Center of Excellence
Global Food and Food Supplements
Regulatory Services

Regulatory Route for Novel Foods globally and challenges with India FSSAI process

By Sakshi Grover, Manager, Strategic Services, Freyr Solutions

Date : October 30, 2021

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Global Food Trends

- The Statistics show that four in 10 consumers closely monitor what they eat
- 43% try to eat healthy but don’t pay close attention & 9% claim to be on a strict diet
- According to a survey, about 68 per cent of respondents from India agreed with the statement that they eat a healthy diet
- Globally, Natural Healthy food sales were $259 billion in February 2020
- India's nutraceutical market was worth 260 billion Indian rupees in 2017. This was estimated to go up to 650 billion rupees by 2022, indicating a high growth potential in the sector
- Growth in Consumer awareness of a healthy diet has given industries an opportunity to come up with new food trends and processes
- As the market size grows, so does the increase in innovations in food science leading to healthier diet globally

A Brief Outlook on the Global Novel Foods Approvals

Globalization of food supply and the rapid advances in technology have brought a new wave of Novel Foods development across the markets. Most of the countries have already put a system in place to evaluate and assess these new foods.

- In Canada, Novel Foods are subjected to safety assessments, under the Food and Drugs Act and Regulations and all Novel Foods must be assessed by Health Canada before they can be sold in Canada
- In the US, all the new dietary ingredients require pre-market approval from the FDA
- Even in the EU, EFSA has a centralized assessment and authorization procedure for scientific risk assessment of all Novel Foods
- The regulation of Novel Foods and ingredients in China are regulated according to the Administrative Measures for Safety Review of New Food Materials (2013). Pre-market approval of Novel Food materials is conducted by the National Health and Family Planning Commission (NHFPC)
- Novel Foods in Australia/New Zealand are regulated under the Food Standards Code, specifically Standard 1.5.1, by Food Standards Australia/New Zealand (FSANZ)
- In India, FSSAI came up with a new regulation in 2017, laying down the rules and procedures for grant of approval to non-specified foods/food ingredients and this covers Novel Foods as well

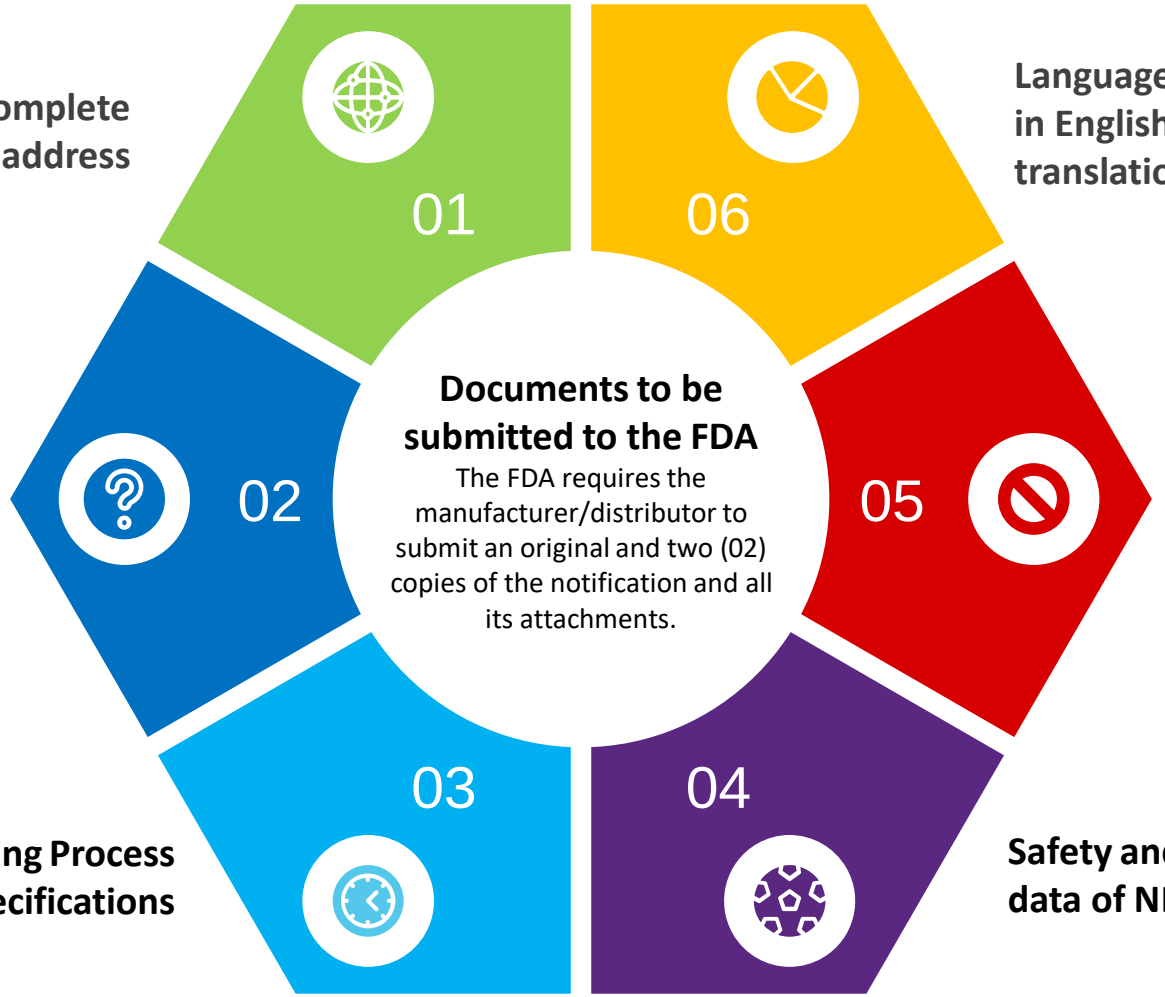
New Dietary Ingredient Registration in USA

