Guidance Information on Requirements for Food Additives

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Contents

1. What are Food Additives?

Food additives are chemical substances which are intentionally added to food, typically in very small known amounts, in order to serve specific technological functions. Food additives can be derived from both natural sources or artificially synthesised. However, they do not include foreign substances arising from contamination or improper handling of food.

In Singapore, additives must be assessed for safety before they can be used in food. The use of food additives in food must comply with the Food Regulations to ensure that:

a) they do not present any health risks to consumer
b) they are only used when there is a technological justification
c) their use does not mislead consumers, and

Only those food additives that have undergone the necessary risk assessments by SFA will be listed in the Food Regulations and permitted for use in food products.

2. Scope of this document

This guidance information aims to provide food traders / businesses with a better understanding of the requirements for use of food additives. It covers information on the:

a) functions of different types of food additives
b) food additives that are permitted for use in Singapore
c) procedure to submit an application to SFA to allow the use of new food additives.

Food traders/businesses are advised to refer to the Sale of Food Act and the Food Regulations for the actual legal text where necessary. The legislation can be downloaded from the following website:

- http://www.sfa.gov.sg/legislation [select Sale of Food Act 1973 > Food Regulations]

3. Types of Food Additives and their Technological Functions

Food additive category	Technological Functions	Relevant Regulations	Examples
Anti-caking agent	• Prevents caking of powdered food such as salt	Regulation 16	silicon dioxide, magnesium stearate
Anti-foaming agent	• Prevents or reduces foaming of food	Regulation 16A	dimethyl polysiloxane

Anti-oxidant	• Delays, retards or prevents the development of rancidity or other flavour deterioration in food due to oxidation	Regulation 17, Third Schedule	butylated hydroxyanisole (B.H.T.), erythorbic acid
Sweetening agent	• Non-sugar, non-carbohydrate and non-polyhydric alcohol compounds that impart a sweet taste to food	Regulation 18, Thirteenth Schedule	steviol glycosides, saccharin,
Chemical preservative	• Inhibits, retards or arrests the process of fermentation, acidification or other deterioration of food caused by micro-organisms • Classified as “Class I”, “Class II”, “Class III” and “Class IV” in the Food Regulations	Regulation 19, Fourth Schedule	sorbic acid, sulphur dioxide
Colouring matter	• Imparts colour to food • Can be natural or synthetic	Regulation 20, Fifth Schedule	red cabbage colour, tartrazine,
Emulsifier or stabiliser	• Emulsifiers aid the formation of dispersion of 2 or more immiscible substances (e.g. oil in water) • Stabilisers maintain the uniform dispersion of 2 or more immiscible substances	Regulation 21, Sixth Schedule	xanthan gum, mono- and di-glycerides of fatty acids
Flavouring agent	• Imparts taste or odour, or both, to food • Can be natural or synthetic	Regulation 22	vanillin, lemonol
Flavour enhancer	• Enhances or improves the flavour of food	Regulation 23	L-glutamic acid, ethyl maltol
Humectant	• Absorbs moisture and maintains the water content of food	Regulation 24	glycerine, sorbitol
Nutrient supplement	• Any amino acid, mineral or vitamin which improves or enriches the nutrient content of food	Regulation 25, Seventh Schedule	vitamin A, magnesium carbonate

Sequestrant	• Stabilises certain characteristics (e.g, colour, flavour and texture) associated with the food by combining with metal ions in food, thereby rendering the metal ions inactive	Regulation 26	citric acid, calcium disodium EDTA
Gaseous packaging agents	• Function as aerating agents or propellant of fluid food • Displaces air in sealed packages of food	Regulation 27	carbon dioxide, nitrogen
Pathogen reduction treatment	• Any antimicrobial substance that, when applied on food, reduces the food's microbial load	Regulation 27A, Seventeenth Schedule	calcium hypochlorite, lactoferrin
General purpose food additive	• Any substance which serves a useful and specific purpose during either the processing or packing of a food and includes processing aid.	Regulation 28, Eighth Schedule	sodium carbonate, catalase

4. Understanding the food additive requirements in the Food Regulations

The sale of food products in Singapore is governed by the Sale of Food Act and the Food Regulations. Food additives that are permitted for use in Singapore are listed in the Food Regulations. Under Regulation 15(2) and 15(4) of the Food Regulations, food additives used in food must comply with their respective specifications as recommended by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), an independent scientific expert committee which performs risk assessments and evaluates the safety of food additives in food. The JECFA provides advice to FAO, WHO and the Codex Alimentarius Commission.

