

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

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Approved Type 1 Use Regulation

<p>Name of the Type of Living Modified Organism</p>	<p>Maize resistant to lepidopterous pests and tolerant to glufosinate herbicide (Modified <i>cry1F</i>, <i>pat</i>, <i>cry1Ab</i>, modified <i>vip3A</i>, <i>Zea mays</i> subsp. <i>mays</i> (L.) Iltis) (1507 × MON810 × MIR162, OECD UI: DAS-Ø15Ø 7-1 × MON-ØØ81Ø-6×SYN-IR162-4) (Includes those that possess a combination of genes introduced to each of <i>B.t.</i> Cry1F maize line 1507, MON810 and MIR162, and of progeny lines segregated from the relevant maize (excluding those already received Approved Type 1 Use Regulation).)</p>
<p>Content of the Type 1 Use of Living Modified Organism</p>	<p>Provision as food, provision as feed, cultivation, processing, storage, transportation, disposal and acts incidental to them</p>
<p>Method of the Type 1 Use of Living Modified Organism</p>	<p>–</p>

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 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

Maize resistant to lepidopterous pests and tolerant to glufosinate herbicide (hereinafter referred to as “this stack line”) was produced by the cross-breeding method using,

- (1) Maize resistant to lepidopterous pests and tolerant to glufosinate herbicide to which modified *cryIF* gene that codes modified CryIF protein and *pat* gene that codes PAT protein were introduced (1507);
- (2) Maize resistant to lepidopterous pests to which *cryIAb* gene that codes Cry1Ab protein was introduced (MON810); and,
- (3) Maize resistant to lepidopterous pests to which modified *vip3A* gene that codes modified Vip3A protein and *pmi* gene that codes PMI protein were introduced (MIR162).

The Bt proteins (modified Cry1F protein, Cry1Ab protein and modified Vip3A protein) produced by the genes introduced to this stack line were considered to specifically act on target pests and exhibit insecticidal activity independently, and thus it was considered that there is no synergistic effect or antagonism occurring due to interaction among them. Since the Bt proteins have no enzyme activity, it was considered that the possibility of them altering the metabolic system of the recipient organism is low. Additionally, while PAT protein (herbicide-tolerant protein) and PMI protein (selective marker protein) exhibit enzyme activity, they have high substrate specificity and the involved action mechanism is mutually independent. Therefore, it was considered that the possibility of them altering the metabolic system of the recipient organism or producing unexpected metabolic products is low.

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.

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

5 (b) Productivity of harmful substances

(c) Crossability

* The results of review on each parental line are available from the links below.

- 10 ● 1507
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
● MIR162
https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=1493&ref_no=2

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

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.

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