



NATIONAL BIOSAFETY AUTHORITY

Summary risk assessment report on the application to carry out confined field trials of transgenic maize with Bt event MON810 containing cry1ab gene to evaluate the efficacy of Bt Alpha (δ) endotoxin against maize stem borers in Kenya

Background information

The National Biosafety Authority (NBA) received the application on 7th May 2012 from Kenya Agricultural Research Institute (KARI) to conduct a confined field trial on maize with Bt event MON810. The objective of the proposed Confined Field Trial (CFT) is to assess the efficacy of transgenic Bt maize event MON810 against the main stem borer species in Kenya under confined field conditions.

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 pest damage. The control of stem borers has in the past been by use of chemical pesticides, biological controls and other pest control practices such as conventional breeding, marker assisted selection and indigenous technical knowledge and cultural methods. These methods have contributed significantly in the control of stem borers but are reported not to be sustainable nor economical, hence the need for more novel approaches. Use of Bt technology has been fronted as the most modern, economical and sustainable method for stem borer control in maize, with presentation of results from many countries where the Bt technology has been deployed.

The applicant (KARI) proposes that if the CFT trial is successful, the Bt will at a later stage be introgressed into maize varieties adapted for Kenya's agro-ecologies to provide insect protection all packaged in the seed technology.

Summary details of the application

Title of application: Application to introduce transgenic maize with Bt event MON810 containing Cry1Ab gene to carry out confined field trials to evaluate the efficacy of Bt Alpha (δ) endotoxin against maize stem borers in Kenya

Applicant: Kenya Agricultural Research Institute (KARI)

Collaborating Institutions: Donald Danforth Plant Centre (DDPSC) and African Agricultural Technology Foundation (AATF).

Type of Application: Confined field trial

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

Parental Organism: Maize (*Zea mays*)

Trait being modified: Insect Resistance (maize stem borers)

Genetic modification method used: Particle acceleration transformation protocol

Risk Assessment Summary Table

No	Issues of concern	Potential adverse effects (Hazard)	Estimation of likelihood	Consequences if the adverse effect were to happen	Estimation of risk (Likelihood x consequence)	Risk management measures	Conclusion (Acceptable or Manageable)
1	Gene Flow / gene transfer	Possibility of out-crossing	Unlikely	Severity of harm from crossing with neighboring maize plants is minor	Low	<ul style="list-style-type: none"> • Dispersal of maize pollen is determined by a variety of environmental and physical factors. The distance that viable maize pollen can travel and disperse has been documented to be about 200 meters depending on prevailing wind conditions and other factors. • The CFT trials on GM maize Event MON810 will be conducted under confinement. The CFT facility at KARI – Kiboko is suitably isolated (<i>located more than 400 meters away from the nearest conventional maize field</i>) and with adequate containment provisions in place to take care of any would be gene flow concerns. • The genetic materials are not to be released outside the CFT site. • Out – crossing between transgenic maize event <i>MON810</i> and wild relatives is not possible since the wild type maize varieties are not native in Kenya. Out crossing is therefore negligible under these CFT conditions. 	Acceptable
2	Weediness / invasiveness	Possibility of the transgenic maize to become a weed or abnormally invasive	Unlikely	Severity of harm from increased fitness or competitiveness is minor	Low	<ul style="list-style-type: none"> • The inserted genes/trait does not alter or confer increased fitness to transgenic maize event MON810 when compared to its conventional non modified maize. • Biological maize seed dispersal is limited and natural dispersal of individual grains requires human or physical intervention. • By virtue of its biology, maize is not known to exhibit weedy or invasive characteristics and this would not be of concern in this trial. • Although maize appears as a volunteer plant in subsequent rotation, it has no inherent ability to propagate or persist. 	Acceptable
3	Biodiversity /	Loss of	Unlikely	Severity of	Low	<ul style="list-style-type: none"> • No GMO commercial release 	Acceptable

