NATIONAL BIOSAFETY AUTHORITY

SUMMARY RISK ASSESSMENT REPORT

APPLICATION FOR THE ENVIRONMENTAL RELEASE OF INSECT PROTECTED MON 15985 BT COTTON AND ITS VARIETAL DERIVATIVES

APPLICANT: MONSANTO KENYA LIMITED

AUGUST 2016

Introduction

The environmental release Application

The National Biosafety Authority received an application for environmental release, cultivation and placing on the market of insect protected MON 15985 cotton and its varietal derivatives in Kenya on 4th August 2015. The application was administratively screened and the applicant was requested to revise the application and re-submit it afresh. The application was subsequently re-submitted on 27th October, 2015 and acknowledged on 10th November 2015. In two instances, 9th February and 26th February 2016, the Authority requested the applicant to provide additional information which was subsequently provided on 25th May 2016. This application was made by Monsanto Kenya Limited on behalf of Monsanto Company. Prior to making the environmental release application, KARI (now KALRO) on behalf of the Applicant had conducted one CFT season with BollGard I (MON 531) and four seasons with BollGard II (MON 15985) field trials of Bt cotton at KALRO – Mwea CFT site in Kirinyaga County from the year 2005 to 2010.

Cotton production in Kenya

Cotton (*Gossypium hirsutum*) is the leading plant fibre crop produced in the world including Kenya where it is grown as a cash crop. Cotton is grown by small scale farmers in various agro-ecological zones in Kenya mainly in low rainfall and semi-arid areas. These zones include areas such as Rift Valley, Central, Coast, Eastern, Nyanza and Western provinces. Cotton offers an opportunity for poverty reduction. The crop's present contribution to the national economy is smaller compared to other cash crops such as coffee, tea and pyrethrum. However, it has great potential in the creation of employment, both at the household and industrial level as it is the principal raw material for the local spinning and textile industry. There has been a decrease in cotton production through the years from a high of 70,000 bales in 1985 to a low of approximately 20,000 bales by year 2001 (Ikiara and Ndirangu, 2002; Waturu, 2012). Several factors contributing to collapse of cotton industry include; high incidence of pests and diseases, weeds, lack of certified seeds, high input costs, collapse of extension services, lack of credit, low producer prices and marketing uncertainties. The declining trend of cotton production has reversed since the Government introduced measures to revitalize the cotton sector. The national production of cotton was estimated at 40,000 bales per annum by year 2006. Current cotton production averages at 572 kg/ha compared to a potential of 2500 kg/ha. The current demand for cotton stands at 140,000 bales with the deficit met from imports.

In terms of pest challenges, the African bollworm alone can destroy entire cotton fields (100% crop damage), if not controlled (Waturu, 2007). The primary pests infesting cotton are the African bollworm (*Helicoverpa armigera*), cotton semilooper (*C. flava*), tobacco budworm and the pink bollworms. Other important pests of cotton include; cotton leaf worm; cotton red spider mite; cotton jassid; aphids; whiteflies and cotton stainers. Pest control and related activities take up about 32% of production costs (Waturu, 2001). Cotton typically requires numerous chemical insecticide treatments for Lepidoptera control. The genetically modified cotton is expected to significantly reduce chemical insecticide use and provide a major benefit to farmers and the environment.

Description of the modified cotton

MON 15985 Bt cotton has been genetically engineered to be resistant to selected insect pests (Lepidoptera) specifically the African bollworm (*Helicoverpa armigera*) and the cotton semi-looper (*C. flava*). Insect resistance was accomplished by the insertion of two genes from naturally occurring bacteria called *Bacillus thurigiensis* which encode for the production of toxins targeting only the Lepidoptera larva but having no adverse effect to mammals, birds, fish and beneficial insects.

The Bt cotton was produced by two subsequent transformations of cotton tissue. Firstly, cotton tissue was genetically modified via *Agrobacterium tumefaciens* mediated transformation, generating MON 531 (BollGard I) with Cry1Ac gene. The transformation of MON 531, using the particle acceleration transformation system, introduced a second genetic modification Cry2Ab2 gene, which is referred to as MON 15947. The final cotton plant, containing both genetic modifications MON 531 and MON 15947, is named MON 15985 commonly referred as BollGard II. MON 15985 Bt cotton is therefore a second-generation stack event developed to produce both Cry1Ac and Cry2Ab2 proteins that confer enhanced protection from certain lepidopteran insect pests in cotton.

