NOVEL FOOD

What are necessary for pre-market approval?

Novel foods, being foods that have not been consumed by a population, often before a certain time, can vary from market to market, hence regulation for novel foods can differ in various countries across Asia. Food safety has been one of the main concerns for novel food, and to bring in new and innovative foods or ingredients into a specific market, companies are obliged to comply with the local regulations. Pertaining to the import of novel food and ingredient, companies would need to ensure that application for the approval of novel food is carried out accordingly to ensure successful entry of products into respective markets. This report aims to help companies understand the relevant documents and details required to apply for the approval of novel food ingredients.

ASIA AT A GLANCE

Regulatory Status	Countries
Novel Food Regulation Implemented	
Novel Food Regulation in Drafting Stage	
No Regulation on Novel Food	

INTRODUCTION

Beyond Asia, novel food is regulated in Australia and New Zealand, Canada, European Union (EU) and the United States of America (USA). Sometimes, the regulation on novel food makes reference with these countries. In Asia, novel food regulations is becoming increasingly looked at, and countries are developing their own novel food regulations. In 2018, Singapore become the 8th country in Asia to start developing novel food regulations. While novel food varies across different markets, the mechanism and pre-market assessment dossiers could be harmonised to allow for trade facilitation. The report looks into the pre-market assessment dossier requirements in various markets for companies to be better informed of the requirements.

AUSTRALIA AND NEW ZEALAND

Food Standards Australia New Zealand (FSANZ) has to approve novel food in Australia and New Zealand before it can be used in food products. There are two steps for the document submission for pre-market assessment:

Step 1: Electronic Submission to the Advisory Committee on Novel Foods (the ACNF)[1] the following:

- Identity of Food or Food Ingredient
- Information on botanical characterization, if any
- Proposed use of the food or food ingredient
- Questions relevant to the consideration of whether a food is non-traditional or not
- Public health and safety considerations

Step 2: Dossiers for Pre-Market Assessment of Novel Food / Ingredient

- Technical information on the type of novel food such as purpose of adding the ingredient to food, physical and chemical properties, manufacturing process and specifications
- Safety information of the novel food or ingredient, which includes:
    - history of use as a food in other countries
    - composition, particularly levels of anti-nutrients and naturally-occurring toxins
    - method of preparation and specifications of a novel food ingredient
    - potential for allergenicity
    - metabolism/ toxicokinetic studies
    - animal toxicity studies
    - human tolerance studies
- Information on dietary exposure
- Information on the nutritional and health impact of the novel food
- Information related to potential impact on consumer understanding and behaviour
- Statement as to whether the application is seeking exclusive permission for the novel food, if applicable

[1] Questionaire for Completion by Enquirer. FSANZ. Available: http://www.foodstandards.gov.au/industry/novel/Pages/default.aspx

CANADA

Health Canada has to approve of the novel food before it can be used in food products. Documents required for pre-market assessment are:[2]

- Common name(s) under which the novel food will be sold
- Name and address of the principal place of business of the manufacturer and, if the address is outside Canada, the name and address of the principal place of business of the importer
- A description of the novel food accompanied with the following:
    - information about its development
    - details of the method by which it is manufactured, prepared, preserved, packaged and stored
    - details of major change(s), if any
    - information respecting its intended use and directions for its preparation
    - information respecting its history of use as a food in a country other than Canada, if applicable
    - information to establish that the novel food is safe for consumption
- Information about the estimated levels of consumption by consumers of the novel food
- Text of all labels to be used in connection with the novel food
- Name and title of the person who signed the notification and the date of signing

USA

The US Food and Drug Administration (FDA) has to approve of the novel food, in the same way as any other ingredient, through the GRAS system before it can be used in food products. Documents required are as follows[3]:

- Signed statements and certification
- Identity, method of manufacture, specifications, and physical or technical effect
    - These would include scientific data to identify the substances such as plant part used, taxonomic source etc, manufacturing method and other product specifications.
- Dietary exposure
    - This refers to information on the quantities of relevant substances that consumers are likely to consume as part of a total diet.
- Self-limiting levels of use
    - This is applicable in circumstances where the amount of the notified substance that can be added to food is limited because food containing levels of the notified substance above a particular level would become unpalatable or technologically impractical. Information or data on the level of use must be provide

[2] Guidelines for the Safety Assessment of Novel Foods. (2006). Health Canada. Retrieved from: https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/guidelines-safety-assessment-novel-foods-derived-plants-microorganisms/guidelines-safety-assessment-novel-foods-2006.html#a4

[3] Food Additives. (2019). ECFR. https://www.ecfr.gov/cgi-bin/text-idx?SID=be76c675e331dcb32f6673c09d47ee16&mc=true&node=pt21.3.170&rgn=div5#se21.3.170_130

- Experience based on common use in food before 1958
    - If the statutory basis for the conclusion of GRAS status is through experience based on common use in food, evidence of a substantial history of consumption of the notified substance for food use by a significant number of consumers prior to 1 January 1958 should be provided.
- Narrative
    - This part refers to a narrative that provides the basis for the conclusion that the notified substance is safe under the conditions of its intended use. This should also take into consideration all dietary sources and any chemically or pharmacologically related substances in diets.
- List of supporting data and information in your GRAS notice

EU

FDA has to approve of the novel food before it can be used in food products. Documents required are as follows[4]:

- Name and address of the applicant
- Name and description of the novel food
- Description of the production process(es)
- Detailed composition of the novel food (including nutritional information)
- Scientific evidence demonstrating that the novel food does not pose a safety risk to human health (including information such as toxicology studies, history of use and source, absorption, distribution, metabolism and excretion (ADME), allergenicity etc)
- Analysis method(s), where appropriate
- A proposal for the conditions of intended use and for specific labelling requirements which do not mislead the consumer or a verifiable justification why those elements are not necessary