Provisions for food additives can be found under the following parts of the Food Regulations:

a) Regulations 15 to 28 – These regulations stipulate the different types of food additives that are permitted under the Food Regulations, and where specified, conditions for their use. You may refer to the section of this Guidance Information titled "Types of food additives and their functions" for more information on the technological functions of each food additive type category.

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b) Third and Fourth Schedules - Food additives listed under these 2 Schedules are only permitted for use in those food categories listed in these Schedules, and up to the maximum levels stipulated therein.

c) Fifth, Sixth and Eighth Schedules - Food additives listed under these Schedules may be used under Good Manufacturing Practice in food products unless prohibited by individual food standards. 'Good Manufacturing Practice' means that the quantity of the additive added to food shall be limited to the lowest possible level necessary to accomplish its desired effect.

d) Seventh Schedule – This Schedule lists the permitted nutrient supplements for use in food. These nutrient supplements may be added to foods at levels that are safe and suitable for the target group of consumers, and must comply with the requirements stated under Regulation 11(4) pertaining to the addition of vitamins and minerals to food. Nutrient supplements that are added to infant formula must comply with the requirements stated in Regulation 252.

e) Seventeenth Schedule – This Schedule lists the permitted pathogen reduction treatment for use in meat and specifies the maximum use levels for the type of meat.

You may find more information on the list of permitted food additives and their regulatory limits from SFA's website. Food traders may also make use of the search tool available on SFA's website to check whether a particular food additive is permitted for use in food.

- https://www.sfa.gov.sg/regulatory-standards-frameworks-guidelines/food-safety-regulatory-limits/regulatory-limits-for-food-additives

5. General information for the assessment of new food additives

SFA evaluates the safety of new food additives in accordance with the Codex general principles for the use of food additives. Only food additives that have been assessed and approved by SFA, and included in the Food Regulations are allowed for use in food in Singapore. Levels of permitted food additives used must be within the maximum levels specified under the Food Regulations.

Applicants should provide the following information for SFA's review:

a) Information on the identity of the food additive.

- Chemical name, structural formula, common name and synonyms. For a new food additive, a common name should be proposed. For additives that are not single chemicals, the name should describe the additive as completely as possible. The sources of the additive should be provided, together with sufficient compositional data to accurately identify the additive.

b) Information on the purity of the food additive

- Demonstrate that the additive conforms to the specifications recommended by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The specifications for each food additive can be found using the search tool available on the JECFA website:http://www.fao.org/food/food-safety-quality/scientificadvice/jecfa/jecfa-additives/en/

- In the absence of JECFA specifications, specifications and purity criteria published in the British Pharmacopoeia (http://www.pharmacopoeia.co.uk/), European Pharmacopoeia (http://www.edqm.eu/) or the Food Chemical Codex (http://www.usp.org/) may be considered.

c) Information on the technological function of the food additive.

