

RISK ASSESSMENT FOR BOLLGARD II™ COTTON - MON15985

1. General Information:	
a. Name of Applicant	Quton Seed Company
b. Risk Assessment Reference Number	RA02260002
c. Date of Assessment	
d. Responsible Authority	National Biotechnology Authority
e. Intended Use of the organism	☐ Contained Use ☒ Trial Release ☐ General Release ☐ Food/Feed Processing
2. Objective and Scope of the Risk Assessment:	This risk assessment encompasses evaluating potential risks associated with conducting confined field trials for the insect resistant Bollgard® II Cotton (Event MON15985) on biodiversity.
3. Details of organism to be introduced:	
a. Identification	
i. Common Name	Bollgard II™ cotton - MON15985
ii. Phylum	Anthophyta
iii. Class	Dicotyledoneae
iv. Order	Malvales
v. Family	Malvaceae
vi. Genus	<i>Gossypium</i>
vii. Species	<i>G. hirsutum L</i>
b. Origin/Natural Habitat	Upland cotton is native to the tropical and subtropical regions of Central and South America
c. Receiving Environment/Proposed release environment	The confined field trials for insect resistant Bollgard® II Cotton (Event MON15985) will be carried out on five agricultural research stations across Zimbabwe.

d. Differences from the conventional counter part	Bollgard® II Cotton has a double gene (cry1Ac and cry2Ab) technology which provides protection against Bollworm complex and <i>Spodoptera spp.</i>
e. Detection	
i. Proposed Method	Event-specific quantitative real-time PCR
ii. Specificity	The detection method is event specific.
iii. Sensitivity	Limit of detection (LOD) is 0.02%
4. Details of modification:	
a. Donor organism	
i. Scientific Name	<i>Bacillus thuringiensis</i>
ii. Source/origin/Natural Habitat	The organism is ubiquitous.
b. Receipt organism	
i. Scientific Name	<i>Gossypium hirsutum L</i>
ii. Source/origin/Natural Habitat	The cotton hybrids to used were developed in India.
c. Vector	
i. Identification	PV-GHBK11; PV-GHBK04
ii. Transformation method	Biolistic / Particle gun.
d. Inserted Genetic Material and Traits	
i. Brief description of modification	MON15985 was generated by re-transforming Bollgard® cotton event MON531, which produces cry1Ac and NPTII marker proteins. Cry2Ab2 and the uidA marker genes were inserted into the MON531 genome through microparticle bombardment of plant cells, resulting in Bollgard® II Cotton MON15985 that produces Cry2Ab2 and GUS proteins.
ii. Intended traits	Production of Cry1Ac and Cry2Ab proteins for effective control of the major lepidopteran insect pests of cotton, including the cotton bollworm, tobacco budworm, pink bollworm and armyworm.

5. Environment Impact Assessment:	
a. Is there potential for a gene flow?	☐ Yes ☒ No ☐ Unknown Comment: Isolation distances have been established for each trial site to avoid potential gene flow.
b. Is there potential adverse impact on non-target organisms?	☐ Yes ☒ No ☐ Unknown Comment:
c. Is there potential adverse impact on biodiversity?	☐ Yes ☒ No ☐ Unknown Comment: Bollgard® II Cotton has been approved and commercialised in countries worldwide and no adverse effects on biodiversity have been reported.
d. Other environmental considerations:	None
6. Impact on Human Health Assessment:	
a. Potential allergenicity	☐ Yes ☒ No ☐ Unknown Comment:
b. Potential Toxicity	☐ Yes ☒ No ☐ Unknown Comment:
c. History of safe use	☒ Available

	☐ None ☐ Unknown Comment: Bollgard® II Cotton has been cultivated in several countries worldwide and no adverse effects have been reported. There is also a history of safe dietary and occupational exposure to Cry proteins derived from <i>Bacillus thuringiensis</i>.
7. Conclusion:	
a. Summary of potential adverse effects	There are no potential adverse effects as the modification does not have deleterious effects to non-target organisms such as beneficial insects, birds, fish and mammals, including humans.
b. Overall risk level	☒ Minimal ☐ Low ☐ Moderate ☐ High
c. Is the risk acceptable?	Yes
d. Socio-economic considerations	None
e. Public consultation feedback	None
f. Post-release monitoring requirements	The applicant must monitor the trial release site, for a period of one (1) for any volunteer plants and make any appropriate relevant actions under the supervision of the National Biotechnology.
g. Decision	Approved for confined field trials
h. Conditions accompanying the decision	Applicant to adhere to the established biosafety guidelines.
8. Overall comment:	Bollgard II™ cotton - MON15985 was approved for use in confined field trials. The NBA will supervise all the activities under the confined field trials in accordance with the provisions of the NBA Act and the relevant regulations.

