

## PART II

**COMMON FORMAT FOR RISK ASSESSMENT**

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

<b>Risk assessment details</b>	
1. Country Taking Decision:	South Africa
2. Title:	Application for a general release of genetically modified MON 89034 x TC1507 x NK603 x DAS-40278-9 maize.
3. Contact details:	Dow AgroSciences Southern Africa (Pty) Ltd., CBI Deleted information
<b>LMO information</b>	
4. Name and identity of the living modified organism:	MON 89034 x TC1507 x NK603 x DAS-40278-9 maize was obtained by conventional breeding of four single events: MON 89034, TC1507, NK603, and DAS-40278-9 maize. The stacked maize contains Cry1A.105, Cry2Ab2, and Cry1F proteins conferring protection against certain lepidopteran target pests. MON 89034 x TC1507 x NK603 x DAS-40278-9 maize also expresses PAT, CP4 EPSPS and AAD-1 proteins conferring tolerance to glufosinate-ammonium (as a selectable marker), glyphosate, and 2,4-D herbicides, respectively.
5. Unique identification of the living modified organism:	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6 x DAS-4Ø278-9
6. Transformation event:	MON 89034 x TC1507 x NK603 x DAS-40278-9
7. Introduced or Modified Traits:	<b>Chemical tolerance</b> - Herbicide tolerance  <b>Pest resistance</b> - Insect resistance
8. Techniques used for modification:	Traditional breeding cross between MON 89034, TC1507, NK603 and DAS-40278-9 maize.

9. Description of gene modification:	<p>No new genetic modification has been introduced in MON 89034 × TC1507 × NK603 × DAS-40278-9 maize, since it was produced through a traditional breeding cross between MON 89034, TC1507, NK603 and DAS-40278-9 maize events.</p> <p>MON 89034 was produced through <i>Agrobacterium</i>-mediated transformation of maize cells using the binary plasmid vector, PV-ZMIR245 to produce the <i>Bt</i> insecticidal proteins Cry1A.105 and Cry2Ab2.</p> <p>TC1507 maize was modified by the insertion of <i>cry1F</i> gene from <i>Bacillus thuringiensis</i> var. <i>aizawai</i> and a gene for phosphinothricin acetyltransferase (<i>pat</i>). TC1507 maize was obtained by biolistic transformation with fragment PHI8999A created by digestion of plasmid PHP8999 with <i>Pme</i> I. Maize TC1507 maize expresses the Cry1F and PAT proteins.</p> <p>NK603 maize was modified by the insertion of two gene cassettes, each containing a glyphosate tolerant form of the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (<i>cp4 epsps</i>) from <i>Agrobacterium</i> sp. strain CP4. NK603 was obtained by particle acceleration technology with the fragment PV-ZMGT32L created by digestion of plasmid PV-ZMGT32 with <i>Mlu</i> I.</p> <p>DAS-40278-9 maize was modified by insertion of aryloxyalkanoate dioxygenase-1 (<i>aad-1</i>) gene obtained from the soil bacterium, <i>Sphingobium herbicidovorans</i>. DAS-40278-9 was developed using direct Whiskers-mediated transformation with a purified <i>Fsp</i> I restriction fragment of plasmid pDAS1740 (also known as pDAB3812) to stably incorporate the <i>aad-1</i> gene into maize genome.</p>
<b>Characteristics of modification</b>	
10. Vector characteristics (Annex III.9(c)):	<p>No vector was used in the production of MON 89034 × TC1507 × NK603 × DAS-40278-9 maize. Traditional breeding methods were used in the traditional crossing between progeny of MON 89034, TC1507, NK603, and DAS-40278-9 maize, to generate MON 89034 × TC1507 × NK603 × DAS-40278-9 maize.</p>
11. Insert or inserts (Annex III.9(d)):	<p>Please refer to section 9 above.</p>

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**Recipient organism or parental organisms (Annex III.9(a)):**


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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 well-known crop plant worldwide. Maize is extensively cultivated in South Africa and has a history of safe use.
16. Centre(s) of origin of recipient organism or parental organisms:	It is believed that maize originated in south central Mexico, specifically in the Pacific slope of the modern Mexican states of Oaxaca, Tehuacán, and the Valley of Mexico. Specific geographic coordinates are unknown.
17. Centres of genetic diversity, if known, of recipient organism or parental organisms:	Centers of genetic diversity of maize are the same as its Centre of origin.
18. Habitats where the recipient organism or parental organisms may persist or proliferate:	Maize does not persist or proliferate outside of agriculture in South Africa. There are no known populations in any natural habitat in the country.

