

■ *[Food Additives]* ■

1. Historical background

In 1947, then Ministry of Health and Welfare (the present Ministry of Health, Labour and Welfare (MHLW)) enacted the Food Sanitation Act (FSA) as the first comprehensive Act for food safety/hygiene, and introduced a positive list system for food additives. Under the system, only additives designated as safe by the Minister of Health, Labour and Welfare may be used in foods. Since 1947, all food additives have been regulated by this act. However, designation system had been applied only to chemically synthesized additives until 1995 when the FSA was amended. Currently, all types of additives are equally subject to the designation system, synthetic or natural origin, with some exceptions.

2. Definition

The FSA, in the first Chapter, defines "food additive" as

- (i) substances used in or on food in the process of manufacturing food, or
- (ii) substances used for the purpose of processing or preserving food.

Consequently, "food additive" includes both substances remaining in the final products, such as food colors and preservatives, and substances not remaining in the final products, such as microorganism control agents and filtration aids.

Regardless of whether they are from natural origin, all substances used for the above purposes are categorized as food additives in Japan

The scope of food additives referred to by the FSA is different from that defined by the Codex Alimentarius Commission (CAC). **The substances given below, which are not defined by the CAC as food additives, are all categorized as food additives in Japan.**

- (i) Processing aids,* like infiltration-supporting agents
- (ii) Vitamins, minerals, and amino acids
- (iii) Flavoring agents

* Processing aid means any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfill a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product (CAC, Procedural Manual, "Section I : Definitions for the purpose of the Codex Alimentarius")

3. Regulation

(1) Designated additives and Existing food additives

Food additives that are permitted for use in food in Japan are limited to those listed at the following URLs, excluding natural flavoring agents, and ordinary foods used as food additives.

Notice: ONLY SUBSTANCES LISTED BELOW are allowed to use for food additives such as coloring, preservative, sterilizing, and manufacturing agents in Japan (excluding Natural flavoring agents and ordinary foods used as food additives).

●Designated Additives

Designated additives are those designated by the Minister of Health, Labour and Welfare as substances that are unlikely to harm human health based on Article 10 of the FSA.

<http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/list-desin.add-x>

●Existing food additives.

Other than the designated additives, certain substances are permitted for use and distribution in Japan, as exception, without through the designation system as provide by the FSA for the reason that they are widely used in Japan and have a long history of consumption by humans. They are referred to as existing food additives and placed on the List of Existing Food Additives. This additive status was created in 1995 when the FSA was revised and all additives (not only chemically synthesized substances but also natural origin) came to be subject to the designation system.

<http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/list-exst.add>

●Standards for Use of Food Additives

Food additives with use standards (i.e., target foods and maximum use limits/residue limits) are shall meet these standards, when these substances are used.

<http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/standr.use>

(2) Other food additives

There are two substance categories that are exempted from the designation system: “natural flavoring agents” and “ordinary foods used as food additives.” Examples of additives coming under these categories are placed on following lists.

●Natural flavoring agents

These substances are natural products that are obtained from animals and plants and used for flavoring food.(e.g., vanilla flavoring and crab flavoring). The amount used is generally very little.

<http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/list-nat.flavors>

●Ordinary foods used as food additives

They are substance that are generally provided for eating or drinking as food and also used as food additives(e.g., strawberry juice and agar).

<http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/list-general.provd.add>

4. Application for designation of food additive or revision of standards

The designation of food additives and the revision of standards both require risk assessment by the Food Safety Commission of Japan (FSC) and review by the Ministry of Health, Labour and Welfare based on the risk assessment by the FSC.

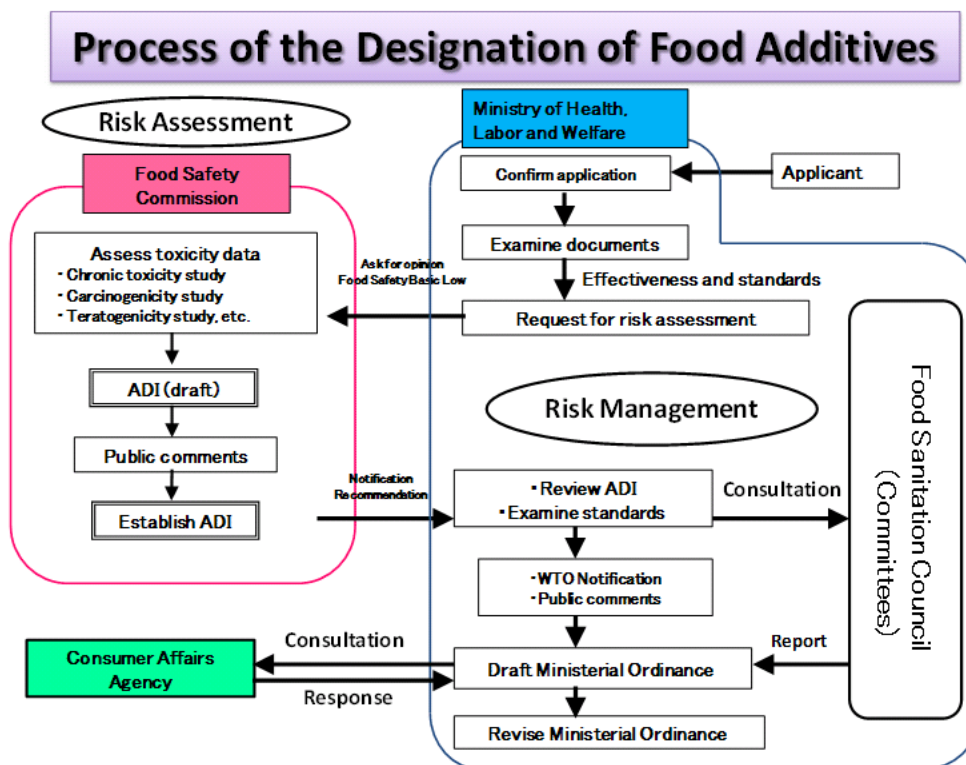
Documents required for risk assessment by the FSC are specified in the guidelines at

[http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/caopdf/\\$FILE/tenkabutu-hyouka-shishin.pdf](http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/caopdf/$FILE/tenkabutu-hyouka-shishin.pdf)

The English translation is available at

[http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/caopdf/\\$FILE/guideline%20en.pdf](http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/caopdf/$FILE/guideline%20en.pdf)

Notice: If the applicant lives overseas, he or she should establish a contact person in Japan for responsible handling of the application.



Standards and Evaluation Division
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