

## Document 4-1

## Results of the study by the crop subcommittee

Name: Herbicide glufosinate and Lepidoptera resistant cotton (modified bar, modified cry1Ab, *Gossypium hirsutum* L.) (T304-40, OECD UI: BCS-GHØØ4-7)

Contents of first-class use, etc. : Use, processing, storage, transportation and disposal for food or feed, and these

Five Acts associated with

Applicant: Bayer CropScience Corporation

Based on the biodiversity impact assessment submitted by the applicant, the Crop Subcommittee

Applicants' assessment of the impact on biodiversity when using this recombinant cotton

Ten The contents were examined. The main items confirmed are as follows.

About result of 1 biodiversity impact assessment

This recombinant cotton is agglutinated with the expression vector pTDL008 constructed from the plasmid pGSV20.

Introduced by the thermium method.

This recombinant cotton is a PAT protein derived from *Streptomyces hygroscopicus* (phosphinothricin

15 Modified Cry1Ab protein derived from *Bacillus thuringiensis*

1 copy of almost complete T-DNA region containing the cry1Ab gene, 1 copy modification

The cry1Ab gene expression cassette and 3'me1 fragment are integrated adjacent to each other on the chromosome.

Stable transmission for gene segregation, Southern blot analysis and sequence analysis

It has been confirmed more. In addition, it is confirmed that the target gene is stably expressed over multiple generations.

20 It has been confirmed by law.

(1) Competitive advantage

Cotton, the species to which the host belongs, has been used for a long time in Japan.

No report has been made.

In FY2008 in Japan's P1P laboratory and in FY2011 in Japan's isolated field, the competition for this recombinant cotton As a result of investigating various traits in the plant, this recombination was performed at the flowering stage, the opening stage and the total number of branches. Differences or statistically significant differences were observed between cotton and control non-recombinant cotton.

30 The flowering and opening periods were both one day earlier for this recombinant cotton than the non-recombinant control cotton, The difference was slight and was not considered to increase competitive advantage. Also, the total number of branches The recombinant cotton was less than the non-recombinant control cotton, and a statistically significant difference was observed. this Is a temporary growth delay in this recombinant cotton strain that was supplemented due to insect damage in the early stages of growth, In particular, there was a tendency for branch development to be delayed, and it was inferred that there was a difference in the investigation during pinching. But, Since no statistically significant difference was observed in the above-ground weight, etc., investigated during the harvest period, this difference was temporary. 35 It was considered to be a typical one.

This recombinant cotton is resistant to glufosinate herbicide by modified PAT protein and modified Cry1Ab protein. It is given resistance to Lepidoptera pests. However, the cultivated cotton is not It is difficult to grow spontaneously in Japan, so it is important to increase competitive advantage in the natural environment in Japan. 40 Hard to think.

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Based on the above, this recombinant cotton has not been identified as wild animals and plants that may be affected. The applicant's conclusion that there is no risk of biodiversity impact due to its superiority I judged.

Five (2) Productivity of hazardous substances

Cotton, the species to which the host belongs, Cyclopropene causes decolorization and reduced hatchability of eggs by inhibiting desaturation of Japanese fatty acids Contains fatty acids. However, there are no reports that wild animals feed on cotton seeds. Cotton also produces harmful substances that affect the habitat or growth of wild animals and plants such as other sensitive substances. Ten The vitality is not known.

In this recombinant cotton, PAT protein and modified Cry1Ab protein are expressed by the introduced gene, etc. However, it has been confirmed that it has no known allergen-like sequence.

15 In isolated fields in Japan, harmful substances of this recombinant soybean (secreted from roots and other plant and soil microbes  
Production of things that affect living organisms, and those that affect other plants after the plant body has died inside  
As a result of examining the presence or absence of sex by soil microflora test, plowing test and succeeding crop test, this recombinant cotton test  
There was no difference between the plot and the control non-recombinant cotton test plot.

20 The modified PAT protein has a high substrate specificity and produces new harmful substances by affecting the metabolic system of the host.  
It was thought that there was nothing to do. When glufosinate is sprayed on this recombinant cotton, the modified PAT protein  
The quality produces *N*-acetyl glufosinate. *N*-acetyl glufosinate is  
It is contained in the regulated compounds of rufosinate residual standard value, and its toxicity is classified as normal.  
It has been confirmed that it is lower than rufosinate.

twenty five This recombinant cotton is given Lepidoptera pest resistance by the modified Cry1Ab protein.  
When inhabiting lepidopterous insects ingested the plant of this recombinant cotton, it was also scattered from this recombinant cotton  
When pollen is ingested, it may affect survival. However, in Japan  
No self-growth has been reported, and imported cotton seeds spilled during transportation and grew under natural conditions.  
Or the possibility of self-growth is low. Even if it grows, cotton pollen is relatively heavy and sticky.  
Therefore, the possibility of being scattered widely by wind is low. Therefore, the Lepidoptera insect species that live in Japan are  
30 The possibility of ingesting the recombinant cotton and exposure to pollen were both considered very low.

Based on the above, this recombinant cotton has not been identified as wild animals and plants that may be affected.  
The applicant's conclusion that there is no risk of biodiversity effects arising from the productivity of  
It was judged.

35 (3) Crossability

There are no wild plants that can be crossed with cotton in the natural environment in Japan.  
A claim that no competent wild plants were identified and that there would be no potential for biodiversity effects due to crossability.  
We concluded that the conclusion of the contractor was valid.

40 Conclusion of 2 crop subcommittee

Based on the above, when this recombinant cotton is used in accordance with the first class regulations,  
We concluded that the conclusion of the biodiversity impact assessment report that there was no risk of impact on gender was appropriate.