

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

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10 Approved Type 1 Use Regulation

Name of the type of Living Modified Organism:	Maize resistant to Lepidoptera and Coleoptera pests and tolerant to glufosinate and glyphosate herbicides (modified <i>cry1F</i> , <i>cry34Ab1</i> , <i>cry35Ab1</i> , <i>pat</i> , <i>cry1Ab</i> , modified <i>cry3Aa2</i> , modified <i>cp4 epsps</i> , <i>Zea mays subsp. mays</i> (L.) <i>Iltis</i>) (4114 × MON810 × MIR604 × NK603, OECD UI: DP-ØØ4114-3 × MON-ØØ81Ø-6 × SYN-IR6Ø4-5 × MON-ØØ6Ø3-6) (Including the progeny lines which are isolated from the maize lines 4114, MON810, MIR604 and NK603, and those which contain a combination of their respective transferred genes (except those already granted an approval regarding Type 1 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:	-

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

A review was made by persons with specialized knowledge and experience concerning Adverse Effect on Biological Diversity (called Experts) for possible Adverse Effect on Biological Diversity caused by the use in accordance with the Type 1 Use Regulation for Living Modified Organism 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

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

- ① Maize resistant to Lepidoptera and Coleoptera pests and tolerant to glufosinate herbicide, to which modified *cry 1F* gene coding for modified Cry1F protein, *cry34Ab1* gene coding for Cry34Ab1 protein, *cry35Ab1* gene coding for Cry35Ab1 protein and the *pat* gene coding for PAT protein are transferred (hereinafter referred to as “4114”);
- ② Maize resistant to Lepidoptera pest, to which *cry1Ab* gene coding for Cry1Ab protein is transferred (hereinafter referred to as “MON810”);
- ③ Maize resistant to Coleoptera pest, to which modified *cry3Aa2* gene coding for modified Cry3Aa2 protein and the *pmi* gene coding for PMI protein are transferred (hereinafter referred to as and “MIR604”); and,
- ④ Maize tolerant to glyphosate herbicide, to which modified *cp4 epsps* gene coding for modified CP4 EPSPS protein is transferred (hereinafter referred to as “NK603”).

It is likely that the pest resistance proteins (modified Cry1F protein, Cry1Ab protein, Cry34Ab1/Cry35Ab1 protein and modified Cry3Aa2) produced from the genes 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 pest resistance proteins do not have enzymatic activity, there is low possibility they will alter the metabolic pathway of the recipient organism. In addition, while herbicide tolerance proteins (PAT protein and modified CP4 EPSPS protein) and PMI protein, which is the selection marker, have enzymatic activity, they have high 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. As such, it is unlikely these proteins affect with each other.

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 traits which the respective parent line had.

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 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.

- 4114
http://www.biodic.go.jp/bch/download/lmo/public_comment/H26_03_18.gakushikiiken3.pdf
- MON810
http://www.biodic.go.jp/bch/download/lmo/public_comment/MON810sp.pdf
- MIR604
http://www.biodic.go.jp/bch/download/lmo/public_comment/MIR604_2_sp.pdf
- NK603
http://www.biodic.go.jp/bch/download/lmo/public_comment/NK603sp.pdf

(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.