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 GHB811>
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:	<Cultivated cotton, *Gossypium hirsutum* L., has been developed using recombinant gene technology techniques to be tolerant to herbicides with glyphosate and HPPD inhibitors as the active ingredients>
5.	Unique identification of the living modified organism:	<BCS-GH811-4>
6.	Transformation event:	<the transformation event is GHB811>
7.	Introduced or Modified Traits:	Choose the trait from the following list: B. Altered growth, development and product quality **Chemical tolerance** - Herbicide tolerance>
8.	Techniques used for modification:	<Standard *Agrobacterium*-mediated transformation methodology for cotton was used to generate the GHB811 transformation event.>

9. Description of gene modification:	< GHB811 cotton was developed through *Agrobacterium*-mediated transformation using the vector pTSIH09 containing *hppdPfW336-1Pa* and *2mepsps* expression cassettes: (i) The double mutant 5-enol pyruvylshikimate-3-phosphate synthase (*2mepsps*) gene that encodes for the 2mEPSPS protein. The *2mepsps* coding sequence was developed by introducing two, point mutations to the wild-type *epsps* gene cloned from maize (*Zea mays*). Expression of the 2mEPSPS protein confers tolerance to glyphosate herbicides. (ii) The *hppdPf W336* gene encodes for the HPPD W336 protein. The *hppdPf W336* coding sequence was developed by introducing a single point mutation to the wild type *hppd* gene derived from *Pseudomonas fluorescens*. gene. Expression of the HPPD W336 protein confers tolerance to HPPD inhibitors, such as isoxaflutole herbicides.>
Characteristics of modification	
10. Vector characteristics (Annex III.9(c)):	<The vector pTSIH09 is derived from pGSC1700 and pUC19. Both were constructed in *E. coli* and thereafter transferred to a suitable *Agrobacterium tumefaciens* strain.>
11. Insert or inserts (Annex III.9(d)):	< Below are the key genetic elements of pTSIH09: ***hppdPfW336-1Pa*:** coding sequence of the 4-hydroxyphenylpyruvate dioxygenase gene of *Pseudomonas fluorescens* strain A32 modified by the replacement of the amino acid Glycine 336 with a Tryptophane (Boudec *et al*., 2001), adapted to cotton codon usage ***TPotpY-1Pa:*** coding sequence of an optimized transit peptide derivative (position 55 changed into Tyr), containing sequence of the RuBisCO small subunit genes of *Zea mays* and *Helianthus annuus* (Lebrun *et al*., 1996), adapted for cotton codon usage **Pcsvmv:** sequence including the promoter region of the Cassava Vein Mosaic Virus (Verdaguer *et al.,* 1996) **Ph4a748:** sequence including the promoter region of the histone H4 gene of *Arabidopsis thaliana* (Chabouté *et al.,* 1987) ***TPotpC:*** coding sequence of the optimized transit peptide, containing sequence of the RuBisCO small subunit genes of *Zea mays* and *Helianthus annuus* (Lebrun *et al*., 1996) ***2mepsps:*** coding sequence of the double-mutant 5-enol-pyruvylshikimate-3-phosphate synthase gene of *Zea mays* (Lebrun *et al*., 1997>
Recipient organism or parental organisms (Annex III.9(a)):	

12. Taxonomic name/status of recipient organism or parental organisms:	< Family:	Malvaceae
	Tribe:	Gossypieae
	Genus:	*Gossypium*
	Species:	*hirsutum* (*Gossypium hirsutum* Linnaeus >
	and <text entry – for other, not on the list>	
13. Common name of recipient organism or parental organisms:	< Cotton, cultivated cotton>	
14. Point of collection or acquisition of recipient or parental organisms:	<The recipient organism is *Gossypium hirsutum, event* GHB811; acquired from the North American commercial variety Coker >	

15. Characteristics of recipient organism or parental organisms related to biosafety:	< *Gossypium hirsutum* has been grown in South Africa since 1922, where it exists almost exclusively as a managed cultigen. There is no evidence that the cultivated species has been able to establish feral populations or out-cross with indigenous *Gossypium* populations. The primary biosafety characteristics to be considered in the proposed trial include: 1. Cotton is a perennial crop by nature, but it is seeded and harvested annually for its fibre and seed. It is normally ploughed out after harvest in preparation for the following crop. 2. Cottonseed that is lost during transport, for example between the farm and the gin, is generally unable to germinate on the hard soil surfaces of roads and road shoulders. Annual road shoulder clearing practices and competition from grasses and broadleaf plants that occur in these environments prevent cotton establishment. Many years of cotton cultivation with non-transgenic cotton has demonstrated its limited ability to colonise and invade unmanaged environments. Thus, cultivated cotton is generally not able to establish without human intervention. Transgenic cotton is expected to behave in the same way as the introduced traits would not provide a selective advantage outside of these environments. The diploid *Gossypium herbaceum* race *africana* is the only wild type of the genus *Gossypium* that occurs in indigenous populations in South Africa. Genetic incompatibility barriers prevent out-crossing between *G. hirsutum* and *G. herbaceum*; cultivated cotton species are allotetraploid. In the event of pollen being transferred to *G. herbaceum* from transgenic *G. hirsutum*, the resulting offspring will be infertile triploids. To date there is no recorded incidence of conventional cotton hybridizing with *G. herbaceum*, despite decades of cultivation in areas where these indigenous populations occur>
16. Centre(s) of origin of recipient organism or parental organisms:	<The genus *Gossypium* is comprised of 50 very diverse species that occur in widely separated parts of the world, typically in relatively arid parts of the tropics and subtropics. Worldwide, four species of cotton are of agronomic importance: the two diploid Old World (or Asiatic) species, *G. arboreum* and *G. herbaceum*, and the two allotetraploid New World species, *G. barbadense* and *G. hirsutum*. Although the old-world species remain important in restricted areas of India, Africa and Asia, the new world species account for 98% of the world's cotton fibre production. *Gossypium hirsutum* accounts for 90% of this production and is native to Mexico and parts of Central America where it was domesticated by indigenous peoples.>

