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

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**Subcommittee on Biotechnology**

**Food Safety Investigation Council**

**1. Background and Introduction**

In late years, a new technology so called “Biotechnology” has internationally come into practical use. It is prospective that application of the biotechnology in the field of food production may lead to the improvement of food quality and productivity.

Modern biotechnology, through the use of recombinant DNA techniques, has been used for food production in these days. So it should be given attention the safety of foods and food additives produced by recombinant DNA techniques (hereinafter referred to GM foods: genetically modified foods)

On this account, our countries set out the “Guideline for safety assessment of foods and food additives produced by recombinant DNA techniques” (hereinafter referred to “Guideline for safety assessment”) and “Guideline for manufacturing foods and food additives produced by the recombinant DNA techniques” (hereinafter referred to “Guideline for manufacturing”) in 1991.

So far, in Japan, 29 foods and 6 food additives has been evaluated based on the Guideline for safety assessment and declared by the Food Safety Investigation Council and have been confirmed individually by the Minister for Health and Welfare. On the other hand, there are no foods and food additives produced by recombinant microorganisms that are subject to be evaluated based on the Guideline for manufacturing. The Guideline for manufacturing is only applicable for assessing safety of recombinant microorganisms.

In response to the request that was made on 12 November 1999 by the Minister to the Council to discuss the matter concerning proposed mandatory requirement for safety assessment of GM foods, the Subcommittee on Biotechnology has carried out in-depth discussions from various aspects.

This report stated hereafter is a conclusion of the Subcommittee compiled based on the discussion in these days to describe draft plan how to legally impose safety assessment of GM foods. It attached the proposed “Draft Revision of Specifications and Standards for Foods, Food Additives and Other Related Products”(Annex I). The other three drafts below are also attached (Annexes II – IV):

- “Draft Proposed Procedure of Application for Safety Assessment of Foods and

Food Additives Produced by Recombinant DNA Techniques"

- "Draft Standard for Manufacturing Foods and Food Additives Produced by Recombinant DNA Techniques"
- "Draft Standards for Safety Assessment of Food and Food Additives Produced by Recombinant DNA Techniques" are also attached.

**2. Need to legally impose the safety assessment**

So far, the safety assessment of GM foods that has been conducted based on the Guideline for safety assessment has been operating on a voluntary basis at this stage. And the Minister for Health and Welfare call for developers, traders and other related persons strongly to accept the safety assessment

In this application, the safety assessment of GM foods would have been done enough.

However, the Subcommittee concluded that safety assessment of GM foods should be legally imposed reasons below:

- GM foods are developed and come into practical. In late years, GM foods are expected to circulate globally and new types of GM foods are expected to develop. So mandatory system for assessing safety of GM foods at pre-market stage is necessary, in order to avoid the distribution of any GM food that has no safety assessment.
- Under the Law Concerning Standardization of Agriculture and Forestry Products and Proper Labeling of These 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.

It is capacitate to deal with when the distribution of GM foods subjected to no safety assessment. At the same time, the mandatory requirement would lead to the promotion of transparency in the process of safety assessment and the building of consumers' confidence.

**2. The way of introducing mandatory requirement**

Under Article 7 of the Food Sanitation Law now in force, the Minister for Health and Welfare has the authority to establish specifications for food components and

standards for manufacturing foods and food additives in view of protecting health hazards and promoting public health. In accordance with this provision, the announcement of the Ministry of Health and Welfare (MHW) entitled "Specifications and Standards for Foods, Food Additives and Other Related Products" has been set up as the regal announcement of the MHW.

