

Corporation obtaining approval, the name of its representative, and the address of its main office

5                                      Name:      Bayer CropScience K.K.  
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10    Approved Type 1 Use Regulation

Name of the type of Living Modified Organism:	Cotton resistant to Lepidoptera pest and tolerant to glyphosate and glufosinate herbicides ( <i>2mepsps</i> , modified <i>bar</i> , modified <i>cry1Ab</i> , <i>cry2Ae</i> , modified <i>vip3A</i> , <i>Gossypium hirsutum</i> L.) (GHB614 × T304-40 × GHB119 × COT102, OECD UI: BCS-GH002-5 × BCS-GH004-7 × BCS-GH005-8 × SYN-IR102-7) as well as combinations included in lines isolated from the relevant cotton lines (except those already granted an approval regarding Type 1 Use Regulation)
Content of the Type 1 Use of Living Modified Organism:	Provision as food, provision as feed, processing, storage, transportation, disposal, and acts incidental to them
Method of the Type 1 Use of Living Modified Organism:	—

## Outline of the Biological Diversity Risk Assessment Report

Results of the review by persons with specialized knowledge and experience concerning Adverse Effects on Biological Diversity

A review was made by persons with specialized knowledge and experience concerning Adverse Effect on Biological Diversity (called Experts) for possible Adverse Effect on Biological Diversity caused by the use in accordance with the Type 1 Use Regulation for Living Modified Organism based on the Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms. Results of the review are listed below.

### 1 Results of the assessment of Adverse Effects on Biological Diversity

The cotton resistant to Lepidoptera pest and tolerant to glyphosate and glufosinate herbicides (hereinafter referred to as “this stacked line”) and combinations included in lines isolated from the relevant cotton lines (except those already granted an approval regarding Type 1 Use Regulation) were developed by crossing multiple lines of:

- ① Cotton tolerant to glyphosate herbicide, to which *2mepsps* gene coding for 2mEPSPS is transferred (hereinafter referred to as “GHB614”);
- ② Cotton tolerant to glufosinate herbicide and resistant to Lepidoptera pest, to which modified *bar* gene coding for modified PAT protein and modified *cry1Ab* gene coding for modified Cry1Ab protein are transferred (hereinafter referred to as “T304-40”);
- ③ Cotton tolerant to glufosinate herbicide and resistant to Lepidoptera pest, to which modified *bar* gene coding for modified PAT protein and the *cry2Ae* gene coding for Cry2Ae protein are transferred (hereinafter referred to as “GHB119”); and,
- ④ Cotton resistant to Lepidoptera pest, to which modified *vip3A* gene coding for modified Vip3A protein and the *aph4* gene coding for APH4 protein are transferred (hereinafter referred to as “COT102”).

It is likely that the pest resistance proteins (modified Cry1Ab protein, Cry2Ae protein and modified Vip3A protein) produced from the genes transferred to this stacked line cotton specifically act to target pests to independently show insecticidal effects and it is unlikely that synergistic effects and antagonistic actions are exerted by affecting with each other. Since the pest resistance proteins do not have enzymatic activity, there is low possibility they will alter the metabolic pathway of the recipient organism. In addition, while 2mEPSPS protein and modified PAT protein, which are herbicide tolerance proteins, and APH4 protein, which is the selection marker, have enzymatic activity, they have high substrate specificity and their metabolic pathways are independent of each other. Therefore, it is unlikely that the metabolism of the recipient organism is altered and that unexpected metabolites are produced. As such, it is unlikely these proteins affect with each other.

Based on the above, it is unlikely that interaction among traits occur in the plant body of this stacked line and combinations included in lines isolated from the relevant cotton lines (except those already granted an approval regarding Type 1 Use Regulation), and therefore it has been concluded that there are no trait changes to be evaluated, except having traits which the respective parent line had.

For the following information, the examination of the respective evaluation items of the parental lines has already been completed\* in the Committee meeting. Based on the results of the examination, the conclusion described in the Biological Diversity Risk Assessment Report that the use of the respective parent lines in accordance with the Type 1 Use Regulation causes no Adverse Effects on Biological Diversity in Japan has been judged to be reasonable.

- (1) Competitiveness
- (2) Productivity of harmful substances
- (3) Crossability

\* The results of the evaluation of the respective parent lines are available as described below.

- GHB614  
[https://ch.biodic.go.jp/bch/OpenDocDownload.do?info\\_id=1495&ref\\_no=2](https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=1495&ref_no=2)
- T304-40  
[https://ch.biodic.go.jp/bch/OpenDocDownload.do?info\\_id=1638&ref\\_no=2](https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=1638&ref_no=2)
- GHB119  
[https://ch.biodic.go.jp/bch/OpenDocDownload.do?info\\_id=1589&ref\\_no=2](https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=1589&ref_no=2)
- COT102  
[https://ch.biodic.go.jp/bch/OpenDocDownload.do?info\\_id=1576&ref\\_no=2](https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=1576&ref_no=2)

## 2 Conclusion based on the Biological Diversity Risk Assessment

Based on the above understanding, the conclusion described in the Biological Diversity Risk Assessment Report that the use of this stacked line and combinations included in lines isolated from the relevant cotton lines (except those already granted an approval regarding Type 1 Use Regulation) in accordance with the type 1 Use Regulation causes no Adverse Effects on Biological Diversity in Japan has been judged to be reasonable.