

Annex II

Procedure of examination conducted by the Minister for Health and Welfare regarding safety assessment / confirmation of manufacturing methods of foods and food additives.

1. Application

Any applicant who intends to undergo an examination conducted by the Minister for Health and Welfare shall submit the necessary documents for application to the Minister in accordance with the Announcements for “Procedures of Application for Safety Assessment” or “Standard for Manufacturing” respectively.

The former announcement is applied to the examination concerning safety assessment of foods or food additives produced by recombinant DNA techniques. The latter one is applied to the examination concerning confirmation of manufacturing methods whether to comply with the Standard, in case the foods and food additives are manufactured by using recombinant microorganisms.

If the applicant live in foreign country, the person (the contact point in Japan) who can deal with the matters relating to the contents of the application responsibly must be defined.

If foods or food additives are manufactured from seed plants obtained through recombinant DNA techniques, application shall be made on each variety of the foods and food additives basis. If foods or food additives are manufactured by using microorganisms obtained through recombinant DNA techniques, application shall be made on each item of the foods or food additives basis.

Applicants shall submit the necessary documents for application to the following division case by case:

- Milk, meat and other animal foods Veterinary Sanitation Division
- Food additives Food Chemistry Division
- Foods for special dietary use Office of Health Policy on Newly Developed Foods
- General foods other than those above Food Sanitation Division

2. Examination

When the application is made, Secretariat of the Food Safety Investigation Council examines the contents of the documents preliminary, prior to the evaluations formally done by the Council. The each division above is assigned as the Secretariat of the Council on each case.

After the Council finishes their evaluations, final report that compiles the results of the evaluations will be submitted to the Minister for Health and Welfare. The Ministry of Health and Welfare will go through the process to publish declaration of the results in official gazettes.

In a process of the evaluation, the Council may request the applicant to submit additional data, if appropriate.

3. A term of a regular examination process

Normally, it will take one year to go through regular process for the examination, from the date to receive the necessary documents for application until the date to publish in official gazettes. However, the term will not contain the time that is to be consumed by the applicant to compensate for some faults / inadequacies in the documents, or to answer questions pointed out by the Council in the process.

4. Necessary documents for application

Applicant shall submit the necessary documents for application in accordance with the Announcements for “Procedures of Application for Safety Assessment” and “Standards for Manufacturing.

Applicant shall prepare the necessary documents for application in a responsible manner and assure the credibility of the documents.

Applicant shall make the summary of the documents in Japanese. The dossier other than the summary may be written in English.

The summary shall be condensed forms for quick reference. In addition, reference numbers of the documents shall be specified in the summary to designate the correlation between the summary and each document.

Any necessary test in preparing the documents shall be performed at the

appropriate laboratories that those facilities, instruments and staffs are adequate for assuring credibility of the test results and they are managed properly.

If possible, applicant shall submit diskette (2HD (1.4MB) and MS-DOS formatted) that records the summary of the documents (not including figures) in the form of text file.

Note: This English version of the Notice 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.