

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

5

Name: Syngenta Japan K.K.

Applicant: Toshiaki Shinohara, President

Address: Office Tower X, 1-8-10, Harumi, Chuo-ku, Tokyo

Approved Type 1 Use Regulation

10

Names of types of living modified organisms	Thermostable α -amylase producing maize, resistant to <i>Lepidoptera</i> and <i>Coleoptera</i> , and tolerant to glufosinate and glyphosate herbicides (modified <i>amy797E</i> , modified <i>cry1Ab</i> , modified <i>cry3Aa2</i> , modified <i>cry1F</i> , <i>ecry3.1Ab</i> , <i>pat</i> , <i>mEPSPS</i> , <i>Zea mays</i> subsp. <i>mays</i> (L.) Ittis) (3272×Bt11×MIR604× <i>B.t.</i> Cry1F maize line 1507×Event 5307×GA21, OECD UI : SYN-E3272-5×SYN-BT011-1×SYN-IR604-5×DAS-01507-1×SYN-05307-1×MON-00021-9) as well as the combinations included in lines isolated from the relevant maize lines (except those already granted an approval regarding Type 1 Use Regulation)
Content of Type 1 Use of living modified organisms	Provision as food, provision as feed, cultivation, processing, storage, transportation, disposal, and acts incidental to them
Method of Type 1 Use of living modified organisms	—

Outline of the Biological Diversity Risk Evaluation Report

Results of the review by persons with specialized knowledge and experience concerning Adverse Effect 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

This stacked line and the combinations included in lines isolated from the relevant maize lines (except those already granted an approval regarding Type 1 Use Regulation) were developed by crossing multiple lines of:

- (1) Thermostable α -amylase producing maize, into which modified *amy797E* gene encoding modified AMY797E α -amylase and *pmi* gene encoding PMI protein are transferred (3272),
- (2) Maize resistant to *Lepidoptera* and tolerant to glufosinate herbicide, into which modified *cry1Ab* gene encoding modified Cry1Ab protein and *pat* gene encoding PAT protein are transferred (Bt11),
- (3) Maize resistant to *Coleoptera*, into which modified *cry3Aa2* gene encoding modified Cry3Aa2 protein and *pmi* gene encoding PMI protein are transferred (MIR604),
- (4) Maize resistant to *Lepidoptera* and tolerant to glufosinate herbicide, into which modified *cry1F* gene encoding modified Cry1F protein and *pat* gene encoding PAT protein are transferred (*B.t.* Cry1F maize line 1507),
- (5) Maize resistant to *Coleoptera*, into which *ecry3.1Ab* gene encoding eCry3.1Ab protein and *pmi* gene encoding PMI protein are transferred (Event 5307), and
- (6) Maize tolerant to glyphosate herbicide, into which *mEPSPS* gene encoding mEPSPS is transferred (GA21).

Pest resistant proteins (modified Cry1Ab protein, modified Cry3Aa2 protein, modified Cry1F protein and eCry3.1Ab protein) which are produced by genes introduced into this stacked line, are considered to act specifically on the target pests and exhibit its insecticidal activity independently, on the other hand, not to provide any synergistic effect or antagonism by interacting each other. Also, pest resistant protein is unlikely to change the metabolic system of its host because it has no enzymatic activity. Furthermore, even though modified AMY797E α -amylase, the proteins tolerant to herbicides, namely PAT protein and mEPSPS protein, and a selection marker protein, namely PMI protein, have enzymatic activity, it is unlikely that they interact each other and generate unexpected metabolites because they have high substrate specificity and their metabolic pathways involved are independent with each other.

Based on the above, it is unlikely that interaction among traits occur in the plant body of this stacked line and combinations included in lines isolated from the relevant maize lines (except those already granted an approval regarding Type 1 Use Regulation), and therefore it has been concluded that there are no trait changes to be evaluated, except having the traits which the respective parent lines had.

The examination of the respective evaluation items of the parental lines has already been completed*. 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

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

- 3272
https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=1501&ref_no=2
- Bt11
https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=906&ref_no=2
- MIR604
https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=938&ref_no=2
- *B.t.* Cry1F maize line 1507
https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=138&ref_no=2
- Event 5307
https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=1613&ref_no=2
- Bt11×GA21
https://ch.biodic.go.jp/bch/OpenDocDownload.do?info_id=941&ref_no=2

2. Conclusion based on the Biological Diversity Risk Evaluation Report

Based on the above understanding, the conclusion described in the Biological Diversity Risk Assessment Report that the use of this stacked line and combinations included in lines isolated from the relevant maize lines (except those already granted an approval regarding Type 1 Use Regulation) in accordance with the type 1 Use Regulation causes no Adverse Effects on Biological Diversity in Japan has been judged to be reasonable.