

COMMON FORMAT FOR Risk Assessment

(In accordance with Annex III of the Cartagena Protocol on Biosafety)

Risk assessment details	
1. Country Taking Decision:	South Africa
2. Title:	Application for import and trial release of genetically modified TC1507xMON810xNK603 maize.
3. Contact details:	<p>DuPont Pioneer P.O Box 8010 Centurion, 0046</p> <p>On behalf of DuPont Pioneer and other affiliated companies.</p> <p>Tel: +27 (0)12 – 683 5700 Fax: +(0)12 – 663 4190</p>
LMO information	
4. Name and identity of the living modified organism:	<p>The LMO is TC1507xMON810xNK603 maize, obtained from traditional breeding methods between progeny of genetically modified TC1507, MON810 and NK603 maize. The LMO contains the genetic elements introduced in TC1507 maize, MON810 maize and NK603 maize.</p> <p>TC1507 maize contains <i>cry1F</i> and <i>pat</i> genes. The Cry1F protein expressed in TC1507 maize confers season-long resistance against certain lepidopteran pests. Also, by producing the PAT protein, encoded by the <i>pat</i> gene introduced as a selectable marker in TC1507 maize, TC1507 maize plants are tolerant to glufosinate-ammonium herbicide.</p> <p>The genetically modified MON810 maize was produced using the particle acceleration method with plasmid vector PV-ZMBK07. The plasmid vector PV-ZMBK07 contained the <i>cry1Ab</i> coding sequence of interest, which was derived from <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i>.</p> <p>NK603 maize was obtained by microprojectile bombardment using particles coated with a purified fragment PV-ZMGT32L obtained from plasmid PV-ZMGT32. The modification is comprised of two copies of a gene element containing a glyphosate tolerant form of the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) from <i>Agrobacterium</i> sp. strain CP4 under the control of two separate promoters. The CP4 EPSPS protein from <i>Agrobacterium</i> is naturally resistant to this inhibition and allows NK603 plants to continue to develop normally in the presence of glyphosate.</p>

5. Unique identification of the living modified organism:	DAS-Ø15Ø7-1 x MON-ØØ810-6 x MON-ØØ6Ø3-6 maize.
6. Transformation event:	TC1507xMON810xNK603.
7. Introduced or Modified Traits:	Herbicide tolerance and insect protection.
8. Techniques used for modification:	Traditional breeding stack.
9. Description of gene modification:	<p>TC1507xMON810xNK603 maize, obtained from traditional breeding methods between progeny of genetically modified maize, TC1507, MON810 and NK603 maize.</p> <p>TC1507 maize was obtained by insertion of a linear DNA fragment (insert PHI8999A) containing the <i>cry1F</i> and <i>pat</i> coding sequences and the necessary regulatory components into maize cells using the particle acceleration method. TC1507 maize expresses the Cry1F protein that confers resistance to certain lepidopteran pests. The PAT protein, as acts as a selectable marker that confers tolerance to glufosinate-ammonium herbicides.</p> <p>MON810 maize was produced using the particle acceleration method with plasmid vector PV-ZMBK07. The plasmid vector PV-ZMBK07 contained the <i>cry1Ab</i> coding sequence of interest, which was derived from <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i>.</p> <p>NK603 maize was obtained by microprojectile bombardment using particles coated with a purified fragment PV-ZMGT32L obtained from plasmid PV-ZMGT32. The modification is comprised of two copies of a gene element containing a glyphosate tolerant form of the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) from <i>Agrobacterium</i> sp. strain CP4 under the control of two separate promoters. The CP4 EPSPS protein from <i>Agrobacterium</i> is tolerant to this inhibition and allows NK603 plants to continue to develop normally in the presence of glyphosate under certain growing conditions.</p>
Characteristics of modification	
10. Vector characteristics (Annex III.9(c)):	No vector was used, as the TC1507xMON810xNK603 maize has been obtained from traditional breeding methods between progeny of the genetically modified TC1507, MON810 and NK603 maize. Therefore, there is no new genetic modification in TC1507xMON810xNK603 maize.
11. Insert or inserts (Annex III.9(d)):	Please refer to 4 and 9.

Recipient organism or parental organisms (Annex III.9(a)):	
12. Taxonomic name/status of recipient organism or parental organisms:	Family name: Gramineae (Poaceae) Genus: <i>Zea</i> Species: <i>Zea mays</i> L.
13. Common name of recipient organism or parental organisms:	Maize; corn.
14. Point of collection or acquisition of recipient or parental organisms:	USA
15. Characteristics of recipient organism or parental organisms related to biosafety:	Maize is a highly domesticated agricultural crop with a long history of safe use.
16. Centre(s) of origin of recipient organism or parental organisms:	Central America (Mexico and Guatemala)
17. Centres of genetic diversity, if known, of recipient organism or parental organisms:	Mexico and Guatemala
18. Habitats where the recipient organism or parental organisms may persist or proliferate:	Maize is a highly domesticated agricultural crop. It is unable to persist or proliferate outside heavily managed agricultural habitats out of its centre of origin.
Donor organism or organisms (Annex III.9(b)):	
19. Taxonomic name/status of donor organism(s)	<i>Bacillus thuringiensis</i> , <i>Zea mays</i> L. and Cauliflower Mosaic Virus are the donor organisms of the introduced regulatory sequences.
20. Common name of donor organism(s):	<i>Bacillus</i> spp. <i>Zea mays</i> L.: Maize, corn; Cauliflower Mosaic Virus
21. Point of collection or acquisition of donor organism(s):	USA

22. Characteristics of donor organism(s) related to biosafety:	<p><i>Bacillus</i> spp. are common soil bacteria. Maize (<i>Zea mays</i>) has a long history as agricultural crop and is not recognized as harmful for the human health.</p> <p>Cauliflower mosaic virus is a DNA caulimovirus with a host range restricted primarily to cruciferous plants.</p>
Intended use and receiving environment	
23. Intended use of the LMO (Annex III 9(g)):	General release of TC1507xMON810xNK603 maize.
24. Receiving environment (Annex III.9(h)):	The receiving environment will be agricultural lands
Risk assessment summary	
25. Detection/Identification method of the LMO (Annex III.9(f)):	The introduced genes can be identified using PCR techniques.
26. Evaluation of the likelihood of adverse effects (Annex III.8(b)):	No identified adverse effects to human and animal health or the environment have arisen from previous releases of TC1507, MON810 and NK603 maize. Therefore, the likelihood of adverse effects to human and animal health or to the environment arising from the proposed use of TC1507xMON810xNK603 maize for cultivation is negligible.
27. Evaluation of the consequences (Annex III.8(c)):	There are no identified adverse effects to human and animal health or the environment from the proposed use. Therefore, any potential consequences that may occur from the general release of TC1507xMON810xNK603 maize will be as negligible as for any commercial maize.
28. Overall risk (Annex III.8(d)):	The combination of negligible likelihood of adverse effects and negligible consequences confirms that the overall risk to human and animal health or the environment posed by the proposed release is negligible.
29. Recommendation (Annex III.8(e)):	The risk to human and animal health or the environment posed by the proposed general release is negligible.
30. Actions to address uncertainty regarding the level of risk (Annex III.8(f)):	Not applicable.
Additional information	
31. Availability of detailed risk assessment information:	Please refer to DuPont Pioneer's application to the RSA authorities.

32. Any other relevant information:	Not applicable.
33. Attach document:	The affidavit is attached. No other applicable documents are attached to the Risk Assessment
34. Notes:	Not applicable.