PART II: Risk Assessment

	Risk assessment details	
1.	**Country Taking Decision:**	South Africa
2.	**Title:**	Application for Commodity Clearance of MON 89034 x MON 88017 in South Africa
3.	**Contact details:**	Monsanto South Africa (Pty) Ltd P.O. Box 69933, Bryanston 2010
	LMO information	
4.	**Name and identity of the living modified organism:**	Maize event MON-89Ø34-3 x MON 88017
5.	**Unique identification of the living modified organism:**	MON-89Ø34-3 × MON 88Ø17-3
6.	**Transformation event:**	MON 89034 X MON 88017
7.	**Introduced or Modified Traits:**	Lepidopteran-and Rootworm-Protected Maize
8.	**Techniques used for modification:**	While MON 89034 × MON 88017 results from traditional breeding, genetic modification was used in the development of the parental plants, MON 89034 and MON 88017. Both MON 89034 and MON 88017 were developed through *Agrobacterium*-mediated transformation of maize. A binary plasmid vector PV-ZMIR245 was used to produce the Bt insecticidal proteins Cry1A.105 and Cry2Ab2 in MON 89034. A plasmid vector PV-ZMIR39 was used to produce Cry3Bb1 and CP4 EPSPS proteins in MON 88017.
9.	**Description of gene modification:**	The multi event stack contains the *cry1A.105, cry2Ab2, cry3Bb1* genes isolated from *Bacillus thuringiensis*, and the *cp4 epsps* gene from *Agrobacterium tumefaciens sp.* strain CP4. With the inserted genes the multi event stack will provide effective above- and below-ground insect protection and herbicide tolerance to maize plants.

Characteristics of modification		
10. Vector characteristics (Annex III.9(c)):	Not applicable...MON 89034 × MON 88017 was obtained through conventional breeding methods.	
11. Insert or inserts (Annex III.9(d)):	MON 89034 × MON 88017 maize was obtained by conventional breeding of two single maize event products: MON 89034 and MON 88017. □ As in the case of MON 89034, MON 89034 × MON 88017 expresses the Cry1A.105 and Cry2Ab2 insecticidal proteins, providing tolerance to *inter alia* maize stalk borers in South Africa. □ As in the case of MON 88017, MON 89034 × MON 88017 expresses the Cry3Bb1 insecticidal protein that provides protection against certain coleopteran insect pests belonging to the Chrysomelidae family (corn rootworm, *Diabrotica* spp.) and the CP4 5-enolpyruvyl shikimate-3-phosphate synthase (CP4 EPSPS) protein that confers tolerance to glyphosate.	
Recipient organism or parental organisms (Annex III.9(a)):		
12. Taxonomic name/status of recipient organism or parental organisms:	Common name: Family name: Genus: Species:	Maize Poaceae (formerly Gramineae) Zea *Zea mays*
13. Common name of recipient organism or parental organisms:	Maize	
14. Point of collection or acquisition of recipient or parental organisms:	The original transformations that produced MON 89034 x MON 88017 used privately owned germplasm acquired for this purpose.	

15. Characteristics of recipient organism or parental organisms related to biosafety:	Maize is the world's third leading cereal, following rice and wheat, in terms of production and area harvested. It has a long history of safe use as a raw material for processed products, and direct uses as a human food or animal feed. Today, maize is produced on every continent except Antarctica, and is exported and imported as viable grain for use as foods or feeds, or directly in processing, without risk to the environment. According to OECD [Consensus Document on the Biology of *Zea mays* subsp. *mays* (Maize), 2003], "Maize has lost the ability to survive in the wild due to its long process of domestication, and needs human intervention to disseminate its seed." In addition, "maize is incapable of sustained reproduction outside of domestic cultivation", and "maize plants are non-invasive in natural habitats." Despite the fact that maize frequently appears as a volunteer plant in a subsequent rotation, is has no inherent ability to persist or propagate. In all regions of the world, volunteer plants are managed with herbicides, tillage, or manual removal of plants. As such, maize is not considered a pest anywhere in the world. When it occurs outside of cultivation, it has no impact on the conservation and sustainable use of biological diversity. Gene flow from maize occurs through dispersal of seed and pollen mediated exchange of genes to sexually compatible plants. Since maize has no biological mechanism to scatter seed, low-level, incidental dispersal of viable grain occurs as a result of human-based activities such as transport and harvesting operations. As was noted by OECD, the few plants that might result from incidental release will not persist or meaningfully reproduce without human intervention. Gene flow via pollen is only possible to other maize plants throughout the world except in Mexico and Guatemala where wild relatives occur. Maize reproduces sexually, is a wind-pollinated, monoecious species with separate staminate (tassels) and pistillate (silk) flowers, which encourages natural cross-pollination between maize plants. The distance that viable pollen can travel depends on prevailing wind patterns, humidity, and temperature. Generally, the pollen dissemination period lasts three to seven days. Because incidental release of maize during importation occurs at very low levels, and because maize in not competitive, pollen mediated gene flow between local maize and rare volunteers has had no effect on the conservation and sustainable use of biological diversity.

