

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

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Applicant Name: Monsanto Japan Limited
 Seiichiro Yamane, President; seal
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Approved Type 1 Use Regulation

Name of the Type of Living Modified Organism:	Soybean tolerant to dicamba and glyphosate herbicides (modified <i>dmo</i> , modified <i>cp4 epsps</i> , <i>Glycine max</i> (L.) Merr.) (MON87708 × MON89788, OECD UI: MON-87708-9 × MON-89788-1)
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

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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 Soybean tolerant to dicamba and glyphosate herbicides (hereinafter referred to as “this stacked line”) was developed with the following lines by crossing:

Soybean tolerant to dicamba herbicide, to which the modified *dmo* gene coding for the modified DMO protein (dicamba monooxygenase) is transferred (hereinafter referred to as “MON87708”), and

20 Soybean tolerant to glyphosate herbicide, to which the modified *cp4 epsps* gene coding for the modified CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) is transferred (hereinafter referred to as “MON89788”).

25 The modified DMO and modified CP4 EPSPS proteins expressed by the genes transferred in this stacked line have different mechanisms of action, act independently, and are highly substrate specific. Therefore, it is unlikely that these proteins interact with each other to change the metabolic pathway of the recipient organism and produce unexpected metabolites when they are expressed in this stacked line.

30 Based on the above, it was unlikely that these proteins derived from respective parent lines functionally interact with each other in the plant body of this stacked line, and therefore it has been concluded that there were no trait changes to be evaluated, except having the traits which the parent line had.

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 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
- 10 c. Crossability

* The results of the evaluation of the respective parental lines are available as described below.

[MON87708]

15 http://www.bch.biodic.go.jp/download/lmo/public_comment/H24_9_26_zikanba_sp3.pdf

[MON89788]

https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=1003&ref_no=2

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

20 Based on the above understanding, the Biological Diversity Risk Assessment Report concluded that there is no risk that the use of this stacked line, in accordance with the Type 1 Use Regulation, causes Adverse Effects on Biological Diversity in Japan. It has been judged that the conclusion above made by the applicant is reasonable.