

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

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Approved Type 1 Use Regulation

Name of the Type of Living Modified Organism:	Cotton resistant to Lepidoptera, and tolerant to glufosinate and glyphosate herbicides (Modified <i>cryIF</i> , Modified <i>cryIAC</i> , Modified <i>vip3A</i> , <i>pat</i> , Modified <i>cp4 epsps</i> , <i>Gossypium hirsutum</i> L.) (281×3006×COT102×MON88913, OECD UI: DAS-24236-5×DAS-21Ø23-5×SYN-IR1Ø2-7×MON-88913-8)
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:	-

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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 resistant to Lepidoptera and tolerant to glufosinate and glyphosate herbicides (hereinafter referred to as “this stacked line”) was developed with the following lines by crossing:

Cotton resistant to Lepidoptera and tolerant to glufosinate herbicide (281/3006) developed by crossing using the cotton resistant to Lepidoptera and tolerant to glufosinate herbicide, to which the modified *cryIF* gene coding for the modified Cry1F protein and the *pat* gene coding for the PAT protein (phosphinothricin acetyltransferase) are transferred (281), and the cotton resistant to Lepidoptera and tolerant to glufosinate herbicide, to which the modified *cryIAC* gene coding for the modified Cry1Ac protein and the *pat* gene coding for the PAT protein are transferred (3006), and

25 Cotton resistant to Lepidoptera, to which the modified *vip3A* gene coding for the modified Vip3A protein (one of the Bt proteins) and the *aph4* gene coding for the APH4 protein (hygromycin B phosphotransferase) are transferred (COT102), and

Cotton tolerant to glyphosate herbicide, to which the modified *cp4 epsps* gene coding for the modified CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) is transferred (MON88913).

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It has been determined that the respective Bt proteins (the modified Cry1F, modified Vip3A and modified Cry1Ab proteins) derived from the genes transferred to this stacked line do not interact with one another to change the specificity of the insecticidal effect in these proteins,

because it is unlikely that the regions involved in the specificity are changed. As for the APH4 protein, an antibiotic selection marker, and the modified CP4 EPSPS and PAT proteins, proteins tolerant to herbicides, their substances and actions are different, their metabolic pathways are independent of each other, and there has been no report that Bt proteins have enzyme activities. Therefore, it is unlikely that these proteins produced from the transfected genes influence each other. It has been determined that that these proteins do not interact to change the metabolic system of the recipient organism and produce unexpected metabolites in this stacked line.

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Based on the above, it is unlikely that these proteins derived from respective parent lines influence 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 parent line had.

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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.

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

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

[Cotton 281/3006]

https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=730&ref_no=1

[COT102]

https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=1576&ref_no=1

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[MON88913]

https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=683&ref_no=1

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

Based on the above understanding, the Biological Diversity Risk Assessment Report concluded

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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.