In the same manner, it would be able to introduce mandatory requirement for safety assessment of GM foods by adding a new provision to the "Specification and Standards for Foods, Food Additives and Other Related Products". The conceivable draft of the provision is:
*"If a food is made of all or part of organism obtained by the recombinant DNA techniques, of if a food contains all or part of organism obtained through the recombinant DNA techniques, the organism shall undergo food safety assessment by the Minister for Health and Welfare".*

It is appropriate rather to amend the provision than to establish a new law or to revise the Food Sanitation Law partly.
The reasons are as below:

- Up to now, based on the "Specifications and Standards for Foods, Food Additives and Other Related Products", various specifications for food components and standards for manufacturing foods and food additives have been regulated. For example, there are bans for containing antibiotics in food or application of radiation in food processing. Therefore, a ban for selling, importing and manufacturing etc. of GM foods whose safety is not assessed will be enabled by revising the existing "Specifications and Standards", as well as the treatment for banning aforementioned cases.
- Widely various biotechnology other than recombinant DNA technique are expected to come into practical use in the field of new foods production such as somatic cell cloning technology, etc. To quickly keep up with the situation that would happen to appear these new foods, it is appropriate rather to amend the provision of the "Specifications and Standards" than to institute a change in the Food Sanitation Law in each case.
- It lacks regal balance to lay down a particular article only for GM foods among other foods.

Regulating the safety assessment of GM foods in the "Specifications and

Standards" brings about effects as follows:

- Manufacturing, importing and selling, etc. of GM foods uncongenial to the Specifications and Standards are banned.
- In case where GM foods uncongenial to the Specifications and Standards go into circulation, administrative dispositions such as the order of abolishment, calling-back and ship-back are applicable.
- Penalty of imprisonment not more than one year or pecuniary penalty not more than a hundred thousand yen are imposed on violations of the Specifications and Standards.

As manufacturing, importing and selling etc. of GM foods uncongenial to the Specifications and Standards are banned as soon as the amendment comes into force, it is required to clarify whether products are congenial or not before the date of enforcement. Otherwise it will introduce confusion into cropping, buying-in and import by traders concerned.

Basically, companies themselves have responsibilities for ensuring the safety of GM foods as well as other foods. Therefore it is appropriate that the Ministry of Health and Welfare assesses the safety of GM foods individually after the experts review the scientific validity and the reliability of the detailed data submitted by the companies that develop GM foods.
To put it concretely, the safety assessment needs to be reviewed by the Food Safety Investigation Council because it requires highly scientific knowledge. The scope of the data to be submitted and the procedure also should be clarified.
These measures comply with the consumers' requests on ensuring the safety of GM foods.

It is appropriate to introduce mandatory requirement of the safety assessment of GM foods without changing the scientific concept of the current two guidelines ("Guidelines for safety assessment" and "Guidelines for manufacturing"), because there seems no need to make alternations to these two guidelines at the present moment.

Based on the above reasons, the draft announcement on the amendment of the Specifications and Standards, the Procedure of Safety Assessment and the Standards for Safety Assessment have drafted as Annexes I - III.

Our committee considers that these drafts are appropriate.

**4. Concept and procedure for safety assessment**

In order to ensure safety of GM foods, appropriate safety assessment should be conducted. In assessing safety of GM foods, safety of all factors that were added to products by using recombinant DNA techniques should be evaluated. Namely, safety assessment of GM foods should be conducted in terms of not only the added properties anticipated as a result of using recombinant DNA techniques, but any effects that originate from the use of such techniques, or the possibility thereof will be evaluated for safety. Moreover, the method of use and processing of such foods should also be considered during the evaluation.

This concept is the basic idea of the "Guideline for safety assessment". This idea should be taken over even after safety assessment system of GM foods changed to mandatory one.

This Committee has established attached "Draft Standard for Safety Assessment of Foods and Food Additives Produced by Recombinant DNA Techniques"(Annex 4) based on previous discussion on safety assessment of GM foods. The safety assessment should be done base on the latest scientific knowledge in the light of the standard. These actions will lead to ensure the safety of GM foods and build consumers' confidence.

The scope of the draft Standard is only seed plants produced by recombinant DNA techniques and foods or food additives produced by using recombinant microorganisms (hereinafter referred to GM microorganisms). The latter means that the GM microorganisms themselves are not directly consumed. The reason why there is a limitation is that the scope of the current Guidelines is the same as the objects mentioned above, and these products have already been commercialized, and the method for evaluating their safety have already been established.

