

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

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#### Approved Type 1 Use Regulation

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Names of types of living modified organisms	Cotton resistant to Lepidoptera, and tolerant to aryloxyalkanoate herbicide and glufosinate herbicide (modified <i>cry1F</i> , modified <i>cry1Ac</i> , modified <i>vip3A</i> , <i>pat</i> , modified <i>aad-12</i> , <i>Gossypium hirsutum</i> L.) ((281×3006)×COT102×DAS1910, OECD UI : (DAS-24236-5×DAS-21023-5)×SYN-IR102-7×DAS-81910-7) As well as the combinations contained in the segregated lines of the above cotton.
Content of Type 1 Use of living modified organisms	Use for provision as food, or animal feed purposes, processing, storage, transportation and disposal, and other acts attendant with these.
Method of Type 1 Use of living modified organisms	—

## Outline of the Biological Diversity Risk Evaluation Report

### Results of review meeting for the Evaluation on Adverse Effect on Biological Diversity

A review was made by experts 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 Evaluation on Adverse Effect on Biological Diversity

This stacked line was created according to crossbreeding method with multiple genic lines by using the followings:

- (1) Cotton resistant to Lepidoptera and tolerant to glufosinate herbicide, into which modified *cry1F* gene encoding modified Cry1F protein and modified *cry1Ac* gene encoding modified Cry1Ac protein, and *pat* gene encoding PAT protein, are transferred (281×3006),
- (2) Cotton resistant to Lepidoptera, into which modified *vip3A* gene encoding modified Vip3A protein and *aph4* gene encoding APH4 protein are transferred (COT102), and
- (3) Cotton tolerant to aryloxyalkanoate herbicide and glufosinate herbicide, into which modified *aad-12* gene encoding modified AAD-12 protein and *pat* gene encoding PAT protein, are transferred (DAS1910).

Destructive insects resistant proteins, namely modified Cry1F protein, modified Cry1Ac protein and modified Vip3A protein, which are produced by genes which were introduced into this stack line are considered to act specifically on the targeted destructive insects and exhibit insecticidal activity independently, on the other hand, not to provide any synergistic effect or antagonism by interacting each other. It is also considered that the destructive insect resistant protein is unlikely to change the metabolic system of its host because it has no enzymatic activity.

Furthermore, even though the both of herbicide-tolerant proteins, namely PAT protein and AAD-12 protein, as well as a selection marker protein, namely APH4 protein, have enzymatic activity, it is considered that they are unlikely to interact each other and generate unexpected metabolites because they have high substrate specificity and their metabolic pathways are independent with each other.

For such reasons, there is extremely low probability for interaction between these proteins.

Based on the above information, it is unlikely that there is an interaction exhibited between these events when stacked in a single plant 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.

The review on the following evaluation items for each parent line, however, has already been completed \* and as the result, it is determined that the conclusion of the Evaluation on Adverse Effect on Biological Diversity, stating that there is no risk of affecting on the biological diversity in Japan if each of those parent lines is used according to Type 1 Use Regulations, is reasonable.

- (a) Competitiveness
- (b) Productivity of harmful substances
- (c) Crossability

\* The result of the review on each parent line is available in the followings.

- 281×3006  
[http://www.bch.biodic.go.jp/bch/OpenDocDownload.do?info\\_id=730&ref\\_no=2](http://www.bch.biodic.go.jp/bch/OpenDocDownload.do?info_id=730&ref_no=2)
- COT102  
[http://www.bch.biodic.go.jp/bch/OpenDocDownload.do?info\\_id=1576&ref\\_no=2](http://www.bch.biodic.go.jp/bch/OpenDocDownload.do?info_id=1576&ref_no=2)
- DAS1910  
[http://www.bch.biodic.go.jp/download/lmo/public\\_comment/H26\\_03\\_18.gakushikiiken4.pdf](http://www.bch.biodic.go.jp/download/lmo/public_comment/H26_03_18.gakushikiiken4.pdf)

## 2. Conclusion based on the Biological Diversity Risk Evaluation Report

From all of the above, we have reached the judgment that the conclusion of the Evaluation on Adverse Effect on Biological Diversity, stating that there is no risk of affecting on the biological diversity in Japan if this stacked line is used according to Type 1 Use Regulations, is reasonable.