MON 15985 was first approved for commercialization in the United States of America in 2002 and since that time, it has been authorized for general cultivation in many other countries such as; Burkina Faso (2009), South Africa (2003), Japan (2004), Brazil (2009), Costa Rica (2009), Mexico (2008), China (2006), Australia (2002), and India (2006). In addition, several countries have authorized the use of products derived from event MON 15985 cotton as food (Australia, Brazil, Burkina Faso, Canada, China, Colombia, EU, Japan, Mexico, New Zealand, Phillipines, Singapore, South Korea, Taiwan and USA (ISAAA 2016).

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 20th November 2015. Public comments were received within 30 days as provided for in the Biosafety Act and Biosafety (Environmental release) Regulations, 2011 up to 19th December 2015. In total, the Authority received 11,719 comments from the public either supporting or opposing the release of Bt cotton into the environment. A public forum on the application was also held on 11th December 2015 at Kenya School of Monitory Studies (KSMS). The application was also sent to other regulatory agencies including KEPHIS, NEMA, PCPB, DVS 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.

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.	Substantial equivalence	Possibility of the MON 15985 cottonseed composition being different from cottonseed from conventional cotton	Unlikely	Cottonseed produced from MON 15985 is compositionally similar to cottonseed from conventional cotton. The risk is therefore negligible	None	Acceptable
		Possibility of the nutritional aspects of the **food** from MON 15985 being different from food from other non GM cotton	Unlikely	Cottonseed produced from MON 15985 is compositionally similar to cottonseed from conventional cotton. MON 15985 cotton seed for use as food is therefore nutritious as conventional cotton. The risk is therefore negligible	None	Acceptable
		Possibility of the nutritional aspects of the **feed** from MON 15985 being different from feed from other conventional cotton	Unlikely	Based on data from USA, cottonseed produced from MON 15985 is compositionally similar to cottonseed from conventional cotton. MON 15985 cottonseed for use as feed is therefore nutritious as conventional cotton. The risk is therefore negligible	None	Acceptable
2	Gene safety	Toxicity: Possibility of Cry1Ac, NptII, GUS E377K and Cry2Ab2 proteins being toxic	Unlikely	The possibility of Cry1Ac, NptII, GUS E377K and Cry2Ab2 proteins being toxic is unlikely.	Post release monitoring of non-targets by the applicant, NBA and Regulatory Agencies	Acceptable
		Allergenicity: Possibility of Cry1Ac, NptII, GUS E377K and Cry2Ab2 proteins being allergenic	Unlikely	The possibility of Cry1Ac, NptII, GUS E377K and Cry2Ab2 proteins being allergenic is unlikely.	Post release monitoring of non-targets by the applicant, NBA and Regulatory Agencies	Acceptable
		Pathogenicity. Possibility of *Agrobacterium tumefasciens* being pathogenic or causing disease to	Unlikely	Risk is negligible	The *Agrobacterium tumefasciens* used as the plasmid vector in developing the 1st event MON 531 was **disarmed**	Acceptable

		cotton plant				
3.	Gene flow	Vertical gene transfer: Possibility of out-crossing with conventional and wild relatives of cotton leading to increased fitness thus causing increased competitive advantage	Likely	Potential adverse effects due to crossing with other sexually compatible plants is negligible	Crossing between Bt cotton and conventional cotton is likely to happen hence the need for a Coexistence policy. There is likely to be no or negligible chance of out crossing between Bt cotton and wild relatives. The cultivated cotton species in Kenya is *Gossypsium hirsutum* which has allotetraploid genome; the wild cotton species found in Kenya are of *G. barbadense, G. harbaceum* and *G.kirkii.* Both the *G. harbaceum* and *G.kirkii* are diploids, therefore are sexually incompatible with the cultivated cotton in Kenya. In the unlikely event of cross pollination between the cultivated and wild cotton varieties in Kenya, it would result in infertile offsprings due to sterility of the hybrids. *G. barbadense,* a allotetraploid is however present in Kenya. This wild relative is capable of out-crossing with *G. hirsutum* and form viable hybrids. This is unlikely due to barriers to gene transfer namely; flowering periods between *G. barbadense* (wild relative of cotton) *and G.*	Manageable, once a Coexistence policy is in place and the applicant has provided a detailed post release monitoring and Stewardship Program to the NBA

