

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 cotton resistant to Lepidoptera pest and tolerant to aryloxyalkanoate, glufosinate and glyphosate herbicides (hereinafter referred to as “this stacked line”) was developed with the following lines by crossing:

- ① Cotton resistant to Lepidoptera pest and tolerant to glufosinate herbicide, to which modified *cryIF* gene coding for modified Cry1F protein, modified *cryIAC* gene coding for modified Cry1Ac protein, and the *pat* gene coding for PAT protein are transferred (hereinafter referred to as “281 × 3006”);
- ② Cotton resistant to Lepidoptera pest, to which modified *vip3A* gene coding for modified Vip3A protein and the *aph4* gene coding for APH4 protein are transferred (hereinafter referred to as “COT102”);
- ③ Cotton tolerant to glyphosate herbicide, to which modified *cp4 epsps* gene coding for modified CP4 EPSPS protein is transferred (hereinafter referred to as “MON88913”); and,
- ④ Cotton tolerant to aryloxyalkanoate and glufosinate herbicides, to which modified *aad-12* gene coding for modified AAD-12 protein and the *pat* gene coding for PAT protein are transferred (hereinafter referred to as “DAS1910”).

It is likely that the pest resistance proteins (modified Cry1F protein, modified Cry1Ac protein and modified Vip3A protein) produced from the genes transferred to this stacked line specifically act to target pests to independently show insecticidal effects and it is unlikely that synergistic effects and antagonistic actions are exerted by affecting with each other. Since the pest resistance proteins do not have enzymatic activity, there is low possibility they will alter the metabolic pathway of the recipient organism. In addition, while herbicide tolerance proteins (PAT protein, modified CP4 EPSPS protein and modified AAD-12 protein) and APH4 protein, which is the selection marker, have enzymatic activity, they have high substrate specificity and their metabolic pathways are independent of each other. Therefore, it is unlikely that the metabolism of the recipient organism is altered and that unexpected metabolites are produced. As such, it is unlikely these proteins affect with 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.

- (1) Competitiveness
- (2) Productivity of harmful substances
- (3) Crossability

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

- 281×3006
https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=730&ref_no=2
- COT102
https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=1576&ref_no=2
- MON88913
https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=683&ref_no=2
- DAS1910
http://www.bch.biodic.go.jp/download/lmo/public_comment/H26_03_18.gakushikiiken4.pdf

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.