

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 a commodity clearance of genetically modified DAS-Ø15Ø7-1xMON-ØØ81Ø-6xSYNIR6Ø4-5xMON-ØØ6Ø3-6, known as TC1507xMON810xMIR604xNK603 maize.
3. Contact details:	DuPont Pioneer. P.O Box 8010 Centurion, 0046 On behalf of DuPont Pioneer and other affiliated companies. Tel: +27 (0)12 – 683 5700 Fax:+(0)12 – 663 4190
LMO information	
4. Name and identity of the living modified organism:	<p>The LMO is TC1507xMON810xMIR604xNK603 maize. DuPont Pioneer has produced TC1507xMON810xMIR604xNK603 maize through the use of traditional maize breeding techniques by combining the four individual transgenic maize lines namely: TC1507, MON810, MIR604 and NK603 maize. As a result, the inserts from these four maize events are not genetically linked and no new genetic modification has been introduced in the combined stacked product TC1507xMON810xMIR604xNK603 maize.</p> <p>The transformation resulted in the introduction of six gene cassettes namely <i>cry1F</i>, <i>cry1Ab</i>, <i>mcry3A</i>, <i>pat</i>, <i>pmi</i> and <i>cp4 epsps</i> genes into TC1507xMON810xMIR604xNK603 maize genome. Expression of the Cry1F and Cry1Ab proteins confer protection against certain lepidopteran maize pests with independent modes of action. In addition, mCry3A protein expressed in TC1507xMON810xMIR604xNK603 maize confers protection against certain coleopteran maize pests. TC1507xMON810xMIR604xNK603 maize also expresses PAT and CP4 EPSPS proteins which confer tolerance to glufosinate-ammonium and glyphosate herbicides, respectively, as well as PMI protein which was used as a selectable marker during transformation of MIR604 maize.</p>
5. Unique identification of the living modified organism:	DAS-Ø15Ø7-1xMON-ØØ81Ø-6xSYNIR6Ø4-5xMON-ØØ6Ø3-6

6. Transformation event:	TC1507xMON810xMIR604xNK603 maize
7. Introduced or Modified Traits:	Insect resistance and Herbicide tolerance.
8. Techniques used for modification:	Traditional maize breeding techniques
9. Description of gene modification:	<p data-bbox="621 489 1386 604">TC1507xMON810xMIR604xNK603 maize is a combination of the four individual transgenic maize lines namely: TC1507, MON810, MIR604 and NK603 maize.</p> <p data-bbox="621 642 1386 741">The expression of Cry1F protein as a result of the <i>cry1F</i> gene present in TC1507 maize confers protection against certain lepidopteran maize pests.</p> <p data-bbox="621 783 1386 951">TC1507 maize also contains a version of the phosphinothricin acetyl transferase (<i>pat</i>) gene from <i>Streptomyces viridochromogenes</i> that has been optimized for expression in maize. Expression of PAT protein confers tolerance to the application of glufosinate-ammonium herbicide.</p> <p data-bbox="621 993 1386 1092">Expression of Cry1Ab protein as a result of <i>cry1Ab</i> gene in MON810 maize confers protection against certain lepidopteran maize pests.</p> <p data-bbox="621 1134 1386 1232">MIR604 maize expresses a mCry3A protein from <i>Bacillus thuringiensis</i>, an insecticidal protein that confers protection against certain coleopteran maize pests.</p> <p data-bbox="621 1274 1386 1404">MIR604 maize also contains the <i>pmi</i> gene (also known as <i>manA</i>) from <i>E.coli</i> encoding a phosphomannose isomerase. Expression of PMI protein was used as a selectable marker during transformation of MIR604 maize.</p> <p data-bbox="621 1446 1386 1614">The insert used in the transformation of NK603 maize (insert PV-ZMGT32L) contained two copies of the <i>cp4 epsps</i> gene from <i>Agrobacterium</i> sp. strain CP4. Expression of CP4 EPSPS proteins in NK603 maize confers tolerance to glyphosate herbicides.</p> <p data-bbox="621 1656 1386 1900">Therefore, TC1507xMON810xMIR604xNK603 maize confers i.) i.) different modes of protection against certain lepidopteran maize pests based on the presence of the Cry1F and Cry1Ab proteins, ii.) protection against certain coleopteran maize pests based on the presence of mCry3A protein and, iii.) herbicide tolerance to glufosinate-ammonium and glyphosate herbicides due to the presence of the PAT and CP4 EPSPS proteins, respectively.</p>