- Reasons why the food additive is needed to fulfil the technological function in each of the foods in which it is proposed to be used in f).
- Evidence that the amounts proposed to be added are consistent with achieving the technological function.

d) Information related to the manufacturing process

- This includes a production flow chart, including clear description of the risk monitoring and mitigation steps that have been established.

e) Information related to the analytical method for detection

- An analytical method for detecting and quantifying the additive, or its degradation products, in the foods in which it will be used. This includes information on available methodology for detecting and quantifying the additive, or its degradation products, in the foods in which it will be used.

f) Information related to the dietary exposure to the food additive

- Proposed list of food groups which will be added with the new food additive
- The maximum intended use levels and typical use levels of the food additive for each food group
- For additives accepted for use by the Codex Alimentarius Commission (CAC), the maximum use levels recommended in the Codex General Standard for Food Additives (CXS 192-1995) can be used as reference.
- When an additive has not been evaluated by JECFA, nor accepted for use by CAC, information from major developed countries such as Australia, Canada, the European Union (EU), New Zealand, Japan and the United States may be considered.
- Information on the likely consumption levels of the food additive. Consumption data used for exposure assessments should accurately reflect the groups of consumers in Singapore that would be expected to consume the food additive

under your intended use conditions. Data can be obtained from the National Nutrition Survey conducted by the Health Promotion Board. Alternatively, you can estimate the dietary exposure based on the latest food consumption data available in Singapore's Total Diet Study (2021-2023), under supplementary material (Table S4). The following publication by the US FDA may also serve as a useful reference to determine the approach taken for estimating consumption data: US FDA Guidance for Industry: Estimating Dietary Intake of Substances in Food [1].

g) Information related to the safety of the food additive

- To include safety assessment of the food additive conducted by JECFA or food safety authorities of major developed countries
- When the above safety evaluations are unavailable, relevant published scientific information such as toxicity studies and human clinical trials may be considered. Substances that are both genotoxic and carcinogenic would generally not be considered acceptable for use as food additives
- For new additives, the following safety information will be considered:
    i. Toxicokinetic and metabolism of the food additive and, if necessary, its degradation products or major metabolites
        - This includes detailed reports of studies conducted in animals or humans to examine the metabolic fate of the food additive and, if necessary, its degradation products or major metabolites
    ii. Toxicity of the food additive and, if necessary, its degradation products and major metabolites. This includes reports of all in vitro and in vivo studies conducted in animals or humans to examine the toxicity of the food additive and, if necessary, its metabolites or degradation products. Toxicity studies should address the following:
        - acute toxicity
        - short-term toxicity
        - long-term toxicity and carcinogenicity
        - reproductive toxicity
        - developmental toxicity
        - genotoxicity
        - special studies, such as neurotoxicity or immunotoxicity

h) Information relating to the use of the food additive in other countries, if applicable

- International recommendations on the foods and use levels in which the food additive is accepted (e.g. relevant Codex standards) and/or regulatory approvals in major developed countries (Australia, Canada, New Zealand, Japan, the European Union and the United States of America).

For a request to extend the use of a currently permitted food additive, SFA will need to assess information including, but not limited to, the technological function of the food additive in the proposed new food categories, information related to the dietary exposure to the food additive and information relating to the use of the food additive in other countries.

6. Information related to the assessment of new food additives derived from precision fermentation

- For new food additives derived from precision fermentation, please refer to section 6 of the safety assessment requirements for novel food ingredients produced through precision fermentation here.

7. How to declare the presence of food additives on food labels

- All ingredients and additives used in food products have to be declared under the statement of ingredients on food labels in descending order of the proportion by weight in which they are present.
- For more information on general labelling requirements and declaration of food additives, SFA has also made available a 'Guide to Food Labelling and Advertisement' which can be downloaded from the SFA website. https://www.sfa.gov.sg/regulatory-standards-frameworks-guidelines/food-labelling-packaging-guidelines/labelling-requirements-for-food

8. Frequently asked questions related to food additive assessments

- **Is the dossier and safety information shared with SFA kept confidential?**
  Confidential information submitted by companies are kept confidential and will not be shared outside of SFA. In any event where information is required to be shared with external parties, SFA will first seek companies' consent.

- **How can a company request for a new food additive to be assessed and included in the legislations?**
  Companies may submit their request to SFA either directly or through service providers such as regulatory consultants or law firms.

