

## PART II

### 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:	<Commodity Clearance of GMB151>
3. Contact details:	<BASF South Africa (Pty) Ltd, on behalf of BASF Agricultural Solutions Seed US LLC  (Reg. No.: 1966/010235/07)  852 Sixteenth Road,  Midrand 1685  South Africa  Tel: +27 11 203 2609  Kelebohile.lekoape@basf.com>
LMO information	
4. Name and identity of the living modified organism:	<GMB151 soybean produces the Cry14Ab-1 protein, which confers resistance to soybean cyst nematode and a modified 4-hydroxyphenylpyruvate dioxygenase (HPPD-4), that confers tolerance to HPPD inhibitor herbicides such as isoxaflutole (IFT)>
5. Unique identification of the living modified organism:	<BCS-GM151-6>
6. Transformation event:	<The transformation event is GMB151>
7. Introduced or Modified Traits:	Choose the trait from the following list:  B. Altered growth, development and product quality <b>Chemical tolerance</b> - Herbicide tolerance <b>Pest resistance</b> - Nematode resistance>
8. Techniques used for modification:	< The standard <i>Agrobacterium</i> -mediated transformation methodology was used to generate the GMB151 transformation event.>

9. Description of gene modification:	<p>&lt;GMB151 soybean was developed through <i>Agrobacterium</i>-mediated transformation using the vector pSZ8832 containing the <i>cry14Ab-1.b</i> and <i>hppdPf-4Pa</i> gene cassettes:</p> <p>(i) The <i>cry14Ab-1.b</i> gene encodes the Cry14Ab-1 protein, a crystal protein derived from <i>Bacillus thuringiensis</i>, . (<i>Bt</i>) which confers protection against soybean cyst nematode (<i>Heterodera glycines</i>). Cry14Ab-1 belongs to the “nematicidal branch” of Cry proteins with the closest homology to Cry14Aa1 (87% identity).</p> <p>(ii) The <i>hppdPf-4Pa</i> gene encodes for a modified 4-hydroxyphenyl pyruvate dioxygenase (HPPD-4) protein which has introduced four amino acid substitutions (Glu335Pro, Gly336Trp, Lys339Ala and Ala340Gln). Expression of the HPPD-4 protein confers tolerance to HPPD inhibitors, such as isoxaflutole herbicides.&gt;</p>
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**Characteristics of modification**

