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 DP-ØØ4114-3, known as DP4114 maize.
3.	Contact details:	DuPont Pioneer. P.O Box 8010 Centurion, 0046 On behalf of DuPont Pioneer and other affiliated companies. Tel: +27 (0)12 – 683 5700 Fax:+(0)12 – 663 4190
	LMO information	
4.	Name and identity of the living modified organism:	The LMO is DP4114 maize and was produced by *Agrobacterium tumefaciens*-mediated transformation with plasmid PHP27118. The transformation resulted in the introduction of four gene cassettes namely *cry*1F, *cry*34Ab1, *cry3*5Ab1 and *pat* genes into maize genome. Expression of Cry1F protein confers protection against certain lepidopteran pests whereas the expression of Cry34Ab1 and Cry35Ab1 proteins confer protection against certain coleopteran pests. DP4114 maize also expresses PAT protein which is a selectable marker that confers tolerance to glufosinate-ammonium herbicide.
5.	Unique identification of the living modified organism:	DP- ØØ4114-3 maize.
6.	Transformation event:	DP4114 maize
7.	Introduced or Modified Traits:	Insect resistance and Herbicide tolerance.
8.	Techniques used for modification:	Recombinant DNA techniques.

9. Description of gene modification:

The T-DNA of plasmid PHP27118 contains four gene cassettes. The first cassette contains a truncated version of the *cry*1F gene from *Bacillus thuringiensis* var. *aizawai.* The insertion of the *cry*1F gene confers protections against certain lepidopteran pests. The Cry1F protein is comprised of 605 amino acids and has a molecular weight of approximately 68 kDa.

Expression of the *cry*1F gene is controlled by the maize polyubiquitin (*ubi*ZM1) promoter (Christensen *et al.*, 1992), providing constitutive expression of the Cry1F protein in maize. This region also includes the 5'untranslated region (UTR) and intron associated with the native polyubiquitin promoter. The terminator for the *cry*1F gene is the polyadenylation signal from open reading frame 25 (ORF 25) of the *Agrobacterium tumefaciens* Ti plasmid pTi15955 (Barker *et al.*, 1983).

The second cassette contains the *cry*34Ab1 gene isolated from *Bacillus thuringiensis* strain PS149B1 (Moellenbeck *et al*., 2001; Ellis *et al*., 2002; Herman *et al*., 2002). The Cry34Ab1 protein is 123 amino acid residues in length and has a molecular weight of approximately 14 kDa. Expression of the *cry*34Ab1 gene is controlled by a second copy of the maize polyubiquitin promoter (*ubi*ZM1) with 5' UTR and intron (Christensen *et al.*, 1992). The terminator for the *cry*34Ab1 gene is the 3' terminator sequence from the proteinase inhibitor II gene (*pin*II terminator) of *Solanum tuberosum* (An *et al.*, 1989; Keil *et al.,* 1986).

The third gene cassette contains the *cry*35Ab1 gene, also isolated from *Bacillus thuringiensis* strain PS149B1 (Ellis *et al*., 2002; Herman *et al*., 2002; Moellenbeck *et al*., 2001). The Cry35Ab1 protein has a length of 383 amino acids and a molecular weight of approximately 44 kDa. Expression of the *cry*35Ab1 gene is controlled by the *Triticum aestivum* (wheat) peroxidase promoter (TA peroxidase promoter) including leader sequence (Hertig *et al.*, 1991). The terminator for the *cry*35Ab1 gene is a second copy of the *pin*II terminator (; An *et al.*, 1989; Keil *et al.,* 1986).

The fourth gene cassette contains a version of the phosphinothricin acetyl transferase (*pat*) gene from *Streptomyces viridochromogenes* that has been optimized for expression in maize. The PAT protein is 183 amino acids residues in length and has a molecular weight of approximately 21 kDa. Expression of the *pat* gene is controlled by the promoter and terminator regions from the cauliflower mosaic virus (CaMV) 35S transcript (Franck *et al.*, 1980; Odell *et al.*, 1985; Pietrzak, *et al.,* 1986).

Characteristics of modification		
10. Vector characteristics (Annex III.9(c)):	No vector was used in producing DP4114 maize.	
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:	Family name: Genus: Species:	Gramineae (Poaceae) *Zea* *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 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 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)	Inserted gene donors: *Bacillus thuringiensis* *Streptomyces viridochromogenes* Regulatory element donors: *Zea mays* L. *Triticum aestivum* Cauliflower mosaic virus *Agrobacterium tumefaciens* *Solanum tuberosum*
20. Common name of donor organism(s):	*Zea mays* L.: Maize, corn; *Triticum aestivum*: Wheat *Solanum tuberosum*: Potato
21. Point of collection or acquisition of donor organism(s):	USA
22. Characteristics of donor organism(s) related to biosafety:	*Bacillus thuringiensis*, *Streptomyces viridochromogenes and Agrobacterium tumefaciens* are common soil bacteria. Maize (*Zea mays)*, wheat (*Triticum aestivum*), and potato (*Solanum tuberosum*) have long histories as agricultural crops and are not recognized as harmful for the human or animal health. Cauliflower mosaic virus is a DNA caulimovirus with a host range restricted primarily to cruciferous plants.
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 DP4114 maize will 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 DP4114 maize to be 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 DP4114 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.