

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

5

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 Glyphosate-induced male-sterile, *Lepidoptera* and *Coleoptera* pest-resistant, and glufosinate and glyphosate herbicide-tolerant maize (including the progeny lines which are isolated from the maize lines, MON87427, MON89034, *B.t.* Cry1F maize line 1507, MON88017 and *B.t.* Cry34/35Ab1 Event DAS-59122-7 and those which contain a combination of their respective transferred genes (except those already granted an approval regarding Type I Use Regulation))
20 (hereinafter referred to as “this stacked line”) was developed with the following lines by crossing:

Glyphosate-induced male-sterile and glyphosate herbicide-tolerant maize, to which the modified *cp4 epsps* gene coding for the modified CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) is transferred (MON87427),

25 Maize resistant to *Lepidoptera* pest, to which the *cry1A.105* gene coding for the Cry1A.105 protein and the modified *cry2Ab2* gene coding for the modified Cry2Ab2 protein are transferred (MON89034),

Maize resistant to *Lepidoptera* pest and tolerant to glufosinate herbicide, to which the *cry1F* gene coding for the Cry1F protein and the *pat* gene coding for the PAT protein (phosphinothricin acetyltransferase) are transferred (*B.t.* Cry1F maize line 1507),

30 Maize tolerant to glyphosate herbicide and resistant to *Coleoptera* pest, to which the modified *cp4 epsps* gene coding for the modified CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the modified *cry3Bb1* gene coding for the modified Cry3Bb1 are transferred (MON88017), and

35 Maize resistant to *Coleoptera* pest and tolerant to glufosinate herbicide, to which the *cry34Ab1* gene coding for the Cry34Ab1 protein, the *cry35Ab1* coding for the Cry35Ab1 protein, and the *pat* gene coding for the PAT protein (phosphinothricin acetyltransferase) are transferred (*B.t.* Cry34/35Ab1 Event DAS-59122-7).

5 It has been determined that the respective Bt proteins (the Cry1A.105, modified Cry2Ab2, Cry1F, modified Cry3Bb1, and Cry34Ab1/Cry35Ab1 proteins) derived from the genes transferred to this stacked line do not interact with one another to change the specificity of the insecticidal effect in these proteins, because it is unlikely that the regions involved in the specificity were changed. As for the PAT and modified CP4 EPSPS proteins, proteins with tolerance to herbicides, their substrates and actions are different and their metabolic pathways are independent of each other. In addition there has been no report that Bt proteins have enzyme activities. Therefore it is unlikely that the proteins with tolerance to herbicides and the Bt proteins interact with one another. It has been determined that these proteins do not interact to change the metabolic system of the recipient organism and produce unexpected metabolites in this stacked line.

15 Based on the above, it is unlikely that these proteins derived from respective parent lines functionally interact with one another in the plant body of this stacked maize line, and therefore it has been concluded that there are no trait changes to be evaluated, except having the traits which the parent line had.

20 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.

- 25 a. Competitiveness
b. Productivity of harmful substances
c. Crossability

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

30 **[MON87427]**

http://www.bch.biodic.go.jp/download/lmo/public_comment/H23_11_24_MON87427sp3.pdf

[MON89034]

https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=1002&ref_no=2

35 **[Cry1F line 1507]**

https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=138&ref_no=2

[MON88017]

https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=727&ref_no=2

[Event DAS-59122-7]

https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=726&ref_no=2

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

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

10 conclusion above made by the applicant is reasonable.