

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

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Approved Type 1 Use Regulation

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Names of types of living modified organisms	Corn resistant to lepidoptera, and tolerant to aryloxyalkanoate herbicide, glufosinate herbicide and glyphosate herbicide (<i>cry1A.105</i> , modified <i>cry2Ab2</i> , modified <i>cry1F</i> , modified <i>vip3A</i> , <i>pat</i> , modified <i>cp4 epsps</i> , modified <i>aad-1</i> , <i>Zea mays</i> subsp. <i>mays</i> (L.) Iltis) (MON89034×B.t. Cry1F maize line 1507×NK603×MIR162×DAS40278, OECD UI: MON-89034-3×DAS-01507-1×MON-00603-6×SYN-IR162-4× DAS-40278-9) As well as the combinations contained in the segregated lines of the above corn. (except for the ones that were already approved under Type 1 Use Regulations.)
Content of Type 1 Use of living modified organisms	Use for provision as food, animal feed or other purposes, cultivation, processing, storage, transportation and disposal, and other acts attendant with these.
Method of Type 1 Use of living modified organisms	—

Summary of the Evaluation on Adverse Effect on Biological Diversity

Results of review meeting for the Evaluation on Adverse Effect on Biological Diversity

A review was made by experts 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 Evaluation on Adverse Effect on Biological Diversity

This stack line was created according to crossbreeding method with multiple genic lines by using the followings:

- (1) Lepidoptera resistant corn, into which *cry1A.105* gene encoding Cry1A.105 protein and modified *cry2Ab2* gene encoding modified Cry2Ab2 protein were transferred (MON89034) ,
- (2) Lepidoptera resistant and herbicide glyphosate-tolerant corn, into which modified *cry1F* gene encoding modified Cry1F protein and *pat* gene encoding PAT protein are transferred (*B.t.* Cry1F maize line 1507),
- (3) Herbicide glyphosate-tolerant corn, into which modified *cp4 epsps* gene encoding modified CP4 EPSPS protein is transferred (NK603),
- (4) Lepidoptera resistant corn, into which modified *vip3A* gene encoding modified Vip3A protein and *pmi* gene encoding PMI protein are transferred (MIR162), and
- (5) Herbicide aryloxyalkanoate tolerant corn, into which modified *aad-1* gene encoding modified AAD-1 protein is transferred (DAS40278).

Destructive insects resistant proteins (Cry1A.105 protein, modified Cry2Ab2 protein, modified Cry1F protein and modified Vip3A protein) which are produced with genes which were transferred into this stack line are considered to act specifically on the targeted destructive insects and exhibit insecticidal activity independently, on the other hand, not to provide any synergistic effect or antagonism by interacting each other. It is also considered that the destructive insect resistant protein is unlikely to change the metabolic system of its host because it has no enzymatic activity.

Furthermore, even though all of the herbicide-tolerant proteins (PAT protein, modified

CP4 EPSPS protein and modified AAD-1 protein) and PMI protein which is a selection marker, have enzymatic activity, it is considered that they are unlikely to interact each other and generate unexpected metabolites because they have high substrate specificity and their metabolism routes are independent of each other. For such reasons, there is extremely low probability for interaction between these proteins.

From the above information, it is considered that the interaction between these events when stacked in a single plant line is unlikely to be exhibited, and also there is no trait changes to be evaluated, except that they have combined traits from the respective parent lines through conventional breeding.

The review on the following evaluation items for each parent line, however, has already been completed * and as the result, it is determined that the conclusion of the Evaluation on Adverse Effect on Biological Diversity, stating that there is no risk of affecting on the biological diversity in Japan if each of those parent lines is used according to Type 1 Use Regulations, is reasonable.

- (a) Competitiveness
- (b) Productivity of harmful substances
- (c) Crossability

* The result of the review on each parent line are available in the followings.

- MON89034
http://www.bch.biodic.go.jp/bch/OpenDocDownload.do?info_id=1002&ref_no=2
- *B.t.* Cry1F maize line 1507
http://www.bch.biodic.go.jp/bch/OpenDocDownload.do?info_id=138&ref_no=2
- NK603
http://www.bch.biodic.go.jp/bch/OpenDocDownload.do?info_id=88&ref_no=2
- MIR162
http://www.bch.biodic.go.jp/bch/OpenDocDownload.do?info_id=1493&ref_no=2

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

From all of the above, we have reached the judgment that the conclusion of the Evaluation on Adverse Effect on Biological Diversity, stating that there is no risk of affecting on the biological diversity in Japan if this stack line is used according to Type 1 Use Regulations, is reasonable.