

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 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

This stack line was produced by the cross-breeding method using

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(1) Herbicide aryloxyalkanoate- and glufosinate-tolerant soybean to which modified *aad-12* gene that codes modified AAD-12 protein and *pat* gene that codes PAT protein were introduced (DAS68416), and

(2) Herbicide glyphosate-tolerant soybean to which modified *cp4 epsps* gene that codes modified CP4 EPSPS protein was introduced (MON89788).

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While the herbicide-tolerant proteins produced by the genes introduced to this stack line, namely modified AAD-12 protein, PAT protein and modified CP4 EPSPS protein, exhibit enzyme activity, they have high substrate specificity and the involved action mechanism is mutually independent. Therefore, it is unlikely that the metabolic pathway of the recipient organism is altered and that unexpected metabolites are produced.

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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, and therefore it has been concluded that there are no trait changes to be evaluated, except having the traits which the respective parent line had.

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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.

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(a) Competitiveness

(b) Productivity of harmful substances

(c) Crossability

* The results of review on each parent line are available from the links below.

- 5 ● DAS68416
http://www.bch.biodic.go.jp/download/lmo/public_comment/H25_11_5.gakushikiiken1.pdf
- MON89788
https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=1003&ref_no=2

10 2. Conclusion based on the Biological Diversity Risk Assessment Report

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

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