CHINA

The National Health Commission (NHC) has to approve of the novel food before they can be used in food products. Documents required to be submitted for registration include[5]:

- Application form
- Research report of novel ingredient
- Safety evaluation report of novel ingredient
- Production technology
- Relevant standards (including safety requirements, quality assessment and testing methods)

[4] Procedures of EU Consultation Request (2018). Available: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32018R0456

[5] Administrative Measures for Novel Food Ingredients. Retrieved from: http://www.nhc.gov.cn/fzs/s3576/201808/b6894ec987b64af3ae75f5140130c869.shtml

- Labels and instructions
- Research and utilisation status at locally and abroad and relevant safety evaluation materials
- Other materials useful for the evaluation
- Sample of the product, or 30 g of raw materials

For imported novel food, additional documents are required to be submitted. This includes:

- Document of approval from the relevant agency in the importing country allowing novel product to be manufactured or sold in China
- Certification document of the manufacturing company by the relevant organisation in the country

CHINA (TAIWAN)

The Taiwan Food and Drug Administration (FDA) has to approve of the non-traditional food ingredient before it can be used. Documents required to be submitted for application include[6]:

- Information of applicant
- Basic information of non-traditional food ingredient
    - Description of appearance and physical characteristics of raw material, name of raw material, source, composition, properties and purpose of use
    - Specifications of ingredient, detailed description of production process, methods of quality control, stability in processing and methods of storage
    - Production by non-traditional breeding techniques or methods
    - Part(s) of raw material used and proposed use for specific types of food or products
    - Type of final product used in food
- Consumption information of non-traditional ingredient
    - Proposed uses and use levels
    - Estimated level and maximum consumption level of general and extreme consumers and consumers with special needs
    - Suggestions for target consumers and excluded consumers
    - History of use as food in Taiwan or other countries
- Toxicological information and other relevant information
- Labelling and instruction manual (including proposed uses, suggested target consumers, precaution and restriction of use)
- Information on approval or rejection of ingredient in other countries
- Other necessary documents

[6] Guidance on Application for Non-traditional Food Ingredients. (2018). Taiwan FDA. Retrieved from: https://www.fda.gov.tw/EN/lawContent.aspx?cid=16&id=3091

INDIA

The Food Safety and Standards Authority of India has to approve of the novel food before it can be used. The information required for application is as follows[7]:

- Information of the applicant and organisation
- Name of food ingredient
- Source of food ingredient (animal, chemical, botanical or microbiological)
- Functional and intended use
- Certificate of analysis from third party National Accredited Board of Laboratories (NABL) or International Laboratories Accreditation Cooperation (ILAC) recognised laboratories
- Manufacturing process
- Regulatory status in other countries
- Safety information
- Target group for the proposed food
- Detailed composition of the product
- Details of new technology
- History of consumption of food product/ food ingredient

JAPAN

The Ministry of Health, Labour and Welfare (MHLW) has to approve of the novel food ingredient before it can be used. Documents required to be submitted for application include[8]:

- Name of ingredient
- Part of plant or animal used, if applicable
- Active components
- Toxicological data
- Information on absence of narcotic, psychotropic or stimulant drug-like action
- Regulatory status in other countries
- How the ingredient will be consumed in Japan and other countries

[7] Approval of Non-Specified Food and Food Ingredients Regulations (2017). FSSAI. https://fssai.gov.in/upload/uploadfiles/files/Gazette_Notification_NonSpecified_Food_Ingredients_15_09_2017.pdf

[8] Pharmaceutical and Non-Pharmaceutical Classification of New Ingredient. MHLW. Retrieved from: http://www.fukushihoken.metro.tokyo.jp/kenkou/kenko_shokuhin/ken_syoku/kanshi/seibun.html

KOREA

The Ministry of Food and Drug Safety (MFDS) has to approve of the novel food ingredient before it can be used. Documents required to be submitted for application include[9]:

- Common and scientific name of raw material
- Country of origin and purpose of use
- Regulatory status in other countries
- Information on the entire manufacturing process
- Raw material characterisation and specifications
- Safety information and toxicology test report

THAILAND

The Thailand Food and Drug Administration (Thai FDA) has to approve of the novel food before it can be used. Information and documents required in the application are as follows[10]:

- Application form consisting of name of food product, production process, preparation method before consumption and daily recommended dose and purpose for consumption
- General information of ingredient and product
- Information on history of consumption of food
- Specification of ingredient and product
- Certificate of analysis
- Storage information
- Production process/synthesis/extraction method
- Basic information on chemicals used in production
- Instruction for use and recommended intake
- Safety information
- Nutritional data
- Result of safety assessment from international risk assessment agency or other recognised countries

[9] Novel Food Ingredients Safety Assessment Guidelines. (2016). MFDS. Retrieved from: http://www.nifds.go.kr/brd/m_15/down.do?brd_id=167&seq=10343&data_tp=A&file_seq=1

[10] Novel Food. (2016). Thailand FDA. http://food.fda.moph.go.th/law/data/announ_moph/V.English/No.376_Re_Novel_food.pdf

SINGAPORE

The Singapore Food Agency (SFA) recently proposed draft regulations for public consultation on novel food in 2018. The regulation on novel food is expected to take some time to be finalised.[11]

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[11] Proposed Regulatory Framework for Novel Food and Novel Food Ingredients Singapore. (2018). SFA. https://www.sfa.gov.sg/docs/default-source/legislation/sale-of-food-act/first-public-consultation-on-proposed-regulatory-framework-for-novel-foo.pdf