

Requirements for the Safety Assessment of Novel Foods

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Introduction

1. This document aims to provide food businesses with a better understanding on SFA's requirements regarding the safety assessment for novel foods.
 - i. Food businesses that intend to produce, import, and sell novel foods are required to conduct and submit safety assessments of their products for SFA's review before they are allowed for sale.
 - ii. Food businesses' safety assessments must show that inputs going into the production as well as the manufacturing process and controls will yield a food product which poses no food safety concern and which complies with food safety standards in the Food Regulations.
2. As novel food is a rapidly evolving area, SFA will periodically update and revise this document to facilitate the safety assessments by industry and ensure food safety.

What are novel foods?

3. SFA considers novel foods to be foods and food ingredients that do not have a history of safe use. A history of safe use is defined as substances that have been consumed as an ongoing part of the diet by a significant human population, for a period of at least 20 years and without reported adverse human health effects. Food and food ingredients which are shown to have history of safe use will not be considered to be novel foods. Novel foods may also include compounds that are chemically identical to naturally-occurring substances, but produced through advances in technology.
4. When assessing whether a substance has a history of safe use, SFA will take into consideration the following information:
 - (i) the length of consumption / use of the ingredient (i.e. how many years the ingredient has been consumed as food or used in food).
 - (ii) extent of use of the ingredient (i.e. whether the ingredient is consumed or used by the general population, sub-population, certain tribes, etc).
 - (iii) quantity (i.e. the level of the ingredient consumed as food or used in food).
 - (iv) purpose/context of use (i.e. whether the ingredient is used for ceremonial purposes such as weddings, during famines, etc).

- (v) evidence demonstrating lack of adverse effects to human health attributed to the substance during the specific period of use as food.

5. Information sources that will be considered include scientific/non-scientific publications, books (e.g. cookbooks, books on the history of food culture), patents, affidavits from two or more independent, reputable authorities, etc. History of use as medicine/ alternative medicine, or short term exposure (e.g. for ceremonial use, during famines, etc.) is insufficient evidence to demonstrate history of safe use as food.

6. When in doubt, food businesses may consult SFA to discuss the available evidence on the history of safe use that they have compiled.

Safety assessment criteria for novel foods

7. Substances that do not have a history of safe use will be considered to be novel foods. Food businesses that intend to use novel foods are required to submit an application to SFA by providing the following information in a safety assessment for SFA's review.

(a) For novel food and food ingredients in general

- (i) Information on the identity and purity of the novel food, including, percentages of major components and impurities present.
- (ii) Information on the novel food's manufacturing process, and inputs used.
- (iii) Intended use and proposed use levels in food. Novel foods which are intended for consumption by specific population groups should be indicated.
- (iv) Toxicity studies (*in-vitro* and *in-vivo*), where relevant. This includes acute, short-term and long-term toxicity studies, carcinogenicity studies, reproductive toxicity studies, developmental toxicity studies and genotoxicity studies.
- (v) Metabolism or toxicokinetics studies, where relevant. These includes absorption, distribution, metabolism and excretion (ADME) studies.
- (vi) Any safety assessment reports conducted by food safety authorities in major developed countries (Australia, Canada, New Zealand, Japan, the European Union and the United States of America)

8. In general, studies referenced in safety assessments should be published in reputable scientific journals. Unpublished studies may be considered if they have been conducted according to Good Laboratory Practice and other relevant guidelines established internationally (such as OECD guidelines).

9. Safety assessments that have been conducted in accordance to the following reference documents published by the US FDA, European Food Safety Authority (EFSA), and FAO/WHO, would be accepted for review.

- US FDA Guidance for Industry and Other Stakeholders Toxicological Principles for the Safety Assessment of Food Ingredients, Redbook 2000
- EFSA Guidance for submission for food additive evaluations
- FAO/WHO Environmental Health Criteria 240 - Principles and Methods for the Risk Assessment of Chemicals in Food

(b) For novel foods that are chemically identical to naturally-occurring substances but produced by unconventional processes

10. For novel food ingredients that are produced via unconventional processes but are chemically identical to naturally-occurring substances found in food, a full safety assessment involving submission of the full set of toxicity studies would not be required. For these ingredients, the following information are to be submitted for safety assessment:

- (i) Information to demonstrate that the ingredient is chemically identical to its naturally-occurring counterpart.
- (ii) Purity information including identity and levels of any impurities (e.g. contaminants, toxins, etc) present.
- (iii) Manufacturing process of the ingredient, including identities and safety of solvents used and any by-products or metabolites produced.

11. In addition, if the novel food ingredients are produced from a genetically modified microorganism, the following information should also be submitted for safety assessment:

- (iv) Safety information of the production strain (e.g. whether genes are known to produce toxins, any toxins produced, etc).
- (v) Allergenicity of the ingredient and residual impurities (if present).

(c) For cultured meat

12. Cultured meat refers to meat developed from animal cell culture. The process to produce cultured meat involves growing the selected cell lines (or stem cells) in a bioreactor. The cells are grown in a suitable growth media, and subsequently onto a “scaffold” to produce products resembling meat muscle.

13. SFA notes that the science for producing cultured meat is still at an early stage. SFA currently requires the following information to be submitted for the safety assessment of cultured meat. Information required may change based on the developments on the science of producing cultured meat.

- (i) A description of the overall manufacturing process.
- (ii) Characterisation of the cultured meat product, including nutritional composition, and comparison of residual growth factors against levels in published literature.
- (iii) Information related to the cell lines used, including:
 - a. Identity and source of cell lines.
 - b. Description of methods used for selection and screening of cells.
 - c. Information on how the cell lines are prepared and banked following their extraction from animals.
 - d. Description of the modifications and adaptations made to the cell lines, and how these relate to the expression of substances that may result in food safety risk.
- (iv) Information related to the culture media used, including:
 - a. Composition of media, including identities and purity of all added substances. Companies should indicate whether the purity of individual substances used in culture media comply with specifications recommended by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, British Pharmacopoeia, European Pharmacopoeia or Food Chemical Codex).
 - b. Clarification on whether the culture media remains in the finished cultured meat product, or is removed completely. Where culture media is removed completely, companies should provide information demonstrating removal.
- (v) Information related to the scaffolding materials, if used, including:
 - a. Identities and purity of scaffolding materials used.
- (vi) Information on how the purity and genetic stability of cell culture is ensured during the manufacturing process.
 - a. Where genetic differences between starter cell lines and finished cultured meat are observed, companies should investigate the differences to determine whether these would result in food safety risks (e.g. upregulation of metabolite production).
- (vii) Safety assessment covering possible hazards arising from the manufacturing of the cultured meat.
- (viii) Other relevant studies to support safety such as digestibility assays, allergen profiling, genetic sequencing, etc.

Information related to the application process for novel foods

14. SFA does not charge any fees for the evaluation of applications for the use of novel foods. SFA estimates a timeline of between 3-6 months to complete an evaluation of a novel food. In order to avoid delays, food businesses are encouraged

to consult SFA early in their product development process to understand the information that would be required to be submitted in order to substantiate the safety of their novel food.

Contact information

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

Revision History

1. 22 November 2019 – First version
2. 23 November 2020 - Updated language for clarity