

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

Applicant Name: Monsanto Japan Limited
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Approved Type 1 Use Regulation

Name of the type of Living Modified Organism type:	Cotton resistant to Lepidoptera pest (modified <i>vip3A</i> , modified <i>cry1Ac</i> , modified <i>cry2Ab2</i> , <i>Gossypium hirsutum</i> L.) (COT102 × 15985, OECD UI: SYN-IR102-7 × MON-15985-7)
Content of the Type 1 Use of Living Modified Organism:	Provision as food, provision as feed, cultivation, 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 The cotton resistant to Lepidoptera pest (hereinafter, referred to as "this stacked line") was developed with the following lines by crossing:

Cotton resistant to Lepidoptera pest, to which modified *vip3A* gene coding for modified Vip3A protein and *aph4* gene coding for APH4 protein are transferred (hereinafter, referred to as "COT102"); and

20 Cotton resistant to Lepidoptera pest, to which modified *cry1Ac* gene coding for modified Cry1Ac protein, modified *cry2Ab2* gene coding for modified Cry2Ab2 protein, modified *uidA* gene coding for GUSE377K protein and *npt II* gene coding for the NPT II protein are transferred (hereinafter, referred to as "15985").

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It is likely that the respective Bt proteins (modified Vip3A protein, modified Cry1Ac protein and modified Cry2Ab2 protein) produced from the genes which are transferred to this stacked line 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 Bt proteins do not have enzymatic activity, there is low possibility they will alter the metabolic pathway of the recipient organism. In addition, APH4 protein, GUSE377K protein and NPT II protein, which are the selection markers and have highly 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.

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Based on the above, it is unlikely that these 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.

5 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
10 Japan has been judged to be reasonable.

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

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

COT102

20 https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=1576&ref_no=215985

https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=95&ref_no=2

(2) Conclusion based on the Biological Diversity Risk Assessment

25 Based on the above understanding, the conclusion described in the Biological Diversity Risk Assessment Report that use of this stacked line in accordance with the type 1 Use Regulation causes no Adverse Effects on Biological Diversity in Japan has been judged to be reasonable.