

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

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10 Approved Type 1 Use Regulation

Name of the type of Living Modified Organism:	Male-sterile fertility-restoring rapeseed tolerant to glyphosate and glufosinate herbicides (modified <i>cp4 epsps</i> , modified <i>bar</i> , <i>barnase</i> , <i>barstar</i> , <i>Brassica napus</i> L.) (MON88302 × MS8 × RF3, OECD UI: MON-88302-9 × ACS-BN005-8 × ACS-BN003-6) (Including the progeny lines which are isolated from the rapeseed lines MON88302, MS8 and RF3, and those which contain a combination of their respective transferred genes (except those already granted an approval regarding Type 1 Use Regulation)).
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

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

The male-sterile fertility-restoring rapeseed tolerant to glyphosate and glufosinate herbicides (hereinafter referred to as “this stacked line”) was developed with the following lines by crossing:

- ① Rapeseed tolerant to glyphosate herbicide, to which modified *cp4 epsps* gene coding for modified CP4 EPSPS protein is transferred (hereinafter referred to as “MON88302”);
- ② Male-sterile rapeseed tolerant to glufosinate herbicide, to which modified *bar* gene coding for modified PAT protein and the *barnase* gene coding for BARNASE protein (induces male sterility) are transferred (hereinafter referred to as “MS8”); and,
- ③ Fertility-restoring rapeseed tolerant to glufosinate herbicide, to which modified *bar* gene coding for modified PAT protein and the *barstar* gene coding for BARSTAR protein (induces restoration of fertility) are transferred (hereinafter referred to as “RF3”).

While the modified PAT protein and modified CP4 EPSPS protein, which are herbicide tolerance proteins, produced from the genes transferred to this stacked line have enzymatic activity, their substrate specificity is high and the involved action mechanism is independent of each other. Therefore, it is unlikely that other metabolic systems of the recipient organism are altered and that unexpected metabolites are produced. Additionally, BARNASE protein and BARSTAR protein specifically act to pollen fertility independent of each other, and the expression is limited to the anther. Therefore, it is unlikely that herbicide tolerance proteins (modified PAT protein and modified CP4 EPSPS protein) and proteins involved with pollen fertility (BARNASE protein and BARSTAR protein) affect each other.

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 except for affecting the fertility of pollen, and therefore it has been concluded that there are no trait changes to be evaluated, except having 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
- b. Productivity of harmful substances
- c. Crossability
- d. Other properties

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

- MON88302
https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=1644&ref_no=2
- MS8
https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=844&ref_no=2
- RF3
https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=908&ref_no=2

(2) Conclusion based on the Biological Diversity Risk Assessment

Based on the above understanding, the conclusion described in the Biological Diversity Risk Assessment Report that the 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.