16. Centre(s) of origin of recipient organism or parental organisms:	Maize is thought to have its origin in Mexico, from where it spread northward to Canada and southward to Argentina. Although secondary centres of origin in South America are possible, the oldest archaeological evidence of domesticated maize (5000 B.C.) was discovered in the valley of Tehuacan in Mexico (Benson and Pearce, 1987). Several theories on the origin of maize have been proposed; the two theories most adhered to being that either teosinte (a wild relative of maize that is endemic to parts of Mexico and Guatemala) or a wild pod maize that is now extinct was the wild ancestor of maize (Benson and Pearce, 1987; Brown *et al.*, 1984). Maize is a member of the genus *Zea,* which is broken into 2 sections: ZEA and LUXURIENTES. The section ZEA includes one species (*mays*), which includes three subspecies: ssp. *mays,* ssp. *mexicana* (formerly *Euchlaena mexicana),* and ssp. *parviglumis.* The former subspecies is known as maize while the latter comprise a portion of the complex known as teosinte. Furthermore, ssp. *mexicana* and ssp. *parviglumis* are further separated into several races (OECD, 2003). Section LUXURIENTES encompasses 3 species: an annual *Z. luxurians,* and perennials *Z. diploperennis* and *Z. perennis.* While the classification of *Zea* continues to be modified, teosintes are the only know wild relatives of maize capable of forming hybrids in nature. Outcrossing and gene exchange between teosinte and maize has been reported with annual teosinte (*Zea mays* ssp. *mexicana*) (2n = 20) and maize (*Zea mays L.*) (2n = 20). A frequency of one F1 hybrid (maize × teosinte) for every 500 maize plants or 20 to 50 teosinte plants in the Chalco region of the Valley of Mexico was reported. However, newer information shows that annual teosintes may be a separate species because of the level of genetic isolation and that hybrids that do form are highly unsuccessful in introgressing genetic material (OECD, 2003). Regardless, Mexico and parts of Central America are regarded as the center of genetic diversity for maize. The natural distribution of teosinte is limited to the seasonally dry, suropical zone with summer rain along the western escarpment of Mexico and Guatemala and the Central Plateau of Mexico. The belief that Central America and southern Mexico are both the center of origin and a center of diversity for maize was supported by (Vavilov, 1992).
17. Centres of genetic diversity, if known, of recipient organism or parental organisms:	Please refer to the response in section 16.

18. Habitats where the recipient organism or parental organisms may persist or proliferate:	As noted by OECD (2003), maize is not invasive of natural habitats, does not persist or disperse anywhere in the world without the human intervention. Early domestication and diversification through selection occurred in Meso-America. Maize is grown across a wide range of ecological conditions including soil types, altitude and rainfall. Currently, maize is grown over a wide range of conditions because of its many divergent types that have been bred for this purpose. The bulk of the maize is produced between latitudes 30°and 55°, with relatively little grown at latitudes higher than 47°latitude anywhere in the world. The greatest maize production occurs where the warmest month isotherms range between 21°C and 27°C and the frost-free season lasts 120 to 180 days. A summer rainfall of 15 cm is approximately the lower limit for maize production without irrigation. Experience with maize imported for use as foods or feeds, or directly in processing, has demonstrated that stable populations do not establish, persist or proliferate as a result of this practice.
Donor organism or organisms (Annex III.9(b)):	
19. Taxonomic name/status of donor organism(s)	MON 89034 × MON 88017 was obtained from conventional breeding of the single events MON 89034 and MON 88017. The donor organisms used in development of the single events MON 89034 and MON 88017 were *Bacillus thuringiensis,* and *Agrobacterium tumefaciens strain CP4.*
20. Common name of donor organism(s):	Bacteria
21. Point of collection or acquisition of donor organism(s):	Bacteria are ubiquitous in nature.
22. Characteristics of donor organism(s) related to biosafety:	Cry proteins have been used as components of microbial pesticides derived from *Bt* for over 45 years. They are generally recognized as non-toxic to humans and other mammalian species (Betz *et al.*, 2000; OECD, 2007; US EPA, 2000; US EPA, 2001a) when tested individually and in combination (*e.g.*, *Bt* microbial formulations). CP4 EPSPS is structurally and functionally related to endogenous EPSPS enzymes. There is a history of safe consumption of related EPSPS enzymes found naturally in plant material of commonly consumed foods. There is also a history of safe use/consumption of CP4 EPSPS present in herbicide tolerant soybeans and maize (Delaney *et al.*, 2008).

