

Provisional translation

The Food Safety Commission

Final decision on November 13, 2019

This English version of the Commission Decision is intended to be reference material to provide convenience for users. In the event of any 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.

**Stance on the Safety Assessment of GM Plants Generated Through
Cross-Breeding (Partial Revision)**

(Interpretation of the stacked GM plants that require safety assessments for “the time being” as defined in (1) a))

1. Background

At the 192nd Expert Committee on Genetically Modified Foods where deliberations on pima cotton MON88701 × MON88913 line tolerant to dicamba, glufosinate and glyphosate herbicides were held, the following decision was drawn for the GM plant produced by cross-breeding among different subspecies or higher taxonomic than subspecies. The decision was specifically made on the stance of the stacked cotton produced by crossing cotton (*Gossypium hirsutum*) and pima cotton (*Gossypium barbadense*).

Gossypium hirsutum and *Gossypium barbadense* are classified into different species of the genus *Gossypium*, however, it is widely known that the hybridization occurs easily between the cotton species in the natural environment. The cottons are amphidiploids having almost the same genome structure and high genetic similarity. Furthermore, no differences have been identified for the dietary intakes, processing methods, edible parts, and harmful physiologically active substances, therefore, the FSCJ judged it appropriate to treat the cottons as the same species in the safety assessment.

2. Previous stance on the safety assessment

In the case where the GM plant is produced by cross-breeding among different subspecies or higher taxonomic than subspecies, the safety assessment has been conducted based on the standard described section (1) a), the safety assessment needs to be conducted for “the time being” as specified in the “Stance on Safety Assessment of GM plants Generated through

Cross-Breeding” (decision of Commission dated 29 January 2004).

3. Revised stance on the safety assessment

The partially-revised definition of the stacked GM plants that require safety assessments for “the time being” as described in the stance), (1) a) is defined below. It should be noted that the safety assessment will not be required for the GM plants in the underlined clause after this revised stance is applied.

The revision is underlined.

«Necessity for the safety assessment of GM plants generated through cross-breeding»

(1) GM plants produced through the following crossings;

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

a) 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 higher taxonomic than subspecies.

However, at the 192nd meeting, for the following cross-breeding, the expert committee judged it appropriate to treat the two cottons as the same species in the safety assessment.

- Cross-breeding of the two cottons

Cotton (<i>Gossypium hirsutum</i>) and Pima cotton (<i>Gossypium barbadense</i>)
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[※][Type I, Type II, or Type III]

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.