

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

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Name: Bayer CropScience K.K.
Applicant Harald Printz, President and Representative Director; seal
Address: 1-6-5, Marunouchi, Chiyoda-ku, Tokyo

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Approved Type 1 Use Regulation

Name of the Type of Living Modified Organism:	Cotton tolerant to glyphosate and glufosinate herbicides, and resistant to Lepidoptera pest (<i>2mepsps</i> , modified <i>bar</i> , modified <i>cryIAb</i> , <i>cry2Ae</i> , <i>Gossypium hirsutum</i> L.) (GHB614×T304-40×GHB119, OECD UI: BCS-GH002-5×BCS-GH004-7×BCS-GH005-8) (Including the progeny lines which are isolated from the cotton lines, GHB614, T304-40 and GHB119 and those which contain a combination of their respective transferred genes (except those already granted an approval regarding Type I 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

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A review was made by persons with specialized knowledge and experience concerning Adverse Effects on Biological Diversity (called Experts) for possible Adverse Effects on Biological Diversity caused by the use in accordance with the Type 1 Use Regulation for Living Modified Organisms 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

15 Cotton tolerant to glyphosate and glufosinate herbicides, and resistant to Lepidoptera pests (including the progeny lines which are isolated from the cotton lines, GHB614, T304-40 and GHB119 and those which contain a combination of their respective transferred genes (except those already granted an approval regarding Type I Use Regulation)) (hereinafter referred to as “this stacked line”) was developed with the following lines by crossing:

20 Cotton tolerant to glyphosate herbicide, to which the *2mepsps* gene coding for the 2mEPSPS protein (2 mutant 5-enolpyruvylshikimate-3-phosphate synthase) is transferred (hereinafter referred to as “GHB614”),

25 Cotton tolerant to glufosinate herbicide and resistant to Lepidoptera pest, to which the modified *bar* gene coding for the modified PAT protein (phosphinothricin acetyltransferase) and the modified *cryIAb* gene coding for the modified Cry1Ab protein are transferred (hereinafter referred to as “T304-40”), and

30 Cotton tolerant to glufosinate herbicide and resistant to Lepidoptera pest, to which the modified *bar* gene coding for the modified PAT protein (phosphinothricin acetyltransferase) and the *cry2Ae* gene coding for the Cry2Ae protein (hereinafter referred to as “GHB119”).

The substrates of the 2mEPSPS protein and modified PAT protein, which are expressed in this stacked line, are different and their metabolic pathways are independent of each other. Because both the 2mEPSPS and modified PAT proteins are highly substrate specific, it is unlikely that

they affect the metabolic pathway of the recipient organism or that the proteins tolerant to herbicides interact with each other to produce unexpected metabolites. Furthermore, the modified Cry1Ab and Cry2Ae proteins expressed in this stacked line bind to the specific receptors in the target insects to show insecticidal effects. This specificity is involved in the protein conformation and it is unlikely that the regions involved in the specificity of both Bt proteins are changed in this stacked line or that there is an impact on the insecticidal effect of each protein. Therefore it is unlikely that the proteins resistant to pests interact with each other.

Moreover, because the Bt proteins do not have enzymatic activity, they will not affect the metabolic pathway of the recipient organism. It is unlikely that proteins tolerant to herbicides and proteins resistant to pests affect each other because of their difference in functions.

Based on the above, it is unlikely that the expressed proteins derived from respective parent lines affect one another in the plant body of this stacked line, and therefore it has been concluded that there are no trait changes to be evaluated, except having the traits which the respective parent line had.

The examination of the respective evaluation items has already been completed* in the overall review 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 I Use Regulation causes no Adverse Effects on Biological Diversity in Japan has been judged to be reasonable.

- a. Competitiveness
- b. Productivity of harmful substances
- c. 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

[T304-40, GHB119]

http://www.bch.biodic.go.jp/download/lmo/public_comment/H24_11_19_gakushiki.sp1.pdf

(2) Conclusion based on the Biological Diversity Risk Assessment Report

Based on the above understanding, the Biological Diversity Risk Assessment Report concluded that there is no risk that the use of this stacked line, in accordance with the Type 1 Use Regulation, causes Adverse Effects on Biological Diversity in Japan. It has been judged that the conclusion above made by the applicant is reasonable.