

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:	Maize resistant to <i>Lepidoptera</i> and <i>Coleoptera</i> , and tolerant to glufosinate and glyphosate herbicides (modified <i>cry1Ab</i> , modified <i>cry3Aa2</i> , modified <i>cry1F</i> , <i>ecry3.1Ab</i> , <i>pat</i> , <i>mEPSPS</i> , <i>Zea mays</i> subsp. <i>mays</i> (L.) Iltis) (Bt11×MIR604× <i>B.t.</i> Cry1F maize line 1507×Event 5307×GA21, OECD UI: SYN-BTØ11-1×SYN-IR6Ø4-5×DAS-Ø15Ø7-1×SYN-Ø53Ø7-1×MON-ØØØ21-9) (Including the progeny lines which are isolated from the maize lines, Bt11, MIR604, <i>B.t.</i> Cry1F maize line 1507, Event 5307 and GA21 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, 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.

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

15 Maize resistant to *Lepidoptera* and *Coleoptera*, and tolerant to glufosinate and glyphosate herbicides (including the progeny lines which are isolated from the maize lines; Bt11, MIR604, *B.t.* Cry1F maize line 1507, Event 5307 and GA21 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 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 protein (phosphinothricin acetyltransferase) are transferred (Bt11),

25 Maize resistant to *Coleoptera*, to which the modified *cry3Aa2* gene coding for the modified Cry3Aa2 protein and the *pmi* gene coding for the PMI protein (phosphomannose isomerase) are transferred (MIR604),

30 Maize resistant to *Lepidoptera* and tolerant to glufosinate herbicide, to which the modified *cry1F* gene coding for the modified Cry1F protein and the *pat* gene coding for the PAT protein (phosphinothricin acetyltransferase) are transferred (*B.t.* Cry1F maize line 1507),

Maize resistant to *Coleoptera*, to which the *ecry3.1Ab* gene coding for the eCry3.1Ab protein is transferred (Event 5307), and

35 Maize tolerant to glyphosate herbicide, to which the *mEPSPS* gene coding for the mEPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) is transferred (GA21).

It has been determined that the respective Bt proteins (the modified Cry1Ab, modified

Cry3Aa2, modified Cry1F and eCry3.1Ab 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 PAT and the mEPSPS proteins, proteins with tolerance to herbicides, their substrates and actions are different and their metabolic pathways are independent of each other. In addition, there has been no report that Bt proteins have enzyme activities. Therefore, it is unlikely that the proteins with tolerance to herbicides and the Bt proteins interact with one another. The PMI protein with high substrate specificity is also unlikely to interact with the proteins with tolerance to herbicides and the Bt proteins. Therefore, it has been determined that these proteins do not interact to change the metabolic system of the recipient organism and produce unexpected metabolites in this stacked line.

Based on the above, it is unlikely that these proteins derived from respective parent lines functionally interact with one another 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.

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 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.

- Bt11
https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=906&ref_no=2
- MIR604
https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=938&ref_no=2
- *B.t.* Cry1F maize line 1507
https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=138&ref_no=2
- Event 5307
http://www.bch.biodic.go.jp/download/lmo/public_comment/H24_3_30_05307sp3.pdf
- GA21
https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=348&ref_no=2

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

5 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.