

# The standard period of time required to designate food additives

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

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This document is the English translation of “食品添加物の指定等手続に係る標準的事務処理期間の設定について” The Ministry of Health, Labour and Welfare offers this translation as a service to a broad international audience/readers. While the ministry has attempted to obtain translation that is as faithful as possible to the Japanese version, we recognize that the translated version may not be as precise, clear, or complete as the original version. The official version of this document is the Japanese version.

## **The standard period of time required to designate food additives**

In designation of food additives, the Food Safety Commission of Japan (FSC) assesses health effects of the additives on humans. The Ministry of Health, Labour and Welfare (MHLW) carries out various procedures for designation based on the assessment by the FSC. For additives for which applicants request designation, the MHLW has established the standard period of time required for processing from the time when the MHLW is notified by the FSC of the assessment results to the time when the designation or revision of standards is completed.

### 1. Target of notification

This notification targets applications from applicants for designation of food additives and the establishment and revision of specifications and standards for food additives.

### 2. Processing period

The standard period of time is one year from the date when the MHLW is notified by the FSC of the assessment results. The MHLW shall endeavor to complete the measure(s) (herein after the “designation of food additives, or the establishment or revision of specifications and standards” is referred to as “measure”) within this period.

### 3. The estimation of the period

The period mentioned in 2 does not include the period given below.

(1) When the Department of Environmental Health and Food Safety, MHLW, takes the measure(s) if the documents provided are not sufficient and applicants are requested to submit additional documents, the period required for the applicant to submit the documents

(2) If the documents provided are not sufficient to make decision as a result of deliberation of the Committee on Food Additives of the Food Sanitation Council established under the Pharmaceutical Affairs and the Food Sanitation Council and the Food Sanitation Council under the Pharmaceutical Affairs and the Food Sanitation Council, and applicants are requested to submit additional documents, the period required for the applicant to submit the documents