

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

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Approved Type 1 Use Regulation

Name of the Type of Living Modified Organism:	Soybean with low saturated fatty acid, high oleic acid and tolerance to glyphosate herbicide (<i>FAD2-1A</i> , <i>FATB1-A</i> , modified <i>cp4 epsps</i> , <i>Glycine max</i> (L.) Merr.) (MON87705×MON89788, OECD UI: MON-87705-6×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 with low saturated fatty acid, high oleic acid and tolerance to glyphosate herbicide (hereinafter referred to as “this stacked line”) was developed with the following lines by crossing:

Soybean with low saturated fatty acid, high oleic acid and tolerance to glyphosate herbicide, to which a segment of the *FAD2-1A* gene coding for the FAD2-1A protein (Δ -12 desaturase), a segment of the *FATB1-A* gene coding for the FATB1-A protein (palmitoyl-acyl carrier protein thioesterase), and the modified *cp4 epsps* gene coding for the modified CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) are transferred (hereinafter referred to as “MON87705”), and

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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”).

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The *FAD2-1A* and *FATB1-A* gene segments expressed in this stacked line specifically inhibit expression of the *FAD2-1A* and *FATB1-A* genes coding for enzymes of fatty acid biosynthesis pathway in soybean by RNAi (RNA interference), and therefore proteins are not produced by these gene segments. The modified CP4 EPSPS protein catalyzes the shikimate synthesis pathway and is highly substrate specific. The metabolic pathways associated with the two gene segments and the modified CP4 EPSPS protein are independent of each other. Furthermore, even if the level of expression of the modified CP4 EPSPS protein in this stacked line, which

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has been developed by crossing MON87705 expressing the modified CP4 EPSPS protein with MON89788 expressing the same modified CP4 EPSPS protein, is higher than that in the parent line, it is unlikely that the two gene segments and the protein, which are derived from the parent lines, functionally interact with each other in the plant body of this stacked line. Also, there are
5 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
10 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
- 15 c. Crossability

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

- **MON87705**
[http://www.bch.biodic.go.jp/download/lmo/public_comment/H23_9_27_FAD2-
20 1Asp1.pdf](http://www.bch.biodic.go.jp/download/lmo/public_comment/H23_9_27_FAD2-1Asp1.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

25 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.