12. Part II: Risk Assessment

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:	Regulatory Affairs Manager
3.	Contact details:	Monsanto Company, represented by Monsanto S.A.(Pty) Ltd Monsanto Company 800 N. Lindbergh Boulevard St. Louis, Missouri 63167 U.S.A Monsanto House, Building No. 4 Fourways Office Park Corner Fourways Boulevard and Roos Streets Fourways South Africa
	LMO information	
4.	Name and identity of the living modified organism:	Maize lines containing MON 87460 event.
5.	Unique identification of the living modified organism:	MON-8746Ø-4
6.	Transformation event:	MON 87460
7.	Introduced or Modified Traits:	**A. Abiotic environmental tolerance** - Drought or water tolerance
8.	Techniques used for modification:	*Agrobacterium*-mediated transformation of embryonic maize cells.
9.	Description of gene modification:	Maize was genetically modified to encode for the cold shock protein B (*CspB)* gene from *Bacillus subtilis* to produce maize plants that are tolerant to abiotic stress factors.
	Characteristics of modification	

10. Vector characteristics (Annex III.9(c)):	The plasmid vector PV ZMAP595 is derived from *Bacillus subtilis*, a soil bacterium ubiquitous in nature.
11. Insert or inserts (Annex III.9(d)):	The following inserts: MON 87460 is a transformant of plasmid vector PV-ZMAP595. Other regulatory inserts include Act1, a fragment containing the rice actin gene from *Oryza sativa*; **transcriptional sequence Tr7 3' the 3' untranslated region of the** transcript 7 gene from *Agrobacterium tumefaciens* that directs polyadenylation of mRNA; and cold shock protein B from *Bacillus subtilis*.
Recipient organism or parental organisms (Annex III.9(a)):	
12. Taxonomic name/status of recipient organism or parental organisms:	Common name: Maize Family name: *Gramineae* Genus: *Zea* Species: *mays*(2n+20)
13. Common name of recipient organism or parental organisms:	Maize or Corn.
14. Point of collection or acquisition of recipient or parental organisms:	The original transformations that produced MON 87460 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 the 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, it 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 to be 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 the 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:	<Text entry - Describe the exact location and give geographical coordinates>

17. Centres of genetic diversity, if known, of recipient organism or parental organisms:	See 16 above.
18. Habitats where the recipient organism or parental organisms may persist or proliferate:	As noted by the OECD (2003), maize is not invasive of natural habitats and does not persist or disperse anywhere in the world without 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. Most 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 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)	*Bacillus subtilis*
20. Common name of donor organism(s):	Soil bacterium
21. Point of collection or acquisition of donor organism(s):	Organisms are ubiquitous in nature and commonly found in soil.
22. Characteristics of donor organism(s) related to biosafety:	Not applicable, since the donor organisms are ubiquitous in nature and therefore do not pose a threat to biodiversity.
Intended use and receiving environment	
23. Intended use of the LMO (Annex III 9(g)):	The objective of the application is for the general release of maize containing MON 87460 in South Africa.

24. Receiving environment (Annex III.9(h)):	The receiving environments are varied and represent the entire maize producing area in South Africa. After general release approval has been obtained the maize will be sold into the entire area currently growing both transgenic and conventional maize. In the event that such an application is successful the general release would be dependent on the hybrid development for planting in both the eastern and western production areas. These include the maize production areas in the Gauteng, Mpumalanga, Free State, North and North West provinces. There are no reported and scientifically documented cases of any impact on biodiversity or animal and human safety concerns.
	Risk assessment summary
25. Detection/Identification method of the LMO (Annex III.9(f)):	Standard molecular biology techniques may be used for detection including, but not limited to Southern or PCR, for terminators and promoters in this construct. A detection method for MON 87460 was provided to the Registrar in March 2009. The detection method for MON 87460 is considered trade secret or otherwise confidential information of Monsanto and is to be distributed by Monsanto only.
26. Evaluation of the likelihood of adverse effects (Annex III.8(b)):	Based on the nature of the recipient species (unable to proliferate) and the lack of related and wild species with which MON 87460 can outcross, the likelihood of adverse effects from out-crossing to other related species is negligible. Transgenic maize hybrids with similar genes have been grown around the world for several years and in South Africa for 15 years without any recorded impact on the environment other than those created by conventional maize production. Any volunteers could, like conventional maize, be removed by current agricultural practices such as ploughing and the use of herbicides.
27. Evaluation of the consequences (Annex III.8(c)):	Studies conducted with MON 87460 confirmed that this event is agronomically and compositionally equivalent to conventional maize and has no increased tendency towards weediness or an increased susceptibility of tolerance to insects normally associated with maize. Thus, should any of the potential risks materialize, the consequences would be negligible.
28. Overall risk (Annex III.8(d)):	Considering the potential risks and the consequences should the potential risks materialize, the overall risk of cultivating MON 87460 is extremely low.

29. Recommendation (Annex III.8(e)):	No risks have been identified and therefore other than the containment parameters 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 for the specific event is 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:	More information on the safety of MON 87460 is contained in the application preceding this document.
32. Any other relevant information:	None
33. Attach document:	*Not applicable to applicant*
34. Notes:	

References:

Benson, G.O. and Pearce, R.B. 1987. Corn perspective and culture. *Corn: Chemistry and Technology*, Chapter 1.

Brown, W.L., Zuber, M.S., Darrah, L.L. and Glover, D.Y. 1984. Origin, adaptation, and types of corn. *Corn: Chemistry and Technology*.

OECD. 2003. Consensus document on the biology of *Zea mays* subsp. *mays* (maize).

Vavilov, N.I. 1992. Origin and geography of cultivated plants.

These references are available should they be required.