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**Donor organism or organisms (Annex III.9(b)):**

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19. Taxonomic name/status of donor organism(s)      MON 89034 × TC1507 × NK603 × DAS-40278-9 maize was obtained by traditional breeding of four single events: MON 89034, TC1507, NK603 and DAS-40278-9 maize.

Inserted gene donor organisms were:

*Bacillus thuringiensis*

*Streptomyces viridochromogenes*

*Agrobacterium tumefaciens*

*Sphingobium herbicidovorans*

Regulatory elements donors:

*Zea mays L.*

Cauliflower mosaic virus

*Agrobacterium tumefaciens*

*Arabidopsis thaliana*

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20. Common name of donor organism(s):      Donor organism (s) for MON 89034 maize

*Bacillus thuringiensis*

Donor organism (s) for TC1507 maize

*Bacillus thuringiensis*

*Streptomyces viridochromogenes*

Donor organism (s) for NK603 maize

*Agrobacterium sp.*

Donor organism (s) for DAS-40278-9 maize

*Shingobium herbicidovorans*

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21. Point of collection or acquisition of donor organism(s):      None of the donor organisms was collected from a specific geographic location. The genes, promoters, or transcription terminator elements were acquired from commercial suppliers or from research collaborators. MON 89034, TC1507 and NK603 maize have all been approved for general release and DAS-40278-9 maize has previously been approved for trial release in South Africa.

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22. Characteristics of donor organism(s) related to biosafety:	<p><i>Bacillus thuringiensis</i> is a common soil bacterium found worldwide.</p> <p><i>Streptomyces viridochromogenes</i> is ubiquitous in the soil. It has no known toxic or pathogenic potential.</p> <p><i>Agrobacterium sp.</i> is a bacterium that is found in soils worldwide. It infects plants but does not infect humans or animals.</p> <p><i>Sphingobium herbicidovorans</i> is a member of the sphingomonads, a widely distributed bacterial group in nature which has been isolated from land and water habitats, as well as from plant root systems. Due to their biodegradative and biosynthetic capabilities, the sphingomonads have been used for a wide range of biotechnological applications such as bioremediation of environmental contaminants and production of extracellular polymers such as sphingans which are used extensively in the food industry.</p>
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**Intended use and receiving environment**

23. Intended use of the LMO (Annex III 9(g)):	General Release of MON 89034 x TC1507 x NK603 x DAS-40278-9 maize.
24. Receiving environment (Annex III.9(h)):	Maize agricultural lands of South Africa.

**Risk assessment summary**

25. Detection/Identification method of the LMO (Annex III.9(f)):	No novel genetic modification has been introduced in the development of MON 89034 x TC1507 x NK603 x DAS-40278-9 maize – produced by conventional breeding methods between MON 89034, TC1507, NK603, and DAS-40278-9 maize. Therefore MON 89034 x TC1507 x NK603 x DAS-40278-9 maize is detectable using the existing PCR / Southern blot detection methods for: MON 89034, TC1507, NK603 and DAS-40278-9 maize.
26. Evaluation of the likelihood of adverse effects (Annex III.8(b)):	As indicated in the body of the application, MON 89034 x TC1507 x NK603 x DAS-40278-9 maize is as safe as conventional maize. Therefore, there are no anticipated adverse effects to human and animal health or the environment.
27. Evaluation of the consequences (Annex III.8(c)):	Studies confirmed that except for the specifically introduced insect protection and herbicide tolerance traits, MON 89034 x TC1507 x NK603 x DAS-40278-9 maize is agronomically comparable to conventional maize. MON 89034 x TC1507 x NK603 x DAS-40278-9 maize would therefore not be able to survive in the environment without the same agricultural practices required to ensure a sustainable maize crop.
28. Overall risk (Annex III.8(d)):	The overall risk posed by this GM maize is negligible.

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29. Recommendation (Annex III.8(e)):	No risks have been identified and therefore other than the containment parameters and permit conditions that might apply through the permit conditions, no additional actions need to be taken.
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30. Actions to address uncertainty regarding the level of risk (Annex III.8(f)):	The potential risks identified are negligible, hence no additional actions are required except compliance with the conditions contained in the permit.
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**Additional information**

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31. Availability of detailed risk assessment information:	Information relating to the risk assessment of MON 89034 x TC1507 x NK603 x DAS-40278-9 maize has been presented in this application as well as in previous applications that have been approved by the Executive Council.
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32. Any other relevant information:	Not applicable.
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33. Attach document:	Not applicable to applicant.
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34. Notes:	Not applicable.
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