

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> pests, and tolerant to glufosinate and glyphosate herbicides (modified <i>cry1F</i> , <i>pat</i> , <i>cry1Ab</i> , modified <i>cry3Aa2</i> , modified <i>cp4 epsps</i> , <i>Zea mays</i> subsp. <i>mays</i> (L.) Iltis) (1507×MON810×MIR604×NK603, OECD UI: DAS-01507-1×MON-00810-6×SYN-IR604-5×MON-00603-6) (Including the progeny lines which are isolated from the maize lines, <i>B.t.</i> Cry1F maize line 1507, MON810, MIR604 and NK603 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* pests, and tolerant to glufosinate and glyphosate herbicides (including the progeny lines which are isolated from the maize lines, 1507, MON810, MIR604 and NK603 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:

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Maize resistant to *Lepidoptera* pest 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) were transferred (1507),

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Maize resistant to *Lepidoptera* pest, to which the *cry1Ab* gene coding for the Cry1Ab protein was transferred (MON810),

Maize resistant to *Coleoptera* pest, to which the modified *cry3Aa2* gene coding for the modified Cry3Aa2 protein and the *pmi* gene coding for the PMI protein (used as a selection marker) were transferred (MIR604), and

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Maize tolerant to glyphosate herbicide, to which the modified *cp4 epsps* gene coding for the modified CP4 EPSPS protein was transferred (NK603).

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It has been determined that the respective Bt proteins (the modified Cry1F, Cry1Ab and modified Cry3Aa2 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 even if they exist in the same plant. As for the PAT and modified CP4 EPSPS 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 each other. 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 was concluded 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 body 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 line had.

The examination of the respective evaluation items 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.

- 1507  
[https://ch.biodic.go.jp/bch/OpenDocDownload.do?info\\_id=138&ref\\_no=2](https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=138&ref_no=2)
- MON810  
[https://ch.biodic.go.jp/bch/OpenDocDownload.do?info\\_id=6&ref\\_no=2](https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=6&ref_no=2)
- MIR604  
[https://ch.biodic.go.jp/bch/OpenDocDownload.do?info\\_id=938&ref\\_no=2](https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=938&ref_no=2)
- NK603  
[https://ch.biodic.go.jp/bch/OpenDocDownload.do?info\\_id=88&ref\\_no=2](https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=88&ref_no=2)

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

Based on the above understanding, the conclusion described in the Biological Diversity Risk Assessment Report that the 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.