



**NATIONAL BIOSAFETY AUTHORITY**

**RISK ASSESSMENT REPORT**

**APPLICATION FOR ENVIRONMENTAL RELEASE, CULTIVATION  
AND PLACING ON THE MARKET OF MON 810 EVENT IN MAIZE  
VARIETIES**

**APPLICANT: KENYA AGRICULTURAL AND LIVESTOCK RESEARCH  
ORGANIZATION (KALRO)**

**CO-APPLICANT: AFRICAN AGRICULTURAL TECHNOLOGY  
FOUNDATION  
(AATF)**

**DECEMBER 2015**

## **INTRODUCTION**

### **1.1.The environmental release Application**

The National Biosafety Authority received an application for environmental release, cultivation and placing on the market of insect protected MON 810 maize and its varietal derivatives in Kenya on 18<sup>th</sup> June 2015. This application was made by the Kenya Agricultural and Livestock Research Organisation (KALRO); who is the main applicant and the African Agricultural Technology Foundation (AATF) as a co-applicant. Prior to making the application, the applicant in collaboration with various partners including the International Maize and Wheat Improvement Centre (CIMMYT) and Monsanto conducted several contained and confined field trials in Kenya at KALRO Biosafety Level II greenhouse facility in Nairobi and CFT site at Kiboko research centre.

### **1.2.Maize production in Kenya**

Maize is the most important cereal crop and staple food for more than 80% of Kenyans both as a subsistence and commercial crop. It is a multi-purpose crop used for food, its grains and stovers are used as feed for livestock. Maize production in Kenya has remained low and the deficit in production is supplemented by imports. The low production is attributed to a wide range of causes including erratic climatic conditions, poor management practices and high incidences of pests such as stem borers. The most economically important stem borers in Kenya are the African stem borers (*Busseola fusca*) predominantly found in the Kenyan highlands and the spotted stem borers (*Chilo partellus*) predominantly found in the Kenyan lowlands and dry areas. Yield losses due to stem borer damage in Kenya are estimated at 400,000 metric tonnes per year (Groote *et al.*, 2004). The major method of controlling the stem borers is through application of pesticides, under the current production system where maize is cultivated. Chemical control using insecticides is ineffective once the borers have tunneled into plant due to the inaccessibility of the chemical to the pest. Genetic engineering provides an alternative to the use of chemical pesticides and also complements other existing technologies of pest management.

### **1.3.Description of the modified maize**

Using modern biotechnology, Kenya Agricultural Research Organization (KALRO) and African

Agricultural Technology Foundation (AATF) have developed insect protected maize event MON 810 (whose unique identifier is MON-ØØ81Ø-6) that produces the naturally occurring *Bacillus thuringensis* (Bt) protein, Cry1Ab. The MON 810 is protected from feeding damage by certain lepidopteran insects (stem borers) specifically; the African stem borer (*Busseola fusca*); and the spotted stem borer (*Chilo partellus*). While benefits of modern biotechnology are recognized, there are also potential adverse effects that may arise from the use of this technology. Among the concerns are impacts on human and animal health as well as the environment where these crops are introduced.

#### **1.4. Review process of the environmental release Application**

As required under the Biosafety Act No. 2, 2009, when the application was received by NBA, it was screened for administrative completeness and acknowledged. When additional information was required, NBA sought this information from the applicant and reviewed for relevance and adequacy. The application summary was posted in the NBA website; a public notice was placed in two nationally circulated newspapers and also in the Kenya Gazette on 24<sup>th</sup> July 2015. Public comments were received within 30 days as provided for in the Biosafety Act and Biosafety (Environmental release) Regulations, 2011 up to 23<sup>rd</sup> August 2015. A public forum on the application was also held on 21<sup>st</sup> August 2015 at Kenyatta International Convention Centre (KICC). The application was also sent to other regulatory agencies including KEPHIS, NEMA, PCPB and Department of Public Health. The Application was further reviewed by independent experts on food safety, environmental safety and socio-economic impact assessment for review. This report addresses risk assessment on two broad areas; food safety and environmental risk assessment. The food safety assessment included consideration of: (i) the genetic modification to the plant; (ii) the potential toxicity and allergenicity of any new proteins; and (iii) the composition and nutritional adequacy of the food, including whether there had been any unintended changes. The environmental risk assessment included consideration of: (i) unintended effects on plant fitness due to genetic modification; (ii) potential for gene transfer (Vertical and horizontal gene transfer); (iii) impact on biodiversity; (iv) potential impact on target organisms leading to development of insect resistance; (v) Impact on non-target organisms; (vi) potential to adversely affect bio-geochemical processes; and (vii) potential for the emergence of secondary pests.

From the received comments and reviews, the NBA has compiled a comprehensive food safety assessment and environmental risk assessment of the insect protected MON 810 maize. On the basis of all available evidence to-date, including detailed studies provided by the applicant, available literature on this event, the NBA concludes that MON 810 is considered substantially equivalent to conventional maize and open field trials during NPT testing pose no risk to humans, animals and the environment. However, cultivation and/or placing on the market of MON 810 Bt maize will only be considered by the NBA once the applicant meets the approval conditions listed in this report.

