

Press release

25 April 2000

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

A report submitted by the Food Safety Investigation Council on “Mandatory Requirement for Safety Assessment of Foods and Food Additives Produced by Recombinant DNA Techniques” and on “Withdrawal and Readjustment of Designated Food Additives”

Today, the Food Safety Investigation Council submitted to the Minister of Health and Welfare a report proposing mandatory requirement of safety assessment of foods and food additives produced by recombinant DNA techniques.

The Council was consulted from the Minister for the Health and Welfare about the matter concerning mandatory requirement for the safety assessment of such foods. And the Council also submitted to the Minister other report about withdrawal and readjustment of designated food additives.

1. The Council decided that the mandatory requirement for the safety assessment of foods and food additives produced by recombinant DNA techniques should be introduced in the light of the report compiled by the Subcommittee on Biotechnology dated on 21 January 2000. (See Attached I: Abstract of the report)
2. The Council also decided that withdrawal and readjustment of food additives designated on the list under Food Sanitation Law should be introduced as reported in attached II.

Attached I

Abstract of the Report on Mandatory Requirement for Safety Assessment of Foods and Food Additives Produced by Recombinant DNA Techniques

(1) Need to legally impose the safety assessment

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

- A) Foods and food additives produced by 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 label GM foods, for which the safety assessments have been conducted by the Ministry of Health and Welfare.

(2) The way of introducing mandatory requirement

It is appropriate to add a new provision, given below, to 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 Recombinant DNA Techniques” and “Guidelines for Manufacturing Foods and Food Additives Produced by 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 Food Additives Produced by Recombinant DNA Techniques,” based on opinions and findings obtained from discussions during conducted to the date.

(4) Certification methods 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 whether the GM foods has been evaluated their safety or not.

(5) Others

It is necessary to collect the latest scientific information on safety of GM foods. It is also necessary to utilize them into the safety assessment.

The Ministry of Health and Welfare (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 collect foreign information promptly.

Attached II

**Withdrawal and readjustment of food additives designated
on the list under Food Sanitation Law**

Outline of proposals

- (1) Methyl Acetyl Ricinolate, Choline Phosphate, Ferrous Pyrophosphate are to be withdrawn under the Article 6 of Food Sanitation Law

- (2) Food additives that are separately designated for both crystal and anhydrous form in the list are appropriate to be re-designated as one chemical substance.
 - Food additives for re-designation -
 - sodium sulfite, citric acid, sodium acetate, sodium hydroxide, sodium carbonate, sodium pyrophosphate, aluminum ammonium sulfate, aluminum potassium sulfate, ferrous sulfate, disodium hydrogen phosphate, sodium dihydrogen phosphate, trisodium phosphate

- (3) Numbers for food additives designated on the list should be re-allocated as consecutive numbers.