

Press Release

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**Food Sanitation Division
Food Chemistry Division
Ministry of Health and Welfare,
Japan**

A Report from the Subcommittee on Biotechnology about mandatory requirement for “Safety Assessment of Foods and Food Additives Produced by Recombinant DNA Techniques”

Today, the Subcommittee on Biotechnology reported on mandatory requirement for “Safety Assessment of Foods and Food Additives Produced by Recombinant DNA Techniques.”

1. Outline

In response to the consultation made on 12 November 1999 by the Minister of Health and Welfare to the Food Safety Investigation Council concerning the safety assessment, the Subcommittee on Biotechnology has carried out in-depth discussions from various aspects. Today, the Subcommittee on Biotechnology compiled a report based on the discussions. Below is an outline of the report.

(1) Need to legally impose the safety assessment

The subcommittee concluded that the safety assessment should be legally imposed for several reasons mentioned below:

- A) Foods and food additives produced by the recombinant DNA techniques (hereinafter referred to GM foods: genetically modified foods) are expected to distribute globally and new types of foods are expected to develop.
- B) Under the Law Concerning Standardization and Proper Labelling of Agriculture and Forestry Products, the Ministry of Agriculture, Forestry, and Fisheries is supposed to change its labelling regulations to be mandate to label GM foods, for which the safety assessment has been conducted by the Ministry of Health and Welfare.

(2) The way of introducing mandatory requirement

To legally impose the safety assessment, it is appropriate to add the provision, given below, in the “Specifications and Standards for Foods, Food Additives and Other Related Products” under Article 7 of the Food Sanitation Law.

“If a food is made of all or part of organism obtained by the recombinant DNA techniques, or if a food contains all or part of organism obtained by the recombinant DNA techniques, the organism shall undergo food safety assessment by the Minister of Health and Welfare ”

(3) Concept of safety assessment

The scientific concept of the existing “Guidelines for Safety assessment of Foods and Additives Produced by the Recombinant DNA Techniques” and “Guidelines for Manufacturing Assessment of Foods and Additives Produced by the Recombinant DNA Techniques” should be adopted without any changes as that of the safety assessment.

The subcommittee compiled standards for safety assessment as “draft standards for safety assessment of foods and additives produced by the recombinant DNA techniques,” based on opinions and findings obtained from discussions during conducted to the date.

(4) Certification of safety assessment at each import point

Certification that the food has undergone safety assessment is necessary, in order to avoid the import of GM foods subjected to no safety assessment. In practice, a certain respective kind of indication should be made in an import notification under Article 16 of the same law at each.

In addition, it is necessary to monitor imported and domestic GM foods by random sampling, to confirm that the food meets the safety assessment standards.

(5) Others

The MHW will have to continue to collect latest scientific information and will have to utilize them into the safety assessment.

The MHW and the people concerned will have to publish scientific information on the safety of GM foods in a manner that is easy to understand.

The MHW will have to convey “why and how the safety assessment should be

conducted” to foreign countries in order to promote adequate implementation of the safety assessment. The MHW should also work to establish a system to obtain foreign information promptly.

1. Schedule of the MHW

- (1) To invite public comments on the report
- (2) To notify WTO
- (3) To hold a session of the Standing Committee under the Food Safety Investigation Council
- (4) To receive an opinion from the Council
- (5) To make an announcement in the official gazette (KANPO)