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**Risk Assessment Report: Genetically Modified Foods and Feeds**

# **Soybean Lines Generated through Cross-breeding of MON87705, MON87708 and MON89788**

## **Summary**

Food Safety Commission of Japan

The Food Safety Commission of Japan (FSCJ) conducted a safety assessment of soybean lines generated through cross-breeding of MON87705, MON87708 and MON89788, based on the documents submitted by the applicant. The safety assessment of all the three parental lines and the MON87705 × MON89788 line had been completed as no safety concern. The safety assessment was judged unnecessary for the MON87708 × MON89788 line. The data and information submitted by the applicant were reviewed from the various points, including the safety of the inserted genes, the induction of allergenicity, the stability of the introduced genes in the progeny, and especially the possible influences of the expressed gene products on the metabolic pathway and the contents of nutritional and hazardous components. It was considered that either trait was independent of the other traits, regardless of the crossings. Consequently, FSCJ thus concluded that the MON87705 × MON87708 × MON89788 and MON87705 × MON87708 soybean lines showed no safety concern relevant to human health.

## **Conclusion in Brief**

The Food Safety Commission of Japan (FSCJ) conducted a safety assessment of soybean lines generated through cross-breeding of MON87705, MON87708 and MON89788, based on the documents submitted by the applicant.

A new line, MON87705 × MON87708 × MON89788, was generated through conventional cross-breeding of the three parental lines, i.e., one line with a trait of lower levels of saturated fatty acid and higher levels of oleic acid (MON87705 line), and two lines (MON87708 and MON89788 lines) with distinct traits of herbicide-tolerance (dicamba- and glyphosate-tolerance, respectively). Thus the new line has all transgenic traits derived from the three parental lines. Due to the genetic segregation, the seeds harvested from the MON87705 × MON87708 × MON89788 line may contain the transgenic traits identical to those of the three parental lines and the following four cross-breeding lines; MON87705 × MON87708 × MON89788, MON87705 × MON87708, MON87705 × MON89788, and MON87708 × MON89788 lines. The safety assessment of all the three parental lines and the MON87705 × MON89788 line had been completed as no safety concern. The safety assessment was judged unnecessary for the MON87708 × MON89788 line (see Reference 1).

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This is an English translation of excerpts from the original full report (August 2016–FS/541/2016). Only original Japanese texts have legal effect.

The original full report is available in Japanese at <http://www.fsc.go.jp/fsciis/attachedFile/download?retrievalId=kya20160523041&fileId=201>

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FSCJ thus conducted the safety assessment on the remaining MON87705 × MON87708 × MON89788 and MON87705 × MON87708 lines.

According to the “Stance on the Safety Assessment of Genetically Modified Plants Generated through Cross-Breeding” (see Reference 2), the safety of a new line, which is generated through conventional cross-breeding among a line, in which the metabolic pathway of the host plant is altered by the inserted gene to raise the content of specific nutrients, and lines with herbicide-tolerance needs to be reviewed along the “Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants)”.

The data and information submitted by the applicant were reviewed from the various points, including the safety of the inserted genes, the induction of allergenicity, the stability of the introduced genes in the progeny, and especially the possible influences of the expressed gene products on the metabolic pathway and the contents of nutritional and hazardous components. It was considered that either trait was independent of the other traits, regardless of the crossings.

Consequently, FSCJ thus concluded that the MON87705 × MON87708 × MON89788 and MON87705 × MON87708 soybean lines showed no safety concern relevant to human health.

## Reference 1

### Revision of Application Procedure of GM Plants Generated through Cross-breeding

Responding to the request from the Ministry of Health, Labor and Welfare (MHLW), FSCJ used to assess new cross-breeded lines to know whether the lines falls in “Type I × Type I” category based on “Stance on the Safety Assessment of Genetically Modified Plants Generated through Cross-Breeding” (see Reference 2) . The MON87708 × MON89788 line was judged as “Type I × Type I”. After receiving the judgment, MHLW added the MON87708 × MON89788 line in the safety confirmed GM foods list published on its website.

Based on the findings obtained so far, FSCJ recognized that the safety assessment on such GM plants were not necessary. In 2014, MHLW thus revised the application procedure (MHLW Public Notice No. 233 (2000), revised June 27, 2014), after receiving the affirmative letter from FSCJ (December 16, 2013) in reply to the inquiry concerning the revision of the procedure. New lines generated through cross-breeding among the Type I GM plants, listed on the MHLW website, are currently only subject to applicant’s notification to MHLW, as long as the following conditions are fulfilled;

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

## Reference 2

### 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.