Characteristics of modification	
10. Vector characteristics (Annex III.9(c)):	<p>Four individual transgenic maize lines namely: TC1507, MON810, MIR604 and NK603 maize, were combined by traditional breeding techniques to result in a combined trait seed TC1507xMON810xMIR604xNK603 maize, containing the molecular insertions of the four individual maize lines.</p> <p>No vector was used in the transformation of TC1507 and NK603 maize. Instead, the intended insert in TC1507 maize consisted of the linear <i>PmeI</i> DNA fragment PHI8999A. The intended insert in NK603 maize consisted of gel-isolated <i>Mlu</i> I restriction fragment, PV-ZMGT32L, containing the <i>cp4 epsps</i> plant gene expression cassettes.</p> <p>MON810 maize was generated by particle acceleration technology using plasmids PV-ZMBK07 and PV-ZMGT10 (that was not integrated).</p> <p>MIR604 maize was produced via <i>A. tumefaciens</i>-mediated transformation of immature maize embryos derived from one proprietary <i>Zea mays</i> lines. The plasmid pZM26 containing T-DNA with <i>mcry3A</i> and <i>pmi</i> genes was used in the transformation of MIR604 maize.</p>
11. Insert or inserts (Annex III.9(d)):	Please refer to 4 and 9 above.
Recipient organism or parental organisms (Annex III.9(a)):	
12. Taxonomic name/status of recipient organism or parental organisms:	<p>Family name: Gramineae (Poaceae)</p> <p>Genus: <i>Zea</i></p> <p>Species: <i>Zea mays</i> L.</p>
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 highly domesticated and is generally unable to persist or proliferate itself in self-sustaining populations outside of cultivation
Donor organism or organisms (Annex III.9(b)):	
19. Taxonomic name/status of donor organism(s)	<p>Inserted gene donors:</p> <p><i>Bacillus thuringiensis</i> <i>Streptomyces viridochromogenes</i> <i>Escherichia coli</i> <i>Agrobacterium tumefaciens</i></p> <p>Regulatory element donors:</p> <p><i>Zea mays</i> L. Cauliflower mosaic virus <i>Agrobacterium tumefaciens</i> <i>Arabidopsis thaliana</i> <i>Rice actin (Oryza sativa)</i></p>
20. Common name of donor organism(s):	<i>Zea mays</i> L.: Maize, corn;
21. Point of collection or acquisition of donor organism(s):	USA

22. Characteristics of donor organism(s) related to biosafety:	<p><i>Bacillus thuringiensis</i>, <i>Streptomyces viridochromogenes</i> and <i>Agrobacterium tumefaciens</i> are common soil bacteria.</p> <p>Maize (<i>Zea mays</i>) has a long history as an agricultural crop and is not recognized as harmful for the human or animal health.</p> <p>Cauliflower mosaic virus is a DNA caulimovirus with a host range restricted primarily to cruciferous plants.</p> <p><i>Escherichia coli</i> one of the main species of bacteria that live in the lower intestines of mammals.</p> <p>Arabidopsis thaliana is a small flowering plant that is widely used as a model organism in plant biology.</p> <p>Rice actin (<i>Oryza sativa</i>) is grown worldwide and is a staple food for about half of the world's population.</p>
Intended use and receiving environment	
23. Intended use of the LMO (Annex III 9(g)):	Food, feed and industrial use.
24. Receiving environment (Annex III.9(h)):	Commodity import of TC1507xMON810xMIR604xNK603 maize is anticipated to be part of the general import of maize and will take place at the same locations dealing with import of other commercial maize into South Africa.
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 adverse effects to human and animal health or the environment are anticipated from the proposed commodity clearance. The toxicological, allergenicity, agronomic, and compositional assessments have found TC1507xMON810xMIR604xNK603 maize to be substantially equivalent to conventional maize.
27. Evaluation of the consequences (Annex III.8(c)):	Please refer to 26 above
28. Overall risk (Annex III.8(d)):	Please refer to 26 above.
29. Recommendation (Annex III.8(e)):	There are no anticipated risks to human and animal health or the environment due to the proposed commodity clearance. It is recommended that TC1507xMON810xMIR604xNK603 maize can be managed as per applicable commodity clearance regulations in South Africa.

30. Actions to address uncertainty regarding the level of risk (Annex III.8(f)):	Not applicable.
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Additional information

31. Availability of detailed risk assessment information:	Please refer to DuPont Pioneer's application to the RSA authorities.
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32. Any other relevant information:	Not applicable.
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33. Attach document:	The affidavit is attached. No other applicable documents are attached to the Risk Assessment
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34. Notes:	Not applicable.
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