

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
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LMO information

4. Name and identity of the living modified organism:
Cotton *Gossypium hirsutum* has been transformed (using recombinant gene technology) to be tolerant to glyphosate the active ingredient of a non selective herbicide called Roundup Ready® herbicide. This pre-commercial product is called Roundup Ready® Flex cotton.
5. Unique identification of the living modified organism:
Currently there are no unique identifiers.
6. Transformation event: Cotton event MON 88913.
7. Introduced or Modified Traits: Herbicide tolerance to Roundup Ready herbicide formulations containing the active ingredient glyphosate.
8. Techniques used for modification: *Agrobacterium*-mediated transformation techniques were used to create MON 88913

Choose the trait from the following list:

- B. Altered growth, development and product quality

Chemical tolerance

- Herbicide tolerance

9. Description of gene modification: MON 88913 represents another gene that was derived from an *Agrobacterium* species that produces a protein, which exhibits an affinity for glyphosate the active ingredient of the Roundup family of herbicides. This enzyme provides the cotton plant with mechanism for tolerance to this non-selective herbicide and is identical to the protein produced by Roundup Ready cotton 1445.

Characteristics of modification

10. Vector characteristics
Plasmid vector PV- GHGT35 derived from *Agrobacterium* species strain CP4
11. Insert or inserts

The MON 88913 cotton contains a single insert containing two cp4 *epsps* gene expression cassettes containing identical cp4 *epsps* coding sequences. As a result MON 88913 produces the CP4 EPSPS protein that displays reduced affinity for glyphosate the active ingredient of the Roundup family of herbicides.

Recipient organism or parental organisms

12. Taxonomic name/status of recipient organism or parental organisms:
Common name: Cotton
Family name: Malvaceae
Genus: *Gossypium*
Species: (*Gossypium hirsutum* Linnaeus)
13. Common name of recipient organism or parental organisms:
Cotton.
14. Point of collection or acquisition of recipient or parental organisms: Initially the cotton seed will be produced in the USA and then shipped to South Africa in sealed containment. This will be collected at the port of entry – Johannesburg International. This seed will then be planted by cotton seed producers who will bulk up seed locally for commercial sales.
15. Characteristics of recipient organism or parental organisms related to biosafety: Cotton is a perennial crop by nature but is seeded and harvested annually for its fiber and seed.
Gossypium hirsutum has been grown in South Africa since 1922. At no time has the cotton plant been able to establish itself as a feral population. The main factors to be taken into account are:
 1. Although the plant is a perennial it is normally ploughed out after harvest. This is in preparation for the following crop where seedbed preparation (mechanical and/or herbicides) prevents volunteer seed from germinating.
 2. Cottonseed lost in transit between the grower's farm and the gins (farm roads and road shoulders) is generally unable to germinate on the hard soil surfaces. Annual road shoulder clearing and natural grass and broadleaf plant competition prevents cotton establishing itself. Cultivated cotton is not able to establish itself without the intervention of man who creates agronomically the ideal germination and sustainable growth conditions. Cultivated cotton cannot compete with natural field grasses. In conclusion, and as 76 years of experience has shown us, it is highly improbable for conventional and therefore cotton genetically modified to escape into the environment as none of the introduced traits would provide a selective advantage to change its survivability.
 3. The diploid *Gossypium herbaceum* race *africana* is the only wild type of the genus *Gossypium*, tribe Gossypieae of the Family Malvaceae, Order Malvales that occurs in South Africa. Cultivated cotton (*Gossypium hirsutum*) is an allotetraploid and in the highly unlikely event of pollen being transferred to *G herbaceum* the resulting offspring would be infertile. To date there is no recorded incidence of conventional cotton hybridizing with *G. herbaceum* after decades of cultivation side by side where these wild types occur.

