

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

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Applicant Name: Syngenta Japan K.K.
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Approved Type 1 Use Regulation

Name of the Type of Living Modified Organism:	Maize resistant to <i>Lepidoptera</i> and tolerant to glufosinate herbicide (modified <i>cry1Ab</i> , modified <i>vip3A</i> , <i>pat</i> , <i>Zea mays</i> subsp. <i>mays</i> (L.) Iltis) (Bt11 × MIR162, OECD UI: SYN-BTØ11-1 × SYN-IR162-4)
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:	-

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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.

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(1) Results of the assessment of Adverse Effects on Biological Diversity

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This stacked line was developed with the following lines by crossing:

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Maize resistant to *Lepidoptera* and tolerant to glufosinate herbicide, to which the modified *cry1Ab* gene coding for the modified Cry1Ab protein and the *pat* gene coding for the PAT (phosphinothricin acetyltransferase) protein are transferred (Bt11), and Maize resistant to *Lepidoptera*, to which the modified *vip3A* gene coding for the modified Vip3A protein and the *pmi* gene coding for the PMI (phosphomannose isomerase) protein (MIR162).

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It has been determined that the respective Bt proteins (the modified Cry1Ab and modified Vip3A proteins) derived from the genes transferred to this stacked line independently show their insecticidal activities and that synergistic and antagonistic effects by interacting with each other do not occur. In addition, the PAT protein, a protein tolerant to herbicides, and the PMI protein, a selection marker protein, are highly substrate specific and are unlikely to change the metabolic pathway of the recipient organism. As the substrate of each protein is different, their metabolic pathways are independent of each other, and there has been no report that the Bt proteins have enzymatic activities, it is unlikely that in this stacked line these two proteins interact with each other to change the metabolic pathways of the recipient organism.

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Based on the above, it is unlikely that these proteins derived from the respective parent lines functionally interact with each other in the plant of this stacked maize line, and therefore it has been concluded that there are no trait changes to be evaluated, except having the traits which the parent lines had.

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The examination of the respective evaluation items of the parent lines has already been completed*. 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
5 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.

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- Bt11
https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=906&ref_no=2
- MIR162
https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=1493&ref_no=2

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

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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.