

PART II

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 maize: MON 89034 x TC1507 x MIR162 x NK603 maize.
3. Contact details:	Dow AgroSciences South Africa, CBI Deleted information.
LMO information	
4. Name and identity of the living modified organism:	MON 89034 x TC1507 x MIR126 x NK603 maize was obtained by conventional breeding of four single events: MON 89034; TC1507, MIR162 and NK603. The stacked maize contains Cry1A.105, Cry2Ab2, Cry1F, and Vip3Aa20 proteins conferring protection against certain lepidopteran maize pests. MON 89034 x TC1507 x MIR126 x NK603 maize also expresses pat and CP4 epsps proteins conferring tolerance to glufosinate-ammonium (as a selectable marker) and glyphosate herbicides, respectively, as well as PMI (manA) protein which was used as a selectable marker during transformation of MIR162 maize.
5. Unique identification of the living modified organism:	MON-89034-3 x DAS-01507-1 x SYN-IR162-4 x MON-00603-6
6. Transformation event:	MON 89034 x TC1507 x MIR162 x NK603
7. Introduced or Modified Traits:	<p>Choose the trait from the following list:</p> <p><u>A. Abiotic environmental tolerance</u></p> <p>Not applicable.</p> <p><u>B. Altered growth, development and product quality</u></p> <p>Chemical tolerance</p> <p>- Herbicide tolerance</p> <p>Pest resistance</p> <p>- Insect resistance</p> <p><text entry for other, not on the list></p>
8. Techniques used for modification:	Traditional breeding cross between MON 89034, 1507, MIR162 and NK603 maize.

9. Description of gene modification:

No new genetic modification has been introduced in MON 89034 × TC1507 × MIR162 × NK603 maize, since it was produced through a traditional breeding cross between MON 89034, TC1507, MIR162 and NK603 maize events.

MON 89034 was developed through *Agrobacterium*-mediated transformation of maize cells to produce the *Bt* insecticidal proteins Cry1A.105 and Cry2Ab2 using the binary plasmid vector, PV-ZMIR245.

TC1507 maize was obtained by insertion of a linear DNA fragment (insert PHI8999A), containing the plant optimized *cry1F* and *pat* coding sequences and the necessary regulatory components, into maize cells using the particle acceleration method. Maize TC1507 maize expresses the Cry1F and PAT proteins.

MIR162 maize was produced by *Agrobacterium*-mediated transformation of maize cells to produce *Bt* insecticidal protein Vip3Aa20 and PMI protein from *E. coli*.

NK603 was also generated by particle acceleration technology using the DNA fragment PV-ZMGT32L containing a 5-enolpyruvylshikimate-3-phosphate synthase (*epsps*) gene from *Agrobacterium* sp. strain CP4 (*cp4 epsps*).

Characteristics of modification

10. Vector characteristics (Annex III.9(c)):

No vector was used in the production of MON 89034 × TC1507 × MIR162 × NK603 maize. Traditional breeding methods were used in the traditional crossing between progeny of MON 89034, TC1507, MIR162 and NK603 maize, to generate MON 89034 × TC1507 × MIR162 × NK603 maize.

11. Insert or inserts (Annex III.9(d)):

Please refer to section 9 above.

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

12. Taxonomic name/status of recipient organism or parental organisms:

Family name: Gramineae (Poaceae)

Genus: *Zea*

Species: *Zea mays* 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.
Donor organism or organisms (Annex III.9(b)):	
19. Taxonomic name/status of donor organism(s)	<p>MON 89034 × TC1507 × MIR162 × NK603 maize was obtained by traditional breeding of four single events: MON 89034, TC1507, MIR162 and NK603 maize.</p> <p><u>Inserted gene donor organisms were:</u></p> <p><i>Bacillus thuringiensis</i> <i>Streptomyces viridochromogenes</i> <i>Agrobacterium tumefaciens</i> <i>Escherichia coli</i></p> <p><u>Regulatory elements donors:</u></p> <p><i>Zea mays</i> L. Cauliflower mosaic virus <i>Agrobacterium tumefaciens</i> <i>Escherichia coli</i> <i>Arabidopsis thaliana</i> <i>Rice actin</i></p>

20. Common name of donor organism(s):	<u>Donor organisms for genes:</u> Bt <i>Streptomyces</i> <i>Agrobacterium</i> <i>E. coli</i>
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, MIR162 and NK603 maize have all been approved for general release in South Africa.
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 exhibits very slight antimicrobial activity, is inhibited by streptomycin, and there have been no reports of adverse effects on humans, animals, or 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>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>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>
Intended use and receiving environment	
23. Intended use of the LMO (Annex III 9(g)):	Commodity Clearance of MON 89034 x TC1507x MIR162 x NK603 maize for food, feed and industrial use.
24. Receiving environment (Annex III.9(h)):	Commodity import of MON 89034 x TC1507x MIR162 x NK603 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)):	No novel genetic modification has been introduced in the development of MON 89034 x TC1507 x MIR162 x NK603 maize – produced by conventional breeding methods between MON 89034, TC1507, MIR162 and NK603 maize. Therefore, MON 89034 x TC1507 x MIR162 x NK603 maize is detectable using the existing PCR / Southern blot detection methods for: MON 89034, TC1507, MIR162 and NK603 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 MIR162 x NK603 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 MIR162 x NK603 maize is agronomically equivalent to conventional maize. MON 89034 x TC1507 x MIR163 x NK603 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.
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.
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.
Additional information	
31. Availability of detailed risk assessment information:	Information relating to the risk assessment of MON 89034 x TC1507 x MIR162 x NK603 maize has been presented in this application as well as in previous applications that have been approved by the Executive Council.
32. Any other relevant information:	Not applicable.
33. Attach document:	<i>Not applicable to applicant</i> <Specific types of entry: option to choose a file from the local source and 'upload' a copy to the BCH server>
34. Notes:	Not applicable.