16. Centre(s) of origin of recipient organism or parental organisms: Cotton is of the genus *Gossypium* of the tribe Gossypieae of the family Malvaceae of the order Malvales (Fryxell, 1979; Munro, 1987). The genus *Gossypium* is comprised of 39 very diverse species that occur in widely separated parts of the world, typically in relatively arid parts of the tropics and subtropics (Fryxell, 1984). 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 two new world species account for about 98% of the world's cotton fiber production. Of this amount *G. hirsutum* accounts for 90% while *G. barbadense* accounts for 8% (Lee, 1984).
17. Centres of genetic diversity, if known, of recipient organism or parental organisms: See question 16 above.
18. Habitats where the recipient organism or parental organisms may persist or proliferate: See question 16 above.

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

19. Taxonomic name/status of donor organism(s):
Agrobacterium tumefaciens strain CP4
20. Common name of donor organism(s):
Agrobacterium species causative agent for crown gall formation in some plants
21. Point of collection or acquisition of donor organism(s):
Not applicable – the gene was introduced into the cotton varieties in the USA and is therefore an integral part of the seeds that will be imported.
22. Characteristics of donor organism(s) related to biosafety:
Question 15 seeing that the gene is already part of the cottonseeds genome covers this.

Intended use and receiving environment

23. Intended use of the LMO : The purpose is to import Roundup Ready® Flex transformed seed to be planted in South Africa for bulking up purposes. This process provides the certified seed that will be sold to growers. The use of Roundup Ready Flex cotton allows the spraying of Roundup Ready herbicide at any stage in the cotton growth cycle for the control of competing weeds. This increased flexibility overcomes the spraying restrictions that were imposed on growers who choose Roundup Ready cotton varieties in the past.
24. Receiving environment:
Reference must be made to question 15 when considering the receiving environment. The cotton seed will be released into the environments where cotton is currently planted.

Risk assessment summary

25. Detection/Identification method of the LMO.
Event specific PCR, ELIZA and diagnostic strip technology can be used. These are specific for DNA sequence, identification and quantitative protein and protein presence, respectively.
26. Evaluation of the likelihood of adverse effects (Annex III.8(b)):
Currently approved cotton varieties, which contain the herbicide tolerance genes (Roundup Ready Flex – MON 88913) will be planted in the USA in 2006 and has been evaluated experimentally in many other world areas including South Africa. To date no adverse effects have been detected in any world area where insect resistant and herbicide tolerant, or stacked varieties have been planted since 1996. In fact, the opposite is true. A dramatic reduction in the use of pesticides represents a positive environmental impact. This second generation Roundup Ready product on its own or as a stacked product provides further security to growers in terms of crop safety to applications of Roundup Ready herbicide.
27. Evaluation of the consequences (Annex III.8(c)):
As described above only positive consequences are anticipated based on the current adoption rates of this technology (86% of all cotton acres in the USA and 90% in South Africa), the dramatic reduction on the use of pesticides and the very substantial yield advantages particularly at small commercial farmer level.
28. Overall risk (Annex III.8(d)):
Varieties containing cotton event MON 88913 have been evaluated in South Africa during the 2003/04 and 2004/05 planting season by Stoneville Pedigree Seeds and Delta and Pinelands. There were no observed differences between these varieties, current transgenic varieties with single traits and conventional cotton. The genes incorporated into the cotton plant genome are very similar to the currently approved commercial varieties, which have demonstrated no adverse effects after more than 6 years of wide spread use. No adverse effects have been identified and therefore we do not anticipate a different result with these varieties.
29. Recommendation (Annex III.8(e)):
No risks have been identified and therefore other than the containment parameters used with the early trials of transgenic cotton varieties, no additional steps need to be taken.
30. Actions to address uncertainty regarding the level of risk (Annex III.8(f)):
There is no uncertainty regarding the risk profile based on previous experience with single and stacked transgenic events in South Africa since 1998. MON 88913, the enhanced Roundup Ready gene for cotton is similar too and derived from the same donor CP4 *Agrobacterium* that the commercialized Roundup Ready Cotton line 1445 is derived from. It can be concluded that the level of risk will be same as exists for both commercialized traits and conventional varieties currently being grown in South Africa.

Additional information

31. Availability of detailed risk assessment information:
Further information is available in the dossier.

32. Any other relevant information:
None.

33. Attach document: Not *applicable to applicant*

34. Notes: <Text entry>