

**Provisional translation**

December 22, 2017  
Expert Committee on Biotech Foods

This English version of the Commission Decision is intended to be reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail. The Food Safety Commission of Japan (FSCJ) shall not be responsible for any consequence resulting from use of this English version.

**Approach on the Safety Assessment of stacked events produced by cross-breeding of genetically modified plants in which the host metabolic systems are altered by the transgenes**

1. Background

- (1) The safety assessment of stacked events produced by cross-breeding among the previously approved GM plants are conducted based on the “Stance on the Safety Assessment of GM Plants Generated through Cross-breeding” (Food Safety Commission Decision of January 29, 2004, hereinafter referred to as “Stance on Cross-Breeding Variety”). The 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.
- (2) Stacked events produced by cross breeding of Type I × Type I are not required to undergo further safety assessment when the following conditions are fulfilled.
  - Cross-breeding of Type I × Type I;
  - Cross-breeding between subspecies or higher taxonomic than subspecies has not

been performed.

- Neither the dietary intake, edible part nor processing methods etc. is changed.

On and after June 2014, stacked events judged by the risk management organizations to fulfill the above conditions are regarded as the safety-assessed GM plants.

(3) On the other hand, in the case where the stacked events are produced by Type I× Type II crossing and Type I× Type III crossing, “Stance on Cross-Breeding Variety” describes that the safety assessment needs to be conducted for the time being.

So far, unpredicted effects on human health have not been caused by any of the six cases of Type I× Type II crossing evaluated under the “Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants)” (hereinafter referred to as “Plant’s Standard”)

## 2. The safety assessment of stacked events produced by Type I× Type II cross breeding

(1) On the basis of the above mentioned background, the safety assessment of the stacked events produced by Type I × Type II crossing should be conducted based on following conditions, including the confirmation item for Type I × Type I crossing “Stance on Cross-Breeding Variety” (corresponding to the following a) and Sections 6-5 to 6-7 of Chapter 2 in the “Plant’s Standard” (corresponding to the following b to d).

### a. Basic description

The following conditions should be fulfilled in addition to identifying the new traits conferred by transgenes into the parental GM plants.

- GM plant is not produced by crossing between different subspecies or higher taxonomic than subspecies.
- Neither the dietary intake, edible part, nor processing methods, etc. is changed.

### b. Stability of transgene

It should be confirmed that new traits conferred by transgenes into parental GM plants are stable in stacked events by using information such as analysis of DNA sequence, or gene product(s) or phenotypic characteristics.

### c. Effect on the host metabolic pathways

It should be confirmed by appropriate rationale that the mechanisms of the host metabolic pathways modified by the transgenes of parental GM plants are independent of each other

and that the metabolic systems are not mutually affected in the stacked events.

d. Differences from the host plants

For the component whose quantitative difference is observed between the parental GM plant and the host (the nutritional compositions altered intentionally is included in the “phenotypic characteristics” mentioned in above b.), it should be confirmed that no significant quantitative change of the component is caused between the host plant and the stacked events.

- (2) Generally the safety of the basic concepts excluding the above a. to d. are regarded as confirmed during the safety assessment of the parental GM plants. Therefore, it is possible to omit those descriptions in the application documents for the stacked events.

3. Others

- (1) The above 2 is applicable to stacked events using Type I in which significant changes in the amount of specific nutritional components are observed compared to host plants, however, no effects are observed on the metabolism.
- (2) This decision specifies only the basic approach of the safety assessment of the stacked events produced by Type I × Type II crossing. Where the Expert Committee recognizes it necessary, the committee will carry further deliberations after requesting additional documents from the applicants.