Intended use and receiving environment	
23. Intended use of the LMO (Annex III 9(g)):	This is an application for commodity clearance approval of MON 89034 x MON 88017.
24. Receiving environment (Annex III.9(h)):	Except for the specifically introduced insect protection and herbicide tolerance traits, MON 89034 × MON 88017 is equivalent to conventional maize. With this application, MON 89034 × MON 88017 is destined for use as food, feed and in processing. No environmental release is proposed. In the unlikely event that some grain should end up in the environment, no differences in ecological impact are anticipated.
	Risk assessment summary
25. Detection/Identification method of the LMO (Annex III.9(f)):	MON 89034 × MON 88017 was produced by crossing plants containing MON 89034 and MON 88017, using conventional breeding methods. Therefore, MON 89034 × MON 88017 is detectable using the combination of the single event-specific PCR method for detecting the introduced DNA present in the single events MON 89034 and MON 88017. For all plants in which two or more events are combined by conventional breeding, the events involved will segregate in the grain; therefore such detection methods when applied to individual grains harvested from fields of MON 89034 × MON 88017 will detect any combination of the four events. Event specific detection methods for detection of MON 89034 and MON 88017 DNA have been validated by the European Commission Joint Research Centre (EU JRC) and are available on the EU JRC website at: http://gmo-crl.jrc.ec.europa.eu/summaries
26. Evaluation of the likelihood of adverse effects (Annex III.8(b)):	Information and data provided in the accompanying application supports the conclusion that except for the specifically introduced insect protection and herbicide tolerance traits, MON 89034 × MON 88017 is equivalent to conventional maize. Grain that may containing MON 89034 × MON 88017 would be used as food, feed and in processing; the grain is not intended for release into the environment. Grain imports are made by international grain traders, with the time of importation dependent on the local or regional need for grain. The grain traders would, as per the requirements in terms of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997) obtain the necessary permits from the Registrar prior to importation. Importation activities would thus be subject to the conditions (such as milling) prescribed in the relevant import permits. The likelihood of adverse effects from importation and use of MON 89034 × MON 88017 as food, feed or in processing, is low.

27. Evaluation of the consequences (Annex III.8(c)):	In the unlikely event that some grain containing MON 89034 × MON 88017 (from grain imports) may end up in the environment of South Africa before being milled, the impact would be negligible as data supported a conclusion that MON 89034 × MON 88017 is equivalent to conventional maize; maize plants cannot survive without human intervention. Furthermore, South Africa is not the centre of origin for *Zea mays* and there are no wild relatives in South Africa with which maize can outcross and if the grain was to be used as seed for planting, it would represent a F2 generation of which the growth, development and yield is extremely variable and predominantly weak.
28. Overall risk (Annex III.8(d)):	Based on the data and information provided in the accompanying application, it can be concluded that there are no meaningful risks to human or animal health from dietary exposure to MON 89034 × MON 88017. Furthermore, MON 89034 × MON 88017 is equivalent to conventional maize and this conclusion extends to the intended foods and feeds derived from MON 89034 × MON 88017. In the unlikely event that MON 89034 × MON 88017 grain is released into the environment, the potential risk is low.
29. Recommendation (Annex III.8(e)):	The overall risk is very low. No recommendations other than procedures that may apply to conventional maize are applicable.
30. Actions to address uncertainty regarding the level of risk (Annex III.8(f)):	There is no uncertainty regarding the risk profile.
Additional information	
31. Availability of detailed risk assessment information:	Information pertaining to the detailed risk assessment is contained in the application (Part I).
32. Any other relevant information:	None.
33. Attach document:	*Not applicable to applicant*
34. Notes:	See references below.