COMMON FORMAT FOR RISK ASSESSMENT
(In accordance with Annex III of the Cartagena Protocol on Biosafety)

Risk assessment details	
1. Country Taking Decision:	Republic of South Africa
2. Title:	Application for commodity clearance of genetically modified organisms: 356043 soybean
3. Contact details:	Pioneer Hi-Bred RSA (Pty) Ltd. P.O. Box 8010 Centurion, 0046 (R.S.A.) Tel: +27 12 683 5700 Fax: +27 12 663 5964
LMO information	
4. Name and identity of the living modified organism:	Name and identity of the LMO is 356043 soybean. The 356043 soybean has been genetically modified to express the GAT4601 and GM-HRA proteins[1]. The GAT4601 protein is a glyphosate acetyltransferase (GAT), encoded by an optimized form of the *gat* gene from *Bacillus licheniformis*, that confers tolerance to the herbicide glyphosate. The GM-HRA protein is an acetolactate synthase (ALS), encoded by an optimized form of the endogenous *als* gene from *Glycine max*, that confers tolerance to ALS-inhibiting herbicides. This application is for commodity clearance of grain and derived products obtained from 356043 soybean for use in foods, animal feed and industrial products. It is not for general release or cultivation of 356043 soybean seed products in South Africa.
5. Unique identification of the living modified organism:	DP-356Ø43-5
6. Transformation event:	The transformation event is 356043 soybean.

[1] Please note that *gm-hra* stands for *Glycine max hra* gene and GM-HRA stands for *Glycine max* HRA protein.

7. Introduced or Modified Traits:	- Chemical tolerance: herbicide tolerance
8. Techniques used for modification:	The 356043 soybean was produced by biolistic methods.
9. Description of gene modification:	The 356043 soybean has been genetically modified to express the GAT4601 and GM-HRA proteins. The GAT4601 protein is a glyphosate acetyltransferase (GAT), encoded by an optimized form of the *gat* gene from *Bacillus licheniformis*, that confers tolerance to the herbicide glyphosate. The GM-HRA protein is an acetolactate synthase (ALS), encoded by an optimized form of the endogenous *als* gene from *Glycine max*, that confers tolerance to ALS-inhibiting herbicides. This application is for commodity clearance of grain and derived products obtained from 356043 soybean for use in foods, animal feed and industrial products. It is not for general release or cultivation of 356043 soybean seed products in South Africa.
Characteristics of modification	
10. Vector characteristics (Annex III.9(c)):	No vector was used in the production of 356043 soybean. The intended insert used in the transformation of 356043 soybean consisted of a linear DNA fragment, containing the *gat4601* and *gm-hra* coding sequences together with the necessary regulatory components only. No additional DNA sequences were used in the transformation of 356043 soybean.
11. Insert or inserts (Annex III.9(d)):	Detailed analyses have demonstrated that the genetic material inserted in 356043 soybean consists of a single and full-length copy of the linear DNA fragment containing the *gat4601* and *gm-hra* coding sequences together with the necessary regulatory components. No other genetic material was inserted into 356043 soybean.

Recipient organism or parental organisms (Annex III.9(a))		
12. Taxonomic name/status of recipient organism or parental organisms:	Family name: Genus: Species:	Leguminosae *Glycine* *G. max* (L.) Merr.
13. Common name of recipient organism or parental organisms:	Soybean, soy	
14. Point of collection or acquisition of recipient or parental organisms:	USA	
15. Characteristics of recipient organism or parental organisms related to biosafety:	Soybean is a highly domesticated agricultural crop with a long history of safe use.	
16. Centre(s) of origin of recipient organism or parental organisms:	China	
17. Centres of genetic diversity, if known, of recipient organism or parental organisms:	China	
18. Habitats where the recipient organism or parental organisms may persist or proliferate:	Soybean is a highly domesticated agricultural crop. It is unable to persist or proliferate outside well managed agricultural habitats.	

Donor organism or organisms (Annex III.9(b))	
19. Taxonomic name/status of donor organism(s)	*Bacillus licheniformis* is the donor of the *gat* gene; Cauliflower Mosaic Virus is the donor of the 35S promoter sequence; Tobacco Mosaic Virus is the donor of the omega 5' untranslated region translational enhancer element; *Solanum tuberosum* is the donor of the proteinase II terminator; and, *Glycine max* is the host plant and donor of the endogenous *als* gene, the SAMS constitutive promoter and the endogenous *als* gene terminator.
20. Common name of donor organism(s):	*Bacillus licheniformis* Cauliflower Mosaic Virus Tobacco Mosaic Virus *Solanum tuberosum*: potato *Glycine max*: soybean, soy
21. Point of collection or acquisition of donor organism(s):	USA
22. Characteristics of donor organism(s) related to biosafety:	The donor organisms have a long history of safety.
Intended use and receiving environment	
23. Intended use of the LMO (Annex III 9(g)):	Commodity clearance of grain and derived products obtained from 356043 soybean for use in foods, animal feed and industrial products. The application is not for general release or cultivation of 356043 soybean seed products in South Africa.
24. Receiving environment (Annex III.9(h)):	Not applicable. The application is for commodity clearance of grain and derived products obtained from 356043 soybean for use in foods, animal feeds and industrial products. It is not for general release or cultivation of 356043 soybean seed products in South Africa.

Risk assessment summary	
25. Detection/Identification method of the LMO (Annex III.9(f)):	A protocol for the detection of 356043 soybean has been developed. The detection protocol provides information for the detection and identification of 356043 soybean and is based on PCR amplification of a DNA sequence specific for the 356043 soybean insert, thereby allowing the event-specific detection of 356043 soybean.
26. Evaluation of the likelihood of adverse effects (Annex III.8(b)):	There are no identified adverse effects to human and animal health or the environment arising from the genetic modification in 356043 soybean. Therefore, the likelihood of adverse effects to human and animal health or to the environment arising from commodity clearance of 356043 soybean in South Africa is negligible.
27. Evaluation of the consequences (Annex III.8(c)):	There are no identified adverse effects to human and animal health or the environment arising from the genetic modification in 356043 soybean. Therefore, any potential consequences that may occur from commodity clearance of 356043 soybean in South Africa are negligible.
28. Overall risk (Annex III.8(d)):	The combination of negligible likelihood of adverse effects and negligible consequences confirms that the overall risk to human and animal health or the environment posed by the commodity clearance of 356043 soybean in South Africa is negligible.
29. Recommendation (Annex III.8(e)):	The risk to human and animal health or the environment posed by commodity clearance of 356043 soybean is negligible. Therefore, there is no need for a risk management strategy for the commodity clearance of 356043 soybean 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:	Detailed risk assessment information for 356043 soybean has been included in the application for commodity clearance of 356043 soybean submitted by Pioneer Hi-Bred RSA (Pty) Ltd.

32. Any other relevant information:	All relevant information is contained in the application submitted to the Department of Agriculture of South Africa.
33. Attach document:	*Not applicable to applicant* <Specific types of entry: option to choose a file from the local source and 'upload' a copy to the BCH server>
34. Notes:	