lives. MON87460 event carries the *cspB* gene from a naturally occurring soil bacterium *Bacillus subtilis* to confer drought tolerance characteristics in the maize. The project is implemented as a public-private partnership called Water Efficient Maize for Africa (WEMA).

#### **Summary details of the application**

**Title of application:** Application to introduce transgenic maize with water efficiency event MON 87460 to carry out confined field trials under moisture stress at Kiboko in Kenya

**Applicant:** Kenya Agricultural Research Institute (KARI)

**Collaborating Institutions:** CIMMYT and Monsanto South Africa (Pty) Ltd

**Type of Application:** Confined field trial

**Location of Research:** KARI-Kiboko Research Centre, Makueni County GPS Coordinate 2°12'42.7"S 37°43'01.6"E

**Parental Organism:** Maize, (*Zea mays*)

**Trait being modified:** Drought Tolerance

**Genetic modification method used:** Agrobacterium mediated transformation

**Risk Assessment Summary Table**

No	Issue of concern	Potential adverse effects	Estimation of likelihood	Evaluation of identified risk/consequences	Estimation of risk	Risk management measures	Conclusion (Acceptable or Manageable)
1.	Gene flow	Out-crossing and gene flow	Unlikely	Risk of Crossing with neighbouring plants is marginal	Negligible risk	No maize in farmers plots.  Planting will be off season CFT field in KARI land	Acceptable
2.	Persistence and invasiveness	Increased persistence and invasiveness	Unlikely	Risk of Wild uncontrolled growth is marginal	Negligible risk	Maize flourish under agronomic practices  Experiment is under strict confinement	Acceptable
3.	Non-target organisms	Adverse effect on other non-target organisms	Unlikely	Risk of adverse effect on Protein toxic to animals is marginal	Negligible risk	Feeding study with birds show protein to be safe.  Biosafety data from informatics show protein to be safe	Acceptable
4.	Impact on biodiversity	Unintended loss of biodiversity	Unlikely	Potential adverse effects on biodiversity is minor	Low risk	CFT sufficiently isolated and confined.	Acceptable

						All materials in site to be destroyed at the end of the trial.	
5	Human and animal health	Genes safety and stability	Unlikely	Potential for introduced gene being Allergenic or Toxic is marginal	Negligible risk	Gene not known to be toxic. Ti plasmid disarmed  No consumption of experimental material expected at this stage, they will be destroyed upon project completion	Acceptable

### Overall conclusion on risk and risk management

Of the abiotic stresses, water is the major environmental constrains that limit production of maize worldwide. The genes which encode components of water/drought stress-related metabolic pathways have potential to mitigate the effects of drought, using well adopted germplasm to select suitable in MON 87460 transgenic maize for further study. Overall, the likelihood of risk arising from this research is extremely low; the risk management measures as indicated in the dossier and proposed approval conditions are stringent enough to contain experimental materials within the proposed CFT facilities.

### Decision:

The application is approved with the following conditions;

1. The applicant to provide a detailed work plan including such activities as movement of materials, storage and planting to facilitate oversight by the regulatory agency (KEPHIS).
2. Quantities and source of the materials to be imported should be specified during importation.
3. KEPHIS to receive and escort the imported transgenic material to the trial site and carry out monitoring and inspection during trial.
4. The Authorized party shall ensure that genetically engineered seed and / or plant material meant for the trial is transported in clearly identified, secure containers and kept separate from other seed and / or plant material.
5. All packaging material, shipping containers, and any other material accompanying the genetically engineered plant material shall be treated or

- disposed of in such a manner so as to prevent the dissemination and establishment of this material or any progeny plants.
6. In the case of accidental release or spillage of genetically engineered plant material during transport, recoverable seeds or seedlings shall be collected and destroyed, the site shall be marked and monitored, and oral notification shall be immediately provided to the National Biosafety Authority. Any plants arising from unrecoverable seed or seedlings shall be destroyed.
  7. Any equipment used during the trial shall be cleaned within the facility prior to movement in order to remove residual plant material.
  8. Surplus seed, transplants, or other plant material remaining after planting, or recovered during the cleaning of equipment, shall be destroyed using an approved method, such as; dry heat, steam heat, incineration, crushing, deep burial, or chemical treatment.
  9. A programme of activities at the facility shall be submitted to the NBA before the commencement of the trial.
  10. The Principal Investigator shall maintain adequate records.
  11. Ensure that no seed or other plant material from the contained trial may enter the human food or animal feed chain.
  12. Submit a report summarizing the completed trial, including any deleterious effects on plants, non-target organisms, or the environment.
  13. An inspector shall be allowed access, during regular business hours, to the place and to any records relating to the trial.
  14. The applicant should provide details of methods including PCR primers or their sources that can be used to detect the *Csp* B trans-gene if and when the need arises.
  15. The applicant should provide data on greenhouse studies that support the movement to confined field trials.
  16. Raise a notification within specified time and manner in the event of the following occurrences:
    - a. Orally notified immediately upon discovery and notify in writing 24 hours in the event of any accidental or unauthorized release of genetically engineered plant material.
    - b. In writing as soon as possible but not later than within 5 working days if genetically engineered plant is found to have characteristics substantially different from those listed in the application or suffers any unusual occurrence.
  17. That should there be any breach of the above, the NBA will order for termination of the trials and KARI will take liability of any risk thereof.

**Approval details:**

**Approval Number:** NBA/G8/9

**Date of approval:** 16<sup>th</sup> August 2010

**Duration of approval:** 5 years (Renewable)

**Approved by,**

A handwritten signature in black ink, appearing to read 'Dorington O. Ogoyi', written over a faint horizontal line.

**Prof. Dorington O. Ogoyi**  
**2020**  
**Chief Executive Officer**  
**National Biosafety Authority - Kenya**

**Date: 18th April**