Where GM foods are not included to the scope, it is impossible to assess their safety of such foods, for the mean while. So when GM plant other than seed plants and GM microorganisms in case such microorganisms themselves are directly

consumed, it is necessary to assess their safety after establishing new Standards that is applicable to their safety assessment.

**5. Certification methods at each import point**

After enforcing the new requirement for safety assessment of GM foods, only the GM foods that their safety is evaluated will be approved to circulate.
So we have to establish some verification methods whether only approved GM foods are circulated or not.

One of the possible method is to ask importers to submit "Notification of imports for foods" based on provision of the Article 16 of the Food Sanitation Law. Currently it is mandate to submit the notification form describing information of names of ingredients, methods of manufacturing for processed foods and name of additives contained the food. After enforcing the new requirement, it is necessary to ask importers to submit notification for the purpose of preventing non-approved GM foods.

Other one is to perform monitoring tests (random inspection) for GM foods that are imported and circulated. Currently, monitoring tests for food additives and microorganisms at quarantine stations are performed to assure the safety of imported conventional foods. Regarding GM foods, it is appropriate to perform monitoring tests to make sure that non-approved GM foods are not circulated in Japan, and it is necessary to establish suitable test system. It is also appropriate to perform monitoring tests domestically by food safety inspectors of local governments. Regarding methods of tests, it is necessary to collect necessary information and update the method based on the latest scientific knowledge in order to perform highly qualified tests.

According to the Draft Standard for Safety Assessment of Foods and Food Additives Produced by Recombinant DNA Techniques, developers will be asked to submit relevant information of inserted genes that are useful to establish monitoring methods to identify the circulation pathways of GM foods. And they also will be asked to store developed seeds. The submitted information will be used as essential information for monitoring conducted by national and regional government and companies in order to assure that only approved GM foods are

circulating.

**6. Research promotion**

To assure the safety of GM foods, it is necessary to collect the latest scientific information about safety of GM foods as well. Recently, apprehension for the safety of GM foods is pointed out. However, there is no apprehension that shows scientific evidences lead to immediate actions. It is also necessary to review and discuss these apprehensions scientifically by specialists towards such apprehensions, if appropriate. The latest scientific information on safety of GM foods has to be utilized in a process of the safety assessment

At the same time of enforcing the new requirement for safety assessment procedure, it should be encouraged to improve an easy and high qualified test method of PCR (Polymelase Chain Reaction) or other relevant test method, so that it enables to identify any GM foods subjected no safety assessment.

**7. Others**

The committee concluded that both the Ministry of Health and Welfare and people concerned will have to publish scientific information on safety of GM foods in a manner that is easy to understand, for example, questions and answers.
Also, information about the safety of GM foods inclusive of other important information such as international situations and scientific papers should be collected promptly.

In addition, it is necessary to establish databases about toxic and allergenic substances in foods, and these databases should be held in common among persons internationally. In case of utilizing information of inserted genes' sequences submitted by developers as a mentioned in forth paragraph of Section 5, necessary measures should be taken to preserve the intellectual property rights of the developer of the GM foods.

Furthermore, it is necessary for the Ministry of Health and Welfare to convey "why and how the safety assessment should be conducted" to foreign countries in order to promote adequate implementation of the safety assessment so that the new

system would be adequate applied.
It is also necessary to establish the system in which we can collect information promptly on foods and food additives produced by recombinant DNA techniques being assessed in other countries. This information includes the progress of development and the present conditions of safety assessment in foreign countries.

These actions, combined altogether, will hopefully lead to the promotion of international trade of foods and to the building consumers' confidence.

Regarding safety assessment of GM foods, it is desired to establish and perform adequate regulation promptly based on this report.

Talking about the labelling of GM foods, the Ministry of Agriculture, Forestry and Fisheries has decided to label GM foods from the aspect of consumers' choice under new JAS Law. It is needed to discuss the necessity of labelling of GM foods from the aspect of public health in accordance with mandatory requirement for safety assessment of GM foods.

Note: This English version of the Report is translated to meet the need of the non-Japanese speaking people. In the case of any discrepancy between the Japanese original and the English translation, the former will take priority.