

Guide to Preparation of Application Documents Required to
Amend Specifications for Substances Contained in Raw Materials
of Food Utensils, Containers, and Packaging

Food Safety Standards and Evaluation Division
Pharmaceutical Safety and Environmental Health Bureau
Ministry of Health, Labour and Welfare

May 29, 2020

I Objectives

Pursuant to the Act Partially Amending the Food Sanitation Act etc. (Act No. 46 of 2018), the Positive List (PL) System (a system in which use of all substances is basically prohibited, and the use of substances proven safe is only permitted) was introduced for the specifications and standards for food Utensils, Containers, and Packaging (UCPs) in Article 18 (3) of the amended Food Sanitation Act (Act No. 233 of 1947). The specifications for substances constituting the material category (hereinafter referred to as “synthetic resin”) specified by Cabinet Order that is stipulated in Article 18 (3) of the amended Food Sanitation Act have been specified in Appended Table 1 of the Specifications and Standards for Food, Food Additives, Etc. (Public Notice of the Ministry of Health and Welfare No.370 of 1959; hereinafter referred to as the “Public Notice”).

This Guide provides the procedures required for when a business operator, etc. who desires to request that a substance be newly listed in Appended Table 1 or that the specifications for a substance listed in the same Table be revised files an application to that effect (hereinafter referred to as “request”).

II Target for requests

This Guide covers the requests below.

<Request for newly listing the following substances>

Substances:

- that were not being used in UCPs sold, manufactured, imported for the purpose of marketing, or used in business (hereinafter these substances are limited to raw materials of synthetic resin) before the enforcement date of the PL system (June 1, 2020); and
- that are used in UCPs manufactured for the first time after the enforcement date for the purpose of marketing; or
- that are being used in UCPs intended to be imported for the purpose of marketing for the first time after the enforcement date.

<Request for revising specifications for the following substances>

Substances:

- that were being used in UCPs sold, manufactured or imported for the purpose of marketing, or used in business before the enforcement date of the PL system; and
- that are used in manufacturing of UCPs beyond the scope of previous use after the enforcement date; or
- that are being used, beyond the scope of previous use, in UCPs intended to be imported after the enforcement date.

Examples

- When a business operator, etc. desires to use an additive in a base polymer in the synthetic resin group* for which the additive has never been used before
- When a business operator, etc. desires to use an additive at an unprecedented increased level
- When a business operator, etc. desires to use a substance in UCPs at an unprecedented

high temperature

- When a business operator, etc. desires to use a substance in UCPs for an unprecedented food category in which the substance have never been used

* Name of item listed in Appended Table 1 of the Public Notice

III Procedures

1. Prior consultation

A person who requests for revising specifications (hereinafter “requester”) shall have a prior consultation with the Food Safety Standards and Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare (hereinafter the “Secretariat”) about documents to be submitted as required for procedures pertaining to the request. It is desirable that, before consultation, the requester prepares documents to be submitted by reference to Section IV “Matters to be included in documents to be submitted” below.

2. Request

A requester shall file an application with accompanying documents using the attached Form 1 or Form 2, whichever is applicable, with the Secretariat. The accompanying documents shall reflect the content of prior consultation. If the requester resides overseas, the application shall contain the name of a person (with address in Japan) who is able to respond in Japanese with responsibility to matters related to the request in Japan.

3. Review

The Secretariat checks the content of the application and submitted documents. Then, the Cabinet Office Food Safety Commission of Japan (FSCJ) assesses the effect of food on human health.

According to the results of assessment by FSCJ, the Pharmaceutical Affairs and Food Sanitation Council reviews the proposed draft specifications for which the request was made, and the Secretariat carries out procedures necessary for revising the Public Notice based on the report thereof.

Note that, during the review process, the requester may be requested to submit additional documents.

4. Withdrawal

If a requester desires to withdraw a request, the requester shall notify the Secretariat of withdrawal of the request using Form 3.

IV Matters to be included in documents to be submitted

- When preparing documents pertaining to a request, the requester should refer to the FSCJ Guidelines for Risk Assessment of Food Apparatus, Containers and Packaging (hereinafter the “FSCJ Assessment Guideline”). As necessary, the requester shall provide rational explanations about the content of the documents.

FSCJ Assessment Guideline:

<https://www.fsc.go.jp/senmon/kiguyouki/>

- A summary description of the substance for which the application is filed shall be prepared in Japanese. Other documents to be submitted may be written in English. If an original paper, etc. is written in a language other than Japanese or English, a Japanese or English translation shall accompany the original paper, etc.

V Notes

- This Guide will be subject to revision as necessary based on discussions at FSCJ or for other reasons.
- If the submission of new documents is specified in the amended Guide as a result of revision of this Guide, a requester may be requested to submit additional documents, even for a substance for which a request has already been made and discussions at FSCJ, etc. are in progress.

Form 1

New listing

Date

To: Minister of Health, Labour and Welfare

Address (address of main office of the corporation)

Name (corporate name and corporation representative name) [Seal]

Request for Newly Establishing Specifications in Appended Table 1 of Standards and
Regulations of Foods, Food Additives, Etc.

I hereby request, with required attached documents, to newly establish specifications for the following substance constituting material categories (materials specified by the Cabinet Order under Article 18 (3) of the Food Sanitation Act) of utensils, containers, and packaging pursuant to the provisions of Article 18 (1) of the Act.

(Name of the substance requested to be newly listed)

Notes:

1. Use JIS A4 paper or its equivalent.
2. Use ink and block letters.
3. If the requester resides overseas, specify the contact address and number in Japan.

The requester may provide a signature instead of affixing a seal.

Revision of specifications

Date

To: Minister of Health, Labour and Welfare

Address (address of main office for corporation)

Name (corporate name and corporation representative name) [Seal]

Request for Revising Specifications of a Substance in Appended Table 1 of Standards and
Regulations of Foods, Food Additives, Etc.

I hereby request, with required attached documents, to revise the specifications for the following
substance constituting material categories (materials specified by the Cabinet Order under
Article 18 (3) of the Food Sanitation Act) of utensils, containers, and packaging pursuant to the
provisions of Article 18 (1) of the Act.

(Substance name and the revised draft specifications and standards)

Notes:

1. Use JIS A4 paper or its equivalent.
2. Use ink and block letters.
3. If the requester resides overseas, specify the contact address and number in Japan.

The requester may provide a signature instead of affixing a seal.

Withdrawal

Date

To: Minister of Health, Labour and Welfare

Address (address of main office for corporation)

Name (corporate name and corporation representative name for) [Seal]

Request for Withdrawing the Establishment or Revision of Specifications in Appended Table 1
of Standards and Regulations of Foods, Food Additives, Etc.

I hereby withdraw the request below to establish or revise specifications for the following
substance constituting material categories (materials specified by the Cabinet Order under
Article 18 (3) of the Food Sanitation Act) of utensils, containers, and packaging pursuant to the
provisions of Article 18 (1) of the Act.

(Substance name)

(Date of request)

(Reason for withdrawal)

Notes:

1. Use JIS A4 paper or its equivalent.
2. Use ink and block letters.
3. If the requester resides overseas, specify the contact address and number in Japan.

The requester may provide a signature instead of affixing a seal.