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10. Vector characteristics (Annex III.9(c)):	<p>&lt;The vector pSZ8832 is derived from pGSC1700 and pUC19. Both were constructed in <i>E. coli</i> and thereafter transferred to a suitable <i>Agrobacterium tumefaciens</i> strain.&gt;</p>
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11. Insert or inserts (Annex III.9(d)):	<p>&lt; Below are the key genetic elements of pSZ8832:</p> <p><b>T35S:</b> sequence including the 3’ untranslated region of the 35S transcript of the Cauliflower Mosaic Virus (Sanfacon et al, 1991);</p> <p><b>Cry14Ab-1.b:</b> coding sequence of the delta-endotoxin gene of <i>Bacillus thuringiensis</i> (GenBank accession number: AGU13817.1);</p> <p><b>Pubi10At:</b> sequence including the promoter region of ubiquitin-10 gene of <i>Arabidopsis thaliana</i> (Grefen et al, 2010);</p> <p><b>T35S:</b> sequence including the 3’ untranslated region of the 35S transcript of the Cauliflower Mosaic Virus (Sanfacon et al, 1991);</p> <p><b>hppdPfW-4Pa:</b> coding sequence of a variant 4-hydroxyphenylpyruvate dioxygenase gene of <i>Pseudomonas fluorescens</i>;</p> <p><b>TPotpY-Pf:</b> coding sequence of the optimized transit peptide, containing sequence of the RuBisCO small subunit genes of <i>Zea mays</i> and <i>Helianthus annuus</i> (Lebrun et al., 1996);</p> <p><b>Ltev:</b> sequence including the leader sequence of the Tobacco Etch Virus genomic RNA (Allison et al., 1985);</p> <p><b>P2x35S:</b> sequence including the double enhanced promoter region of the Cauliflower Mosaic Virus 35S genome transcript (Kay et al., 1987)&gt;</p>
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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:	<p>&lt; Family name: <i>Leguminosae</i></p> <p>Genus: <i>Glycine</i></p> <p>Sub-genus: <i>Soja</i></p> <p>Species: <i>max</i></p> <p>Sub-species: none designated</p> <p>Cultivar/breeding line: GMB151&gt;</p>
13. Common name of recipient organism or parental organisms:	<Soya bean>
14. Point of collection or acquisition of recipient or parental organisms:	<The recipient organism is <i>Glycine max</i> , event GMB151; acquired from the North American commercial variety Thorne >
15. Characteristics of recipient organism or parental organisms related to biosafety:	<p>&lt; <i>Glycine max</i> has been grown in South Africa since 1903, where it exists almost exclusively as a managed crop. There is no evidence that the cultivated species has been able to establish feral populations or out-cross.</p> <p>The primary biosafety characteristics to be considered in the proposed commodity clearance include:</p> <ol style="list-style-type: none"> <li>1. Soybean is largely self-pollinating with very low levels of cross-outcrossing.</li> <li>2. Soybean seeds rarely display characteristics of dormancy. If they do survive and grow as volunteers the year after cultivation, they are unlikely to compete well with the succeeding crop.</li> <li>3. There are no wild relatives in South Africa.&gt;</li> </ol>
16. Centre(s) of origin of recipient organism or parental organisms:	<p>&lt; Historical and geographical evidence suggests that soybeans were first domesticated in eastern China, between the 17th and 11th century BC. Successful cultivation generally occurs in climates with hot summers, with optimum growing conditions achieved in mean temperatures of 20 to 30 °C. Temperatures below 20 °C and over 40 °C tend to retard growth significantly. Today soybeans are a commercial crop in over 90 countries.&gt;</p>

17. Centres of genetic diversity, if known, of recipient organism or parental organisms: <*Glycine max* (L.) Merr., the cultivated soybean, is a summer annual herb that has never been found in the wild (Hymanitz, 1970). This domesticate is in fact extremely variable, due primarily to the development of soya bean "land races" in East Asia. The subgenus *Soja* contains, in addition to *G. max* and *G. soja*, the form known as *G. gracilis*, a form morphologically intermediate between the two. This is a semi-cultivated or weedy form and is known only in Northeast China.

*Glycine soja*, considered the ancestor of cultivated soybean, is an annual procumbent or slender twiner that is distributed throughout China, the adjacent areas of the former USSR, Korea, Japan and Taiwan. It grows in fields and hedgerows, along roadsides and riverbanks>

18. Habitats where the recipient organism or parental organisms may persist or proliferate: <Soybean, *Glycine max* can grow in a wide range of soils, with optimum growth in moist alluvial soils with a good organic content. Soya beans, like most legumes, perform nitrogen fixation by establishing a symbiotic relationship with the bacterium *Bradyrhizobium japonicum*; Jordan 1982. Soybeans rarely display any dormancy characteristics (OECD, 2000 <sup>M-201734-02-1</sup>) and the soybean plant is not weedy in character and is not found outside of cultivation areas. It is very susceptible to frost damage, excessive drought and extended flooding. Seeds survive poorly in soil, normally less than one year.>

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

19. Taxonomic name/status of donor organism(s) < *Bacillus thuringiensis*;  
*Pseudomonas fluorescens* >

20. Common name of donor organism(s): < Bacteria;  
Bacteria >

21. Point of collection or acquisition of donor organism(s): <*Bacillus thuringiensis* is a soil isolate considered ubiquitous in natural environments;  
*P. fluorescens* is ubiquitous in the environment, including soil, water and food>