The term "new dietary ingredient" means **a dietary ingredient that was not marketed in the United States as a dietary supplement before October** 15, 1994.

A manufacturer/distributor planning to market a dietary supplement that contains a new dietary ingredient:

- Must submit a NDIN to the FDA at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce
- Must submit detailed information based on which they have concluded that the dietary supplement containing the new dietary ingredient is expected to be safe

Documents to be Submitted



Novel Food Approval Process in EU

A novel food is defined as ‘foods and food ingredients that have not been used for human consumption to a significant degree in the EU before 15 May 1997’ as defined by Regulation (EU) 2015/2283.

Novel foods have to be authorized in the Novel Foods Catalogue before being permitted for sale in the EU. Such foods are subject to a pre-market safety assessment before a decision is made on EU-wide authorization.

The Regulation requires that all applications for the authorization of novel foods shall be submitted to the Commission who may then request a risk assessment from the European Food Safety Authority (EFSA). In assessing the safety of novel foods, EFSA shall, where appropriate, consider the following:

1. Whether the novel food concerned is as safe as food from a comparable food category already existing on the market within the Union;
2. Whether the composition of the novel food and the conditions of its use does not pose a safety risk to human health in the Union;
3. A novel food, which is intended to replace another food, does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

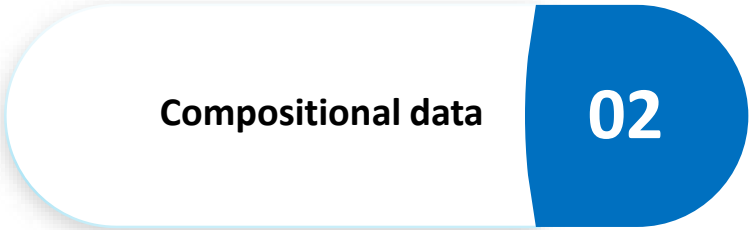
Novel Food Approval Process in EU

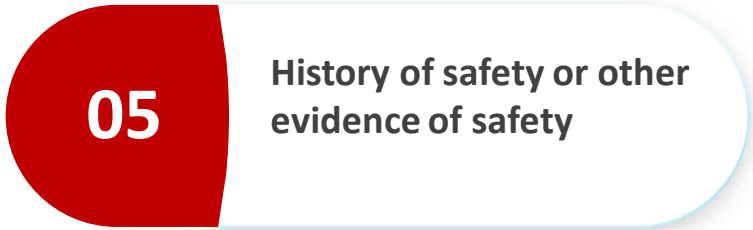
Regulatory Pathway

Before a new novel food can be marketed, it must be subjected to a pre-market safety assessment before a decision is made on EU-wide authorization. The ultimate aim of the assessment is to make sure the food is safe. During this:

