

## 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: 305423x40-3-2 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

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### LMO information

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4. Name and identity of the living modified organism:	<p>Name and identity of the LMO is 305423x40-3-2 soybean.</p> <p>305423x40-3-2 soybean has been obtained from traditional breeding methods between progeny of two genetically modified (GM) soybeans. The two GM soybeans are DP-305423-1 soybean, referred to as 305423 soybean, and MON-04032-6 soybean, referred to as 40-3-2 soybean. No new genetic modification has been introduced in 305423x40-3-2 soybean.</p> <p>305423 soybean has been obtained by introducing the <i>gm-fad2-1</i><sup>1</sup> gene fragment and the <i>gm-hra</i><sup>1</sup> 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 acts to suppress transcription of endogenous omega-6 desaturase, resulting in the high oleic phenotype. 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, used as a selectable marker for transformation, confers tolerance to ALS-inhibiting herbicides.</p> <p>40-3-2 soybean has been genetically modified to express the 5-enolpyruvyl-shikimate-3-phosphate synthase gene isolated from the <i>Agrobacterium</i> sp. strain CP4 (<i>cp4 epsps</i>), which encodes the CP4 EPSPS protein. Expression of the CP4 EPSPS protein confers tolerance to glyphosate herbicide.</p> <p>This application is for commodity clearance of grain and derived products obtained from 305423x40-3-2 soybean for use in foods, animal feed and industrial products.</p>
5. Unique identification of the living modified organism:	<p>The unique identification code assigned to 305423x40-3-2 soybean is DP-305423-1xMON-04032-6 soybean.</p>
6. Transformation event:	<p>The transformation event is 305423x40-3-2 soybean.</p>

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<sup>1</sup> Please note that throughout this application, 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*.

7. Introduced or Modified Traits:	<p>- High oleic phenotype</p> <p>- Herbicide tolerance</p>						
8. Techniques used for modification:	<p>305423x40-3-2 soybean has been obtained from traditional breeding methods between progeny of two genetically modified (GM) soybeans. The two GM soybeans are DP-305423-1 soybean, referred to as 305423 soybean, and MON-04032-6 soybean, referred to as 40-3-2 soybean. No new genetic modification has been introduced in 305423x40-3-2 soybean.</p> <p>The 305423 soybean was obtained by means of particle co-bombardment using two linear DNA fragments, PHP19340A that contains the <i>gm-fad2-1</i><sup>2</sup> gene fragment cassette and PHP17752A that contains the <i>gm-hra</i><sup>2</sup> gene cassette.</p> <p>Plasmid PV-GMGT04 that contains the <i>cp4 epsps</i> gene cassette was used to produce 40-3-2 soybean by means of the particle acceleration method.</p>						
9. Description of gene modification:	Please refer to 4 and 8 above.						
<b>Characteristics of modification</b>							
10. Vector characteristics (Annex III.9(c)):	No vector was used in the production of 305423x40-3-2 soybean. Please refer to 4 and 8 above.						
11. Insert or inserts (Annex III.9(d)):	Please refer to 4 and 8 above.						
<b>Recipient organism or parental organisms (Annex III.9(a))</b>							
12. Taxonomic name/status of recipient organism or parental organisms:	<table border="0"> <tr> <td style="padding-right: 20px;">Family name:</td> <td>Leguminosae</td> </tr> <tr> <td>Genus:</td> <td><i>Glycine</i></td> </tr> <tr> <td>Species:</td> <td><i>G. max</i> (L.) Merr.</td> </tr> </table>	Family name:	Leguminosae	Genus:	<i>Glycine</i>	Species:	<i>G. max</i> (L.) Merr.
Family name:	Leguminosae						
Genus:	<i>Glycine</i>						
Species:	<i>G. max</i> (L.) Merr.						
13. Common name of recipient organism or parental organisms:	Soybean.						

<sup>2</sup> Please note that throughout this application, 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*.

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.
<b>Donor organism or organisms (Annex III.9(b))</b>	
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 KT13 promoter and terminator sequences, the SAMS promoter region and the <i>als</i> terminator.  The <i>cp4 epsps</i> gene originated from the CP4 strain of the common soil bacterium <i>Agrobacterium tumefaciens</i> .
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 organisms have 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 305423x40-3-2 soybean for use in foods, animal feed and industrial products.
24. Receiving environment (Annex III.9(h)):	Not applicable. The application is for commodity clearance of grain and derived products obtained from 305423x40-3-2 soybean. It is not for general release or cultivation of 305423x40-3-2 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)):	PCR detection techniques.
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 305423x40-3-2 soybean when compared to conventional soybeans. Therefore, the likelihood of adverse effects to human and animal health or to the environment arising from commodity clearance of 305423x40-3-2 soybean in South Africa is negligible.
27. Evaluation of the consequences (Annex III.8(c)):	Please refer to 26.
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 305423x40-3-2 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 305423x40-3-2 soybean is negligible. It is recommended that the Event 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.

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**Additional information**

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31. Availability of detailed risk assessment information: Detailed risk assessment information for 305423x40-3-2 soybean has been included in the application for commodity clearance of 305423x40-3-2 soybean submitted by Pioneer Hi-Bred RSA (Pty) Ltd.

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32. Any other relevant information: All relevant information is contained in the application submitted to DAFF.

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33. Attach document: The affidavit is attached. No other applicable documents are attached to the Risk Assessment.

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34. Notes: Not applicable.

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