- **Is there a specific format for the food additive assessment?**
  Companies are required to submit an organised dossier containing the safety narratives based on SFA's requirements in a single PDF document. Supporting documents, such as CoAs, analysis reports, and large data sets, can be sent in separate files.

- **Can SFA share what requirements are needed for testing of food additives?**
  There is no one-size-fits-all approach to the testing of food additives and companies should adopt effective testing strategies based on their understanding of the hazards that may be present in the food additive.

  Useful resources include but are not limited to the official testing methods for chemical and microbiological hazards listed under the Official Methods of Analysis published by the Association of Official Agricultural Chemists (AOAC), Pharmacopoeia methods (e.g. British Pharmacopoeia, European Pharmacopoeia), and international guidelines such as those published by the Organisation for Economic Co-operation and Development (OECD)

  For determination of approach for toxicity testing, the following publications may serve as useful references:
  - US FDA Guidance for Industry and Other Stakeholders, Redbook 2000 Toxicological Principles for the Safety Assessment of Food Ingredients [2]
  - US FDA Guidance for Industry: Summary Table of Recommended Toxicological Testing for Additives Used in Food [3]
  - EFSA Guidance for submission for food additive evaluations [4]
  - FAO/WHO Environmental Health Criteria 240 - Principles and Methods for the Risk Assessment of Chemicals in Food [5]

- **Why does SFA consider information on specification and purity when evaluating new additives?**
  Specifications of identity and purity are necessary in safety assessments for food additives. Evaluations of food additives by JECFA depend on studies performed with a chemical substance or product of defined identity, purity and physical form. The safety assessment is valid only for products that do not differ significantly in identity and quality profile from the material used to generate the data used in the evaluation.

- **How many batches are required to be tested to generate the data needed to provide product specifications?**
  SFA does not prescribe a specific requirement for the number of batches to be tested. Submissions will be considered if the companies have demonstrated that the study design is statistically sound. Nevertheless, we observe that companies typically provide data from 3 or 5 non-consecutive batches of the end-product as an indication of reproducibility. The end-product for which data is generated on should be produced at a scale that is representative of the eventual manufacturing scale. If significant changes to the inputs and/or processes are required during scaling up, it may affect the validity of the original assessment submitted to SFA.

- **What is the regulatory pathway for food additives derived from precision fermentation?**
  In Singapore, food additives derived from precision fermentation must also be assessed and approved by SFA, and included in the Food Regulations before they can be added to food. Levels of permitted food additives used must not exceed the maximum levels specified under the Food Regulations. The requirements for the safety assessment of new food additives derived from precision fermentation are found in section 6 of the safety assessment requirements for novel food ingredients produced through precision fermentation.

- **How long is the review process?**
  SFA estimates that the review process to take about 9-12 months. However, this timeline assumes that the safety assessment dossier is complete with no further need for questions or clarifications from SFA. As this is typically not the case, it is important for companies to engage in pre-submission consultations with SFA.

- **How much is the review fee?**
  SFA does not charge any fees for the review of new food additives.

For further clarifications, please submit enquiries electronically via the online feedback form: https://csp.sfa.gov.sg/feedback

9. References

[1] US FDA. (2006). *Guidance for Industry: Estimating Dietary Intake of Substances in Food.*

[2] US FDA. (2006). *Guidance for Industry: Summary Table of Recommended Toxicological Testing for Additives Used in Food | FDA.*

[3] US FDA. (2007). *Guidance for Industry and Other Stakeholders: Redbook 2000 Toxicological Principles for the Safety Assessment of Food Ingredients*. Maryland: US FDA.

[4] EFSA. (2012). Guidance for submission for food additive evaluations. *EFSA Journal, 10*(7). https://doi.org/10.2903/j.efsa.2012.2760

[5] FAO, WHO. (2009). *Principles and methods for the risk assessment of chemicals in food*. Geneva: WHO Press.

10. Revision history

1. 19 January 2026 – Updated to reflect new technological function included in the Food Regulations, to include general information related to the assessment of new food additive and new additive derived from precision fermentation, and to include FAQs