1. The applicant must prepare a dossier on the new novel food, providing the information needed so the European Food Standards Agency can carry out a safety assessment.
2. The applicant must submit the dossier to the European Commission. Submission occurs via the e-submission system for Novel Foods.
3. The European Commission must verify the validity of the dossier within 30 days.
4. The dossier and novel food is subject to a risk assessment by the European Food Safety Authority over a 9-month period which can be extended if further information is required.
5. An opinion on the novel food is formed if no further information is needed.
6. The Commission have 7 months from a positive opinion to draft an implementing decision to update the Union List of novel foods which consist of a specification and conditions of use.
7. The food is added to the Union list of Novel foods, which means it can now be market in the EU.

Documents to be Submitted





Novel Food Registration in Singapore

Regulatory pathway

Novel food is food that

(a) was not used for human consumption by a significant population in Singapore or by a significant population in a region outside Singapore before 1 January 1997; and

(b) is from an unconventional food source or is prepared by an unconventional process.

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 that are shown to have a 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.

Current regulatory approach: All members of the local food industry are responsible for ensuring that any novel foods and novel food ingredients imported / manufactured and sold in Singapore are safe for consumption. AVA currently works closely with the industry members on a one-to-one basis in verifying the safety of such novel foods and novel food ingredients. Novel foods and novel food ingredients which have been assessed to be safe would also be listed in the legislation, which is openly available to all members of the food industry.