22. Characteristics of donor organism(s) related to biosafety:	<p>&lt; <i>Bacillus thuringiensis</i> produce insecticidal crystal proteins that have been used in agriculture for decades (as microbial agents or in transgenic crops). They are classified as non-pathogenic and found to be nontoxic to humans or mammals (Betz <i>et al.</i>, 2000);</p> <p><i>Pseudomonas fluorescens</i>, from which the HPPD protein was isolated to obtain the HPPD-4 protein, has a good history of safe use. It has many beneficial uses in agriculture, human health and bioremediation. Despite this widespread presence, it is not described as allergenic, toxic or pathogenic to healthy humans and animals&gt;</p>
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**Intended use and receiving environment**

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23. Intended use of the LMO (Annex III 9(g)):	<GMB151 soybean will enter South Africa by import as a commodity seed or derived products, used for downstream processing as conventional soybeans. The major food/feed products derived from soybeans are whole soybeans, oil and meal.>
24. Receiving environment (Annex III.9(h)):	<The purpose of this application is for food, feed and/or processing. It is not our intention to release the organism into the environment.>

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**Risk assessment summary**

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25. Detection/Identification method of the LMO (Annex III.9(f)):	<p>&lt;The LMO can be detected or identified in four ways:</p> <ol style="list-style-type: none"> <li>1. Detection of the <i>cry14Ab-1.b</i> and/or <i>hpdPf-4Pa</i> genes can be achieved by using event specific PCR-based methods.</li> <li>2. Detection of the Cry14Ab-1 and/or HPPD-4 proteins can be achieved by using event specific ELISA methods.</li> <li>3. Diagnostic lateral flow strip technology for Cry14Ab-1 and/or HPPD-4 protein detection in seeds.</li> <li>4. Plants of the LMO will survive application of high doses of herbicides containing HPPD inhibitors as the active ingredient&gt;</li> </ol>
26. Evaluation of the likelihood of adverse effects (Annex III.8(b)):	<p>&lt;The scope of this application is for the authorization of GMB151 soybean for food, feed and processing. As such, cultivation of the event is excluded in the Republic of South Africa.</p> <p>Environmental exposure would be limited to the persistence and/or invasiveness of GMB151 as a consequence of accidental release during transportation and/or processing for food and feed. It has been shown that GMB151 soybean is no different from its non-GM conventional counterpart in composition, agronomic, morphologic, nutritional and safety characteristics that could lead to changes in its interactions with the biotic and/or abiotic environment&gt;</p>

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27. Evaluation of the consequences (Annex III.8(c)):	<Soybean, <i>Glycine max</i> , is a cultivated, self-pollinating annual species, propagated commercially by seed. Soybeans rarely display any dormancy characteristics (OECD, 2000 <sup>M-201734-02-1</sup> ) and the soybean plant is not weedy in character and is not found outside of cultivation area. It is very susceptible to frost damage, excessive drought and extended flooding. Seeds survive poorly in soil, normally less than one year>
28. Overall risk (Annex III.8(d)):	<Given the above, the overall risk of persistence or invasiveness of conventional soybean is highly unlikely should volunteers be established. Since GMB151 behaves in a similar manner to conventional soybean the overall risk of adverse effects being realized remains highly unlikely>
29. Recommendation (Annex III.8(e)):	<Volunteer plants, should they emerge in an area due to accidental spillage from transport or during processing, can be destroyed either mechanically or through the use of an herbicide other than an HPPD inhibitor>
30. Actions to address uncertainty regarding the level of risk (Annex III.8(f)):	<Field trials of GMB151 have been conducted in the US (with EPA approval registered in June 2020), Brazil and Argentina and the event is the subject of deregulation submissions in these countries. FFP applications have been submitted in other trading countries including the EU. To date, the level of risk posed by GMB151 has not been questioned. However, should any scientifically valid information come to light that contradicts any aspect relating to the safety of GMB151, BASF will take the necessary steps to manage the risks and inform the authorities>

**Additional information**

31. Availability of detailed risk assessment information:	< Most of the information has been supplied with this application>
32. Any other relevant information:	< Text entry - any other information that is relevant to the risk assessment. e.g. information of non CBI nature that was included in the original application but is not included in this form>
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>
34. Notes:	<Text entry>