					hirsutum (cultivated cotton) are different, G. hirsutum is not commercially cultivated in Kenya and rarely globally. Post release monitoring on potential adverse effects due to possible outcrossing with wild relatives needed.	
		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	Gene transfer from plants to microorganisms under natural conditions is unlikely.	Acceptable
4.	Persistence and invasiveness	Possibility of increased fitness or competitive advantage	Unlikely	Risk of wild uncontrolled growth is low	Cotton is not considered to be a weed nor invasive in an agricultural setting. It does not possess any of the attributes commonly associated with weeds. Seed is the only reproductive survival structure of cotton and natural regeneration from. The appearance of cotton volunteers developing from dropped bolls or seeds can be easily controlled by current agronomic practices, including cultivation or the use of herbicides. Seed mediated gene flow outside uncultivated fields, unmanaged habitats is unlikely as cotton is	Acceptable

					incapable of sustained reproduction without human intervention. The potential for lepidopteran protection trait in MON 15985 to cause a selective advantage of cotton outside an agro-ecosystem is exceedingly low as cotton cannot persist in the agricultural environment without human intervention	
5.	Target organisms (cotton bollworms)	Development of insect resistance	Likely	Moderate risk	• Structured Refuge strategy of 80/20 • Strict adherence to a stewardship program that will involve farmers training • Post release monitoring by applicant, NBA and other relevant Regulatory agencies	Manageable
6	Secondary pests	Emergence of secondary pest	Likely	Moderate risk	• Strict adherence to a stewardship program that will involve farmers training • Post release monitoring by applicant, NBA and other relevant Regulatory agencies	Manageable
7	Non target organisms	Adverse effect on other non-targeted organisms leading to loss	Unlikely	There is negligible risk for harmful effects of MON 15985 on non-target organisms (vertebrates and	Post release monitoring by applicant, NBA and other relevant	Acceptable

		of bio-diversity		invertebrates), either through direct or indirect contact with the expressed Cry1Ac and the Cry2Ab2 proteins. 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.	Regulatory agencies	

Overall conclusion on risk assessment

MON 15985 cotton is considered as safe as conventional cotton as evaluated by Technical Committee of the NBA Board with food/feed safety data based on data from the USA. Overall, on the basis of all available evidence to-date, including detailed studies provided by the applicant, available literature on this event, it is concluded that MON 15985 cotton is considered as safe as the conventional cotton and its environmental release for the purpose of conducting National Performance Trials (NPTs) pose no risk to humans, animals and the environment. However, confirmatory tests for absence of AadA proteins in leaf tissues and cotton seed as well as compositional analysis for Bt cotton varieties adopted in Kenya's agro-ecologies need to be conducted during NPTs prior to Varietal Release and Placing in the Kenyan Market.

As performance data is not available at this point in time, it is proposed that the applicant submits an application for open field cultivation and placing on the market of Bt cotton varieties at no extra cost once cleared by KEPHS and NEMA.

Should new information become available on the safety of this approved Bt cotton during the NPT, necessary measures and regulatory decisions will be taken as appropriate.

Decision

The National Biosafety Authority approves the Application by Monsanto Kenya Ltd for limited environmental release for the purpose of conducting National Performance Trials (NPTs), confirmatory tests for absence of AadA proteins in leaf tissues and cotton seed, compositional analysis data as per Codex Alimentarius

guidelines and Environmental Impact Assessment (EIA) for NPT sites, concurrently for MON 15985 event in cotton varieties in Kenya. The Applicant should submit an application for placing on the market with Kenyan generated data to NBA at no extract fees for approval after meeting NEMA and KEPHIS requirements.

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 15985 event in cotton varieties adapted to Kenya's agro-ecologies;

5. Carry out confirmatory tests for absence of AadA protein on cotton seed and leaf tissues on Kenyan MON 15985 event in cotton varieties adapted to Kenya's agro-ecologies;