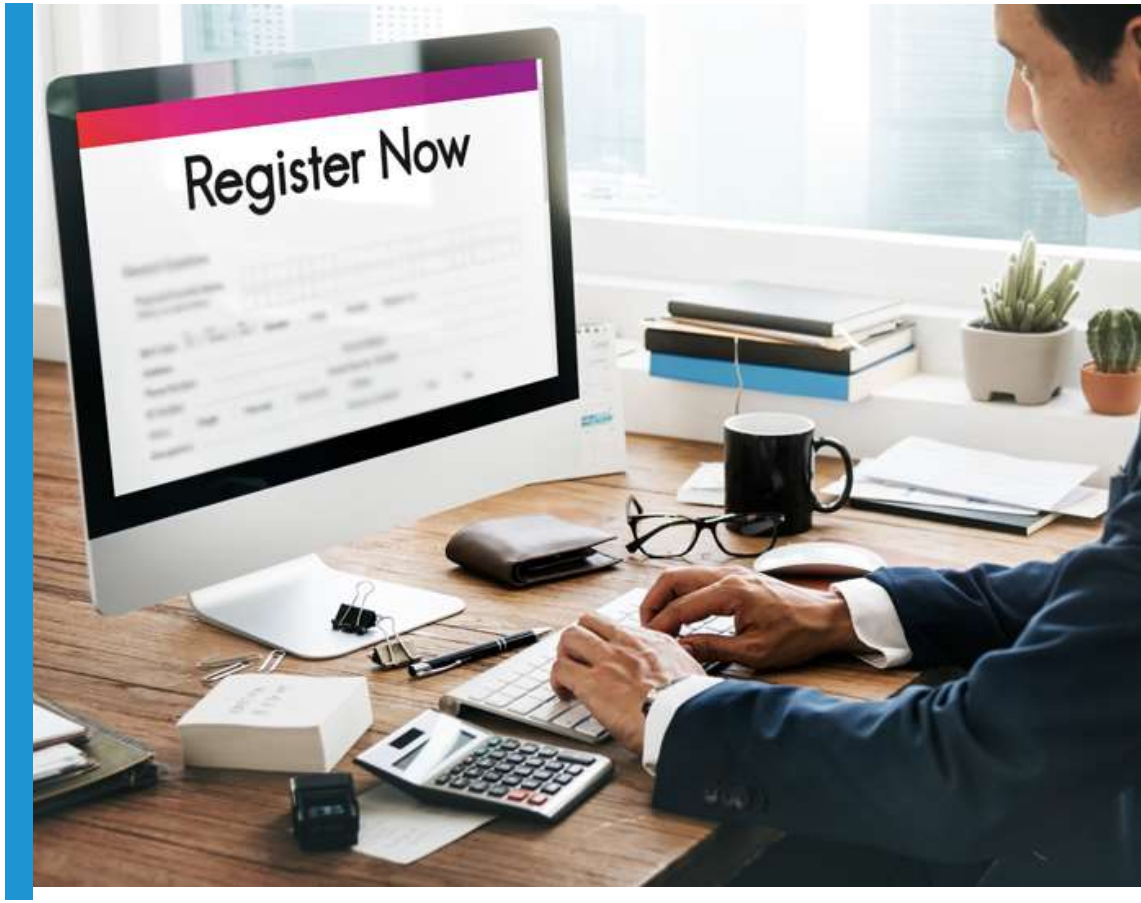
Novel Food Registration in Singapore

Food traders who intend to use novel foods should submit an application to SFA by providing the following information in a safety assessment for SFA's review.

Safety assessments that have been conducted in accordance with 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

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 novel food. In order to avoid delays, food traders 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.



Novel Food Approval in Canada

Regulatory Pathway

A novel food is :

- a substance, including a microorganism (a living thing so small you need a microscope to see it), that does not yet have a history of safe use as a food
- a food that has been manufactured, prepared, preserved or packaged by a process that:
- has not been previously used for that food, and
- causes the food to undergo a major change
- a food that comes from a plant, animal or microorganism that has been genetically modified so that the plant, animal or microorganism:
- shows characteristics that it didn't before
- doesn't show characteristics that it did before
- has 1 or more characteristic that no longer fall within the expected range

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Submission of a Novel Food Notification	• Notification shall be signed by the manufacturer or importer, or a person authorized to sign on behalf of the manufacturer or importer • **Screening period:** Within 45 days after receiving a notification the Director shall review the information. If any additional information is submitted, within 90 days after receiving the additional information, the Director shall notify the manufacturer or importer in writing that the information is sufficient • Three copies of this notification should be sent to the Food Directorate's Submission Management and Information Unit
Submission of a Safety Assessment Data Package	• If the information provided in the notification for a novel food is not considered adequate to determine the novel food's safety, additional data supporting the safety of the food will be required.
When to apply	• Written notification should be provided as far in advance as possible of the period when the manufacturer intends to market the product.
Where to apply	• Notifications and safety assessment data packages should be addressed to: • Submission Management and Information Unit, Food Directorate, Health Products and Food Branch, Health Canada. • Sir Frederick G. Banting Research Centre, Room E222, 251 Sir Frederick G. Banting Driveway, Tunney's Pasture, PL 2202E • Ottawa, Ontario.
Standard Operation Procedure	• The Novel Foods Section distributes the submission material to relevant Food Directorate bureaux, namely the Bureau of Chemical Safety for evaluation of chemical and toxicological considerations, the Bureau of Nutritional Sciences for nutritional considerations, and the Bureau of Microbial Hazards for microbial and molecular biological aspects of the files.

Challenges with FSSAI Process

Ambiguity in regulations and various categories have been clubbed under NSF

Longer time to hear back on the applications

For novel foods and new ingredients, safety data on Indian population is mandatory

Various manufacturers /importers of same ingredient which has already received approval, have to still apply for approval to FSSAI until the same is included in the regulations

Limited guidance available on dossier requirements

International manufacturers cannot apply without a local importer

Key Differentiators

- **Novel foods are altogether a different category in all countries and are different from non specified foods**
- **Some countries do not require publicly available safety documentation**
- **Shorter timeframe for Authority's response i.e., 60 - 75 days**
- **Less burden to establish safety**
- **Well established systems**
- **Guidance documents available on Authority portals for step by step process**

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+1 908 483 7958

sales@freyrsolutions.com

https://foodsupplements.freyrsolutions.com

Freyr Locations

USA
+1 908 483 7958

UK
+44 2037 0123 79

Germany
+49 618 170 79007

UAE
+1 908 483 7958

India
+91 40 4848 0999

Canada
+1 778 308 4671

Malaysia
+603 9212 5527

Mexico
+52 554 161 3365

South Africa
+27 105 002 556

Singapore
+65 315 894 72

Slovenia
+386 360 004 05

Sri Lanka
+1 908 483 7958

Australia
+61 2 8607 5105

Poland
+49 618 170 79007

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