

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

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<b>Risk assessment details</b>	
1. Country Taking Decision:	Republic of South Africa
2. Title:	Application for commodity clearance of genetically modified organisms: 305423 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
<b>LMO information</b>	
4. Name and identity of the living modified organism:	<p>Name and identity of the LMO is 305423 soybean.</p> <p>The 305423 soybean has been obtained by introducing the <i>gm-fad2-1</i> gene fragment<sup>1</sup> and the <i>gm-hra</i> gene<sup>1</sup> into the soybean genome.</p> <p>The inserted <i>gm-fad2-1</i> gene fragment is part of the coding region of the soybean omega-6 desaturase gene 1 (<i>FAD2-1</i>) and does not code for a functional protein. Transcription of the <i>gm-fad2-1</i> gene fragment in 305423 soybean seeds acts to suppress transcription of endogenous omega-6 desaturase, resulting in the high oleic phenotype.</p> <p>The <i>gm-hra</i> gene encodes the GM-HRA protein, an optimized version of the soybean acetolactate synthase (ALS). Expression of the GM-HRA protein in 305423 soybean confers tolerance to ALS-inhibiting herbicides.</p> <p>This application is for commodity clearance of grain and derived products obtained from 305423 soybean for use in foods, animal feed and industrial products. It is not for general release or cultivation of 305423 soybean seed products in South Africa.</p>

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<sup>1</sup> Please note that the prefix *gm* that is used in *gm-fad2-1* and *gm-hra* has been chosen to indicate that both genes are derived from soybean, *Glycine max*.

5. Unique identification of the living modified organism:	DP-305423-1
6. Transformation event:	The transformation event is 305423 soybean.
7. Introduced or Modified Traits:	- high oleic phenotype - herbicide tolerance
8. Techniques used for modification:	The 305423 soybean was produced by means of particle co-bombardment.
9. Description of gene modification:	<p>The 305423 soybean has been obtained by introducing the <i>gm-fad2-1</i> gene fragment and the <i>gm-hra</i> gene into the soybean genome.</p> <p>The inserted <i>gm-fad2-1</i> gene fragment is part of the coding region of the soybean omega-6 desaturase gene 1 (<i>FAD2-1</i>) and does not code for a functional protein. Transcription of the <i>gm-fad2-1</i> gene fragment in 305423 soybean seeds acts to suppress transcription of endogenous omega-6 desaturase, resulting in the high oleic phenotype.</p> <p>The <i>gm-hra</i> gene encodes the GM-HRA protein. The GM-HRA protein is an acetolactate synthase (ALS), encoded by an optimized form of the endogenous <i>als</i> gene from <i>Glycine max</i>, that confers tolerance to ALS-inhibiting herbicides.</p> <p>This application is for commodity clearance of grain and derived products obtained from 305423 soybean for use in foods, animal feed and industrial products. It is not for general release or cultivation of 305423 soybean seed products in South Africa.</p>

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### Characteristics of modification

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

No vector was used in the production of 305423 soybean. Two linear DNA fragments, *i.e.* fragments PHP19340A and PHP17752A, were used to obtain 305423 soybean. Fragment PHP19340A contains the *gm-fad2-1* cassette that is comprised of the KTi3 promoter, the *gm-fad2-1* gene fragment and the KTi3 terminator. Fragment PHP17752A contains the *gm-hra* cassette that is comprised of the SAMS promoter region, the *gm-hra* gene and the *als* terminator.

No additional DNA sequences were used in the transformation of 305423 soybean.

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

Extensive Southern blot analysis of 305423 soybean together with very detailed DNA sequence analysis confirms that the inserted DNA in 305423 soybean consists of four insertions that comprise:

- Insertion 1: one truncated PHP19340A fragment with a truncated KTi3 terminator and intact *gm-fad2-1* gene fragment and intact KTi3 promoter, one intact PHP19340A fragment, one intact PHP17752A fragment, one truncated PHP19340A fragment with an intact KTi3 promoter and a truncated *gm-fad2-1* gene fragment, and one truncated PHP19340A fragment with a truncated KTi3 promoter and truncated *gm-fad2-1* gene fragment
- Insertion 2: one truncated PHP19340A fragment with a truncated KTi3 promoter and with intact *gm-fad2-1* gene fragment and intact KTi3 terminator
- Insertion 3: one truncated copy of the KTi3 promoter with a non-functional 495 bp fragment of the plasmid backbone; and
- Insertion 4: two truncated PHP19340A fragments in an inverted repeat configuration, both with a truncated KTi3 promoter and intact *gm-fad2-1* gene fragment and KTi3 terminator.

Southern blot analysis confirmed that the inserted DNA in 305423 soybean is genetically linked and segregates following a typical pattern of Mendelian inheritance expected for a single, genetically-linked insertion locus.

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

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12. Taxonomic name/status of recipient organism or parental organisms:	Family name: Genus: Species:	Leguminosae <i>Glycine</i> <i>G. max</i> (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.	

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**Donor organism or organisms (Annex III.9(b))**

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19. Taxonomic name/status of donor organism(s)	<i>Glycine max</i> is the donor of the <i>gm-hra</i> gene, the <i>gm-fad2-1</i> gene fragment, the KTi3 promoter and terminator sequences, the SAMS promoter region and the <i>als</i> terminator. This means that all functional elements, intended for insertion in 305423 soybean, are derived from soybean.
20. Common name of donor organism(s):	<i>Glycine max</i> : soybean, soy
21. Point of collection or acquisition of donor organism(s):	USA
22. Characteristics of donor organism(s) related to biosafety:	The donor organism has a long history of safety.

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**Intended use and receiving environment**

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23. Intended use of the LMO (Annex III 9(g)):	Commodity clearance of grain and derived products obtained from 305423 soybean for use in foods, animal feed and industrial products. The application is not for general release or cultivation of 305423 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 305423 soybean for use in foods, animal feeds and industrial products. It is not for general release or cultivation of 305423 soybean seed products in South Africa.

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**Risk assessment summary**

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25. Detection/Identification method of the LMO (Annex III.9(f)):	A protocol for the detection of 305423 soybean has been developed. The detection protocol provides information for the detection and identification of 305423 soybean and is based on PCR amplification of a DNA sequence specific for the 305423 soybean insert, thereby allowing the event-specific detection of 305423 soybean.
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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 305423 soybean. Therefore, the likelihood of adverse effects to human and animal health or to the environment arising from commodity clearance of 305423 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 305423 soybean. Therefore, any potential consequences that may occur from commodity clearance of 305423 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 305423 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 305423 soybean is negligible. Therefore, there is no need for a risk management strategy for the commodity clearance of 305423 soybean in South Africa.
30. Actions to address uncertainty regarding the level of risk (Annex III.8(f)):	Not applicable.
<b>Additional information</b>	
31. Availability of detailed risk assessment information:	Detailed risk assessment information for 305423 soybean has been included in the application for commodity clearance of 305423 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:	<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>

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34. Notes:

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