

# A Guide to Apply for the Approval of Novel Foods

## Scope & Purpose

This guide is concerned with the information needed to obtain SFDA approval for handling novel and traditional foods as laid out in SFDA FD 5031:2020 “*the General Requirements for Novel Foods*”.

**To apply for the approval of a novel food, the following application requirements must be met:**

### Requirements and application format

- A comprehensive table of contents.
- Company Address/ contact information of company representative.
- If the applicants have previously applied to one or more foreign international authorities to obtain approval for the concerned novel food, they must show the assessment status, and dates of these applications, the justifications and instructions for use, along with a copy of the scientific opinion issued by these bodies.

### Novel Food Description and Associated Scientific and Technical Information:

The description of novel foods and associated scientific and technical information must include the following:

- A prelude containing a brief description of the novel food, its source, scientific principles and stages for production, compositional characteristics and intended use.
- The identity of the novel food.
- A detailed production process.
- The accredited methods of chemical analysis.

### General Requirements:

- TDS (Technical Data Sheet)
- Compositional Information on single substances and simple mixtures.
- Definition of complex mixtures and whole foods, in addition to a detailed quantitative and qualitative description of the main components.
- Product characteristics, including information on the limits and precise method for:
  - ❖ Reporting the analyses of disease-causing microorganisms.
  - ❖ Reporting heavy metal analyses.
  - ❖ Reporting pesticide analyses.
  - ❖ Identifying biological or nutritional active ingredients.
  - ❖ Concentrations of food components.

- Consumption durability period for the novel food or its source.
- Proposed method of consumption, intended consumption levels, and target populations.
- Estimated nutritional value shared by novel food and other sources.
- Estimated dietary exposure likely to be present in the novel food.
- Clearly stated precautions and restrictions of use (if applicable), indicating target populations, and vulnerable groups supported by scientific evidence.
- ADME (absorption, distribution, metabolism and excretion) Studies and data.
- A summary of the toxicological and human consumption studies conducted on the novel food to have an all-round picture of how such data, along with the above information, support food safety considerations in light of the intended and proposed use.

#### **Application Requirements for Traditional Foods from Countries other than Saudi Arabia**

- Compositional Data.
- The experience of continued use in other countries
- Suggested use for the Saudi market.
- Attachments including:
  - The glossary or abbreviations of terms quoted throughout the dossier.
  - The certificates (on the accreditation of laboratories, certificates of analyses).
  - Full copies/ reprints of all pertinent scientific data (published and unpublished).
  - Full study reports.
  - Scientific opinions of national/international regulatory bodies.

*Disclaimer: The English version is a translation of the original in Arabic for information purposes only. In case of a discrepancy, the Arabic original will prevail.*