	Ecological impacts	Biodiversity		harm from loss of genetic variability which is necessary in future breeding programs is minor		<p>is intended for this activity at this stage.</p> <ul style="list-style-type: none"> • Kenya is not considered to be a centre of origin or diversity for maize. • All transgenic maize plant materials are to be uprooted, destroyed by incineration or burying in the soil at the end of the CFT trial. • There are no endangered species in or near the CFT site 	
4	Non target organisms	Adverse effect on other non-target organisms	Unlikely	Severity of harm from Protein toxicity to non-target animals is minor	Low	<ul style="list-style-type: none"> • The mode of action of Cry1Ab protein in MON810 indicates that Cry1Ab has selective toxicity against certain lepidopteran pests and not other insect orders. • No receptors for Cry proteins have been found in fish or birds; hence adverse effect on non-target organisms is not anticipated. • The expression levels of the Cry1Ab proteins in the MON810 are anticipated to be equivalent to those in the donor organism so that the gene products will not be over expressed to result in dosages that may exceed the acceptable safety levels. 	Acceptable
5	Persistence	GM persisting in the environment	Unlikely	Severity of harm from wild uncontrolled growth is minor	Low	<ul style="list-style-type: none"> • Maize is incapable of sustained reproduction outside domestic cultivation and non – invasive in natural habitats since it has lost its ability to survive in the wild as a result of intensive domestication. Maize volunteers that may result from MON810 field trials could easily be controlled by available agronomic practices such as manual uprooting, ploughing in or use of herbicides just as other volunteers from the conventional maize. • Maize is not known to exhibit seed dormancy 	Acceptable
6	Human/animal safety	Adverse effects on human and or animal health	Unlikely	Severity of harm from Allergenicity, Toxicity, safety of genes is minor since there is no consumption of experimental materials	Low	<ul style="list-style-type: none"> • The transgenic maize in this trial will not be consumed as all plants shall be destroyed after harvest and the grains and seeds will be milled and the resulting flour to be burnt. • In addition, the inserted gene products (Cry1Ab proteins) are not known to be toxic or allergic to mammals. • The source of the gene 	Acceptable

						<p><i>(Bacillus thuringiensis)</i> raises no significant safety concerns as it exists naturally in the soil and Bt pesticides have been in commercial use for long with a history of safe use. As a result, human contact with the maize plants in the course of the trial does not pose safety concerns.</p> <ul style="list-style-type: none"> • The <i>np1II</i> used as a marker has been demonstrated to be safe. Furthermore, these markers are to be removed and will not be present in MON810 transgenic maize. 	
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Overall conclusion on risk and risk management

The application meets the laid down Biosafety requirements for the approval of a CFT research activity under the Kenyan Biosafety Law. The information provided on the environmental impacts associated with the cultivation of the event MON 810 in the stated CFT site indicates that the likelihood of the MON810 maize to escape, spread and be established in the surrounding environment is minimal. There is enough scientific literature and regulatory decisions pertaining to the environmental, food and feed safety associated with Bt maize. The scope of the management, contingency, monitoring plans and their enforcement as provided for by the applicant are adequate to mitigate against any unforeseen risk that may arise from the use of maize line MON 810 in this CFT facility. Scientific and regulatory capacity also exists in executing this CFT activity in Kenya.

Decision

The application is approved with the following conditions;

1. Progress reports on the experiment should be provided to the NBA and Kenya Plant Health Inspectorate Service (KEPHIS);
2. Import permit to be obtained from KEPHIS;
3. Quantities and source of materials to be imported should be specified during importation;
4. NBA and KEPHIS to receive and escort the transgenic material to the trial site and carry out monitoring and inspection during the trial;
5. All transgenic material generated from this study to be uprooted and destroyed by incineration at the end of the trial.

Approval details

Approval number: NBA/GMO/C09/18/6

Approval Date: 30th October 2012

Duration of approval: 5 years (Renewable)

Approved by,

A handwritten signature in black ink, appearing to read 'D. Ogoi', written over a light grey rectangular background.

Prof. Dorington O. Ogoi
Chief Executive Officer
National Biosafety Authority - Kenya

Date: 18th April 2020