

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

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Name of Entity: Monsanto Company
 Name of Applicant: Seiichiro Yamane, President
 Address: 2-5-18, Kyobashi, Chuo-ku, Tokyo

Approved Type 1 Use Regulation

Names of types of living modified organisms	Glyphosate induced male sterility, Lepidoptera resistant and glyphosate-tolerant maize(modified <i>cp4 epsps</i> , <i>cry1A.105</i> , modified <i>cry2Ab2</i> , modified <i>vip3A</i> , <i>Zea mays</i> subsp. <i>mays</i> (L.) Iltis) (MON87427 × MON89034 × MIR162 × NK603, OECD UI: MON-87427-7 × MON-89034-3 × SYN-IR162-4 × MON-00603-6) As well as the combinations contained in the separated lines of the above maize. (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	-

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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 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 Evaluation on Adverse Effect on Biological Diversity

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

- ① Glyphosate induced male sterility and glyphosate tolerant maize, into which modified cp4 epsps gene encoding modified CP4 EPSPS protein was transferred. (MON87427) 、
- ② Lepidoptera resistant maize, into which cry1A.105 gene encoding Cry1A.105 protein and modified cry2Ab2 gene encoding modified Cry2Ab2 protein were transferred (MON89034) ,
- ③ Lepidoptera resistant maize, into which modified vip3A gene encoding modified Vip3A protein and pmi gene encoding PMI protein were transferred (MIR162)、
- ④ glyphosate-tolerant maize, into which modified cp4 epsps gene encoding modified CP4 EPSPS protein was transferred (NK603),

Insects resistant proteins (Cry1A.105 protein, modified Cry2Ab2 protein and modified Vip3A protein) which is produced with genes which were transferred into this stacked line was considered to specifically act on the targeted insects and exhibit insecticidal activity independently, on the other hand, not to provide any synergistic effect or antagonism by interacting each other. It was also considered that the insect resistant protein is unlikely to change the metabolic system of its host because it has no enzymatic activity. Furthermore, even though the both of modified CP4 EPSPS protein which is herbicide-tolerant protein and PMI protein which is a selection marker, have enzymatic activity, it was believed that they are unlikely to interact each other and generate unexpected metabolites because they have excellent substrate specificity and their metabolism routes are independent of each other. For such reasons, it is hard to think that there is interaction between these proteins.

From the above, it was considered that the interaction between characters inside the plant bodies of this stacked line is unlikely to be exhibited, and also there was no change in the characters to be evaluated except that they have combined characters from parents' lines.

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, saying 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.

- MON87427
http://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=1612&ref_no=2
- MON89034
http://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=1002&ref_no=2
- MIR162
http://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=1493&ref_no=2
- NK603
http://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=88&ref_no=2

(2) The conclusion based on the Evaluation on Adverse Effect on Biological Diversity

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 stacked line is used according to Type 1 Use Regulations, is reasonable.