## RISK ASSESSMENT SUMMARY

No.	Issues of concern	Potential adverse effects (Hazard)	Estimation of likelihood	Estimation of risk/consequences (Hazard x Likelihood)	Consideration of risk management	Acceptable/Manageable
1	Gene flow	Vertical gene transfer: Possibility of out-crossing with conventional maize and wild relatives of maize leading to increased fitness thus causing increased competitive advantage	Unlikely	Crossing with neighbouring sexually compatible plants is negligible	<ul style="list-style-type: none"> <li>Out-crossing of Mon 810 with conventional maize in Kenya calls for a stringent stewardship program and a national policy on co-existence.</li> </ul>	Manageable, once a Coexistence policy is in place and the applicant has provided a detailed Stewardship Program to the NBA
		Horizontal gene transfer with a possibility of causing antibiotic resistance	Unlikely	Development of antibiotic resistance by bacteria through horizontal gene transfer from plants is unlikely	<ul style="list-style-type: none"> <li>Gene transfer from plants to microorganisms under natural conditions is unlikely.</li> </ul>	Acceptable
2	Persistence and invasiveness	Possibility of increased fitness or competitive advantage	Unlikely	Risk of wild uncontrolled growth is low	<ul style="list-style-type: none"> <li>Maize is not considered to be a weed nor invasive in an agricultural setting;</li> <li>Seed mediated gene flow outside uncultivated fields, unmanaged habitats is unlikely as maize is incapable of sustained reproduction without human intervention.</li> <li>It is well documented that maize does not possess the potential to become weedy due to characteristics such as lack of seed dormancy, the non-shattering and enclosed aspects of maize cobs and poor competitive ability of seedlings.</li> </ul>	Acceptable
3	Gene safety	Adverse effects on human and animal health	Unlikely	The risk of Allergenicity, Toxicity and Pathogenicity occurring is low based on studies using bacterial surrogate protein data.	<ul style="list-style-type: none"> <li><i>Bacillus thuringiensis</i> is the source of Cry1Ab and has no history of causing allergy. The Cry1Ab has demonstrated history of safe use and has been used in Bt microbial pesticides to control lepidopterans insect pests for more than 45 years.</li> <li>The Cry1Ab protein substitute produced in <i>E. coli</i> does not show amino acid sequence homology to known toxins or allergens.</li> </ul>	unlikely to cause adverse effect
4	Stability of inserted gene	Gene disintegration	Unlikely	The risk of gene disintegration in subsequent generations is low	<ul style="list-style-type: none"> <li>Segregation and stability data are consistent with a single active site of insertion of Cry1Ab gene into genomic DNA of MON 810.</li> <li>Furthermore, generation of homozygous lines further demonstrates the stability of the insert.</li> <li>Generation Stability of the MON 810 event has also been demonstrated</li> </ul>	Acceptable

					using three generations of MON810 under field trials. The results demonstrate that the insertion event has been stable during the maize breeding.	
5	Non target organisms	Adverse effect on other non-targeted organisms leading to loss of bio-diversity	Unlikely	The risk of the inserted genes causing adverse effects on non-targets is negligible	<ul style="list-style-type: none"> <li>• Mon 810 expresses the introduced Cry1Ab protein which protects the plants against predation by stem borers.</li> <li>• The Cry Protein exhibits selective toxicity towards certain lepidopterans pests, but not against other insect orders. Therefore, this protein has no deleterious effect on beneficial or other non-target insects since they do not have receptors for this toxin.</li> </ul>	Acceptable

## **OVERALL CONCLUSION**

MON 810 maize is considered as safe as conventional maize as evaluated by Technical Committee of the NBA Board with food/feed safety data based on data from the USA. However, compositional analysis on Kenyan maize varieties under Kenyan environmental conditions needs to be conducted during NPTs prior to Varietal Release and Placing in to the Kenyan Market.

## **Recommendation**

The NBA approves the application by Kenya Agricultural and Livestock research organization (KALRO) and African Agricultural Technology Foundation (AATF) to conduct an environmental release subject to; conducting National Performance Trials (NPTs), collecting compositional analysis data as per guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA plants (KS CAC/GL 45-2003) and carrying out Environmental Impact Assessment (EIA) for NPT sites, concurrently for MON 810 event in maize varieties in Kenya.

The approval is subject to the following conditions:

1. Prior to establishment of NPT sites, conduct an Environmental Impact Assessment (EIA) and submit an Environmental and Socio Impact Assessment (ESIA) Project Report to NEMA for review and approval;
2. Comply with other existing national laws and policies relevant to this approval;
3. Provide a detailed Biosafety Stewardship Program and Monitoring Roadmap to NBA for approval.
4. Provide compositional analysis as per the guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA plants (KS CAC/GL 45-2003) on Kenyan MON 810 event in maize varieties adapted to Kenya's agro-ecologies.

Once the applicant meets the above conditions, the applicant may make a request for NBA consideration on cultivation and placing on the market of MON 810 Bt maize.

## **SIGNED**

NAME .....SIGN.....      DATE: 21<sup>st</sup> December 2015

**CHIEF EXECUTIVE OFFICER**