17. Centres of genetic diversity, if known, of recipient organism or parental organisms:	<Genera of the tribe *Gossypiae* originated in the tropics and subtropics, with major developments of the genus *Gossypium* occurring in Africa and Australia, minor developments in South America through Middle America, and scattered development throughout Oceania. *Gossypium hirsutum* is native to Mexico and parts of Central America where it was domesticated by indigenous peoples.>
18. Habitats where the recipient organism or parental organisms may persist or proliferate:	<As an established agricultural field crop, cultivated cotton is grown commercially in the warmer regions of more than 50 temperate and tropical countries of the world. Major production areas include the USA, India, China, Central and South America, the Middle East and Australia. Climatic conditions in these regions are characterised by periods of hot and dry weather, with adequate moisture usually obtained through irrigation. In cotton growing districts, transient cotton plants may occur on roadsides, but these generally do not persist outside of unmanaged environments.>
Donor organism or organisms (Annex III.9(b)):	
19. Taxonomic name/status of donor organism(s)	< *Zea mays;* *Pseudomonas fluorescens* >
20. Common name of donor organism(s):	< Maize; Bacteria >
21. Point of collection or acquisition of donor organism(s):	<*Zea mays* is a cultivated crop that is ubiquitous in agricultural environments worldwide. Based on area planted it is the world's third largest cereal crop (see http://www.faostat.fao.org); *P. fluorescens* is ubiquitous in the environment, including soil, water and food>
22. Characteristics of donor organism(s) related to biosafety:	<*Zea mays* from which the wild type EPSPS protein was isolated is common in nature, commonly consumed by animals and humans with an excellent history of safe use. It is not considered as an allergenic food or toxic food for humans and animals, despite its widespread consumption for centuries; *Pseudomonas fluorescens*, from which the HPPD protein was isolated to obtain the HPPD W336 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>
Intended use and receiving environment	

23. Intended use of the LMO (Annex III 9(g)):	<GHB811 cotton will be imported into South Africa for use as food, feed and for processing. Commodity Clearance approval of GHB811 will enable the use of all material containing or produced from this cotton event>
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.>
Risk assessment summary	
25. Detection/Identification method of the LMO (Annex III.9(f)):	<The LMO can be detected or identified in four ways: 1. Detection of the *2mepsps* and/or *hppdPfW336-1Pa* genes can be achieved by using event specific PCR-based methods. 2. Detection of the 2mEPSPS and/or HPPD W336 proteins can be achieved by using event specific ELISA methods. 3. Diagnostic lateral flow strip technology for 2mEPSPS and/or HPPD W336 protein detection in seeds. 4. Plants of the LMO will survive application of high doses of herbicides containing glyphosate and/or HPPD inhibitors as the active ingredient>
26. Evaluation of the likelihood of adverse effects (Annex III.8(b)):	<The scope of this application is for the authorization of GHB811 cotton for food, feed and processing. As such, cultivation of the event is excluded in the Republic of South Africa. Therefore, any environmental exposure would be limited to the persistence and/or invasiveness of GHB811 as a consequence of accidental release during transportation and/or processing for food and feed. It has been shown that GHB811 cotton 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. Because *Gossypium* is unable to survive without human intervention, the likelihood of adverse effects is minimised>
27. Evaluation of the consequences (Annex III.8(c)):	<Cotton is a cultivated, largely self-pollinating annual species, propagated commercially by seed. Although seeds that remain in the soil may germinate, all conditions have to be right for this to happen, otherwise the seeds are likely to rot and die.>
28. Overall risk (Annex III.8(d)):	<Given the above, the overall risk of persistence or invasiveness of conventional cotton is highly unlikely should volunteers be established. Since GHB811 behaves in a similar manner to conventional cotton the overall risk of adverse effects being realized remains highly unlikely>

29. Recommendation (Annex III.8(e)):	<Volunteer plants, should they emerge due to accidental spillage during transport or processing, can be destroyed either mechanically or through the use of an herbicide other than HPPD inhibitors and glyphosate>
30. Actions to address uncertainty regarding the level of risk (Annex III.8(f)):	<Field trials of GHB811 have been conducted in Brazil, Canada and the US and the event is the subject of deregulation submissions in these countries. FFP applications have been submitted in other trading countries including Australia, Argentina and Japan. To date, the level of risk posed by GHB811 has not been questionable. However, should any scientifically valid information come to light that contradicts any aspect relating to the safety of GHB811, 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:	*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:	<Text entry>