

Stance on the Safety Assessment of GM Plants Generated through Cross-Breeding (FSCJ Decision, January 29, 2004)

The safety assessment as for food has been conducted on genetically modified plants (GM plants), mainly focusing on the equivalency of safety compared to the conventional counterpart food.

Before FSCJ was established, the GM plants generated through conventional cross-breeding between the GM and non-GM plants had been already described in MHLW Public Notice No. 233 (2000), in which such GM plants are called “progeny cultivar through cross-breeding” and regarded as the safety confirmed GM plants, as long as the following conditions are fulfilled;

- i) Properties newly acquired through recombinant DNA technology have not altered in progeny cultivar.
- ii) Cross-breeding between subspecies has not been performed.
- iii) Neither the amount of ingestion, edible part nor processing methods, etc. is changed

The stance on the safety assessment of GM plants generated through cross-breeding among the previously approved GM plants, including the “progeny cultivar,” are shown below.

<Categorization of parental GM plants>

Parental GM plants are categorized into the following three types according to the introduced traits.

- 1) Type I: GM plants with traits, such as herbicide tolerance, insect resistance, or virus resistance, in which no effects are observed on the metabolisms of the host plants by the inserted genes.
- 2) Type II: GM plants with traits, such as increased amount of nutritional components, or altered content of cell wall components, in which metabolic pathways of the host plants are altered by the inserted genes.
- 3) Type III: GM plants with “de novo generated substances,” in which new substances are produced by the inserted genes, using metabolites of the host plants.

<Necessity for the safety assessment of GM plants generated through cross-breeding>

(1) GM plants generated through the following crossings;

- [Type I, Type II, or Type III] × non-GM plants
- Type I × Type I

Only in the following cases, the safety assessment of the GM plants needs to be conducted for the time being;

- In the case where the GM plant is generated through crossing among different subspecies or the higher taxonomic rank;
- In the case where the change in the amount of ingestion, or edible part, or processing methods etc., is intended.

(2) GM plants generated through the following crossings;

- Type I × Type II
- Type I × Type III

The safety assessment of the GM plants needs to be conducted for the time being.

(3) GM plants generated through the following crossings;

- Type II × Type II
- Type II × Type III
- Type III × Type III

The safety assessment of the GM plants needs to be conducted.