

COMMON FORMAT FOR Risk Assessment

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

Risk assessment details

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| 1. Country Taking Decision: | South Africa |
| 2. Title: | Application for a commodity clearance of genetically modified DAS-Ø15Ø7-1xDAS-59122-7xMON-ØØ81Ø-6xSYN-IR6Ø4-5xMON-ØØ6Ø3-6, known as TC1507x59122xMON810xMIR604xNK603 maize. |
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LMO information

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| 4. Name and identity of the living modified organism: | <p>The LMO is TC1507x59122xMON810xMIR604xNK603 maize. DuPont Pioneer has produced TC1507x59122xMON810xMIR604xNK603 maize through the use of traditional maize breeding techniques by combining the five individual transgenic maize lines namely: TC1507, 59122, MON810, MIR604 and NK603 maize. As a result, the inserts from these five maize events are not genetically linked and no new genetic modification has been introduced in the combined stacked product TC1507x59122xMON810xMIR604xNK603 maize.</p> <p>The transformation resulted in the introduction of eight gene cassettes namely <i>cry1F</i>, <i>cry34Ab1</i>, <i>cry35Ab1</i>, <i>cry1Ab</i>, <i>mcry3A</i>, <i>pat</i>, <i>pmi</i> and <i>cp4 epsps</i> genes into TC1507x59122xMON810xMIR604xNK603 maize genome. Expression of the Cry1F and Cry1Ab proteins confer protection against certain lepidopteran maize pests. Expression of Cry34Ab1/Cry35Ab1 binary protein and mCry3A protein confer protection against certain coleopteran maize pests. TC1507x59122xMON810xMIR604xNK603 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> |
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5. Unique identification of the living modified organism:	DAS-Ø15Ø7-1xDAS-59122-7xMON-ØØ81Ø-6xSYN-IR6 Ø4-5xMON-ØØ6Ø3-6
6. Transformation event:	TC1507x59122xMON810xMIR604xNK603 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:

TC1507x59122xMON810xMIR604xNK603 maize is a combination of the five individual transgenic maize lines namely: TC1507, 59122, MON810, MIR604 and NK603 maize.

The expression of Cry1F protein as a result of the *cry1F* gene present in TC1507 maize confers protection against certain lepidopteran maize pests.

The expression of Cry34Ab1/Cry35Ab1 binary protein as a result of the *cry34Ab1* and *cry35Ab1* genes present in 59122 maize confers protection against certain coleopteran maize pests.

TC1507 and 59122 maize also contains a version of the phosphinothricin acetyl transferase (*pat*) gene from *Streptomyces viridochromogenes* that has been optimized for expression in maize. Expression of PAT protein confers tolerance to the application of glufosinate-ammonium herbicide.

The expression of Cry1Ab protein as a result of the *cry1Ab* gene in MON810 maize confers protection against certain lepidopteran maize pests.

MIR604 maize expresses a mCry3A protein from *Bacillus thuringiensis*, an insecticidal protein that confers protection against certain coleopteran maize pests.

MIR604 maize also contains the *pmi* gene (also known as *manA*) from *E.coli* encoding a phosphomannose isomerase. Expression of PMI protein was used as a selectable marker during transformation of MIR604 maize.

The DNA fragment used in the transformation of NK603 maize (insert PV-ZMGT32L) contained two copies of the *cp4 epsps* gene from *Agrobacterium* sp. strain CP4. Expression of CP4 EPSPS proteins in NK603 maize confers tolerance to glyphosate herbicides.

Therefore, TC1507x59122xMON810xMIR604xNK603 maize confers i.) different modes of action against certain lepidopteran maize pests based on the presence of the Cry1F and Cry1Ab proteins, ii.) different modes of action against certain coleopteran maize pests based on the presence of Cry34Ab1/Cry35Ab1 binary protein and mCry3A protein and, iii.) herbicide tolerance to glufosinate-ammonium and glyphosate herbicides due to the presence of the PAT and CP4 EPSPS proteins, respectively.

Characteristics of modification

10. Vector characteristics (Annex III.9(c)):	<p>Five individual transgenic maize lines namely: TC1507, 59122, MON810, MIR604 and NK603 maize, were combined by traditional breeding techniques to result in a combined trait seed TC1507x59122xMON810xMIR604xNK603 maize, containing the molecular insertions of the five individual maize lines.</p> <p>No vectors were used in the transformation of TC1507 or NK603 maize lines. 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>Both 59122 and MIR604 maize were produced via <i>Agrobacterium tumefaciens</i>-mediated transformation with PHP17662 and pZM26 plasmids, respectively. The vector used for the genetic modification of 59122 maize was a Ti plasmid of <i>A. tumefaciens</i>, strain LBA4404, that was pathogenically disarmed by removing its native T-DNA. As a result, the inserted T-DNA from the PHP17662 plasmid contained the <i>cry34Ab1</i>, <i>cry35Ab1</i> and <i>pat</i> genes. 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:	The organisms are ubiquitous in nature.

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>Agrobacterium tumefaciens</i> <i>Escherichia coli</i></p> <p>Regulatory element donors:</p> <p><i>Zea mays</i> L. Cauliflower mosaic virus <i>Agrobacterium tumefaciens</i> <i>Escherichia coli</i> <i>Triticum aestivum</i> <i>Arabidopsis thaliana</i> <i>Rice actin</i> <i>Solanum tuberosum</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):	The organisms are ubiquitous in nature.

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><i>Triticum aestivum</i> (wheat) is a bread wheat that is most widely grown food crop in the world.</p> <p><i>Arabidopsis thaliana</i> is a small flowering plant that is widely used as a model organism in plant biology.</p> <p>Rice (<i>Oryza sativa</i>) is grown worldwide and is a staple food for about half of the world's population.</p> <p><i>Solanum tuberosum</i> is the world's fourth most important food crop and is cultivated worldwide.</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 TC1507x59122xMON810xMIR604xNK603 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 TC1507x59122xMON810xMIR604xNK603 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 TC1507x59122xMON810xMIR604xNK603 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.
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.