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

Name of Entity: Monsanto Company
Name of Applicant: Seiichiro Yamane, President
Address: 2-5-18, Kyobashi, Chuo-ku, Tokyo

Approved Type 1 Use Regulation

Names of types of living modified organisms	Lepidoptera-resistant, and tolerant to dicamba, glufosinate, and glyphosate cotton. (Modified *vip3A*, modified *cry1Ac*, modified *cry2Ab2*, modified *dmo*, *bar*, modified *cp4 epsps*, *Gossypium hirsutum* L.) (COT102 × 15985 × MON88701 × MON88913, OECD UI: SYN-IR1Ø2-7 × MON-15985-7 × MON-887Ø1-3 × MON-88913-8) As well as the combinations contained in the separated lines of the above cottons. (Except for the ones that were already approved under Type 1 Use Regulations.)
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 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 Evaluation on Adverse Effect on Biological Diversity

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

(1) Lepidoptera resistant cottons, into which modified *vip3A* gene encoding modified Vip3A protein and *aph4* gene encoding APH4 protein are transferred (COT102),

(2) Lepidoptera resistant cottons, into which modified *cry1Ac* gene encoding modified Cry1Ac protein, modified *cry2Ab2* gene encoding modified Cry2Ab2 protein, modified *uidA* gene encoding GUSE377K protein, and *nptII* gene encoding NPTII protein are transferred (15985),

(3) Cottons tolerant to dicamba and glufosinate, into which modified *dmo* gene encoding modified DMO protein and *bar* gene encoding PAT protein are transferred (MON88701), and

(4) Cottons tolerant to glyphosate, into which modified *cp4 epsps* gene encoding modified CP4 EPSPS protein is transferred (MON88913).

Insects resistant proteins, namely modified Vip3A protein, modified Cry1Ac protein and modified Cry2Ab2 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 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 modified DMO protein, PAT protein, and modified CP4 EPSPS protein, as well as a selection marker proteins, namely APH4 protein, GUSE377K protein and NPT II protein, have enzymatic activity, it is considered that they are unlikely to interact each other and generate unexpected metabolites because they have excellent substrate specificity and their metabolic pathways are independent with each other.

For such reasons, it is hard to think that there is interaction between these proteins.

From the above information, it was considered that the interaction between characters inside the plant bodies of this stacked line is unlikely to be exhibited, and also there is no trait changes to be evaluated, except that they have combined traits from the respective parent line.

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 results of the review on each parent line are available in the followings.

- COT102
  http://www.bch.biodic.go.jp/bch/OpenDocDownload.do?info_id=1576&ref_no=2
- 15985
  http://www.bch.biodic.go.jp/bch/OpenDocDownload.do?info_id=95&ref_no=2
- MON88701
  http://www.bch.biodic.go.jp/download/lmo/H27.1.30_wata_sp1.pdf
- MON88913
  http://www.bch.biodic.go.jp/bch/OpenDocDownload.do?info_id=683&ref_no=2

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.