Smart Regulatory Solutions

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Novel Food Navigation Tool – Supplementary Information

Definitions

Traditional food / food ingredient – food or substance derived from a food that has a history of consumption in the country of interest. Foods may be traditional foods in one country and non-traditional or novel in another country, depending on how widely it is consumed by the global population. For example, foods containing plants endemic to Aotearoa New Zealand may be considered traditional foods in New Zealand and Australia but novel foods in another country where there is no documented use in food products in that country.

Novel food / ***food ingredient*** – a non-traditional food or substance derived from foods/ingredients that require safety assessment before being permitted for use in food products. This could be a substance from a new source or derived from new manufacturing process technology.

Therapeutic (medicinal) use – preventing, curing or alleviating a disease, defect, ailment or injury, or influencing or modifying a physiological process in persons. A food or food ingredient used as a traditional medicine can mean there is a potential pharmacological (medicinal) effect. If this has been the primary function of the food or substance, this can result in classification as a novel food or possibly a therapeutic goods. If most published data relates to a therapeutic or traditional medicinal effect by consuming the substance, then it is likely that either the substance will not be classed as a food ingredient and/or additional toxicology data is required to demonstrate that there is no pharmacological/medicinal effect at the intended level of use.

Food additives – substances that perform a specific technological function in a food product such as emulsifier, preservative, intense sweetener, or colour. The USA definition of food additive differs from the generally accepted definition. In the USA, the terms 'food additive' is used to describe any substance added to food. Approval for use as a food additive is a separate process from novel food approval.

Processing technology – There is a range of processing technologies available for various aspects of plant extracts, their isolate bioactives, or functional foods containing such extracts/bioactives. These technologies alone or in combination with other factors such as source material and history of consumption can impact the classification of a food or food ingredient as novel. Examples of these technologies are:

- Preparation (freeze drying, air drying, milling)
- Extraction (accelerated solvent extraction, green (water), ultrasound, microwave assisted)
- Isolation (chromatographic methods)
- Protection/encapsulation (spray drying, complexation, gelation, liposomes/niosomes, co-precipitation, self assembly)
- Quantification of specific bioactives (Spectrophotometry, HPLC, GC-MS)
- Behaviour of extracts/bioactives in food matrix (molecular interactions; NMR, FTIR, Raman, confocal microscopy, electron microscopy)

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- Assessment of various properties of the functional foods containing extracts/bioactives (physicochemical, rheological, structural, and sensorial; every possible technique from AOAC analysis to FEAST facilities)

Techniques such as preparation (e.g., freeze drying, air drying, milling) and extraction (e.g., accelerated solvent extraction, green (water), ultrasound, microwave assisted) have been widely used to develop both conventional and novel food ingredients. UV treatment is one method that has been part of several novel food applications globally as historically this has not been used a traditional food processing technique. Technologies such as encapsulation (both nano and micro) have been widely used to create novel food ingredients that can be added to a variety of conventional food and beverages, to create functional food products.

Summary of Considerations for Novel Foods Assessments for Key Markets

	NZ/AUS	USA	SINGAPORE	CHINA	JAPAN	SOUTH KOREA
Definition	Novel food – food ingredient or component with no history of consumption in NZ/AUS and safety concerns	Any substance added to food without GRAS status	Novel food – foods and food ingredients without a history of safe use.	New food raw material – materials that are not traditionally consumed in China	Novel food – foods and food ingredients without a history of safe use.	Ingredients not approved for use in food – ingredients with safety concerns and no history of safe use in South Korea
Format and Source	Animals, plants and micro-organisms or compounds from these sources, or isolated and highly purified components with no history of use in the conventional diet are likely to have safety concerns. Also includes compounds that are chemically identical to naturally occurring substances but are produced through alternative/new technologies.					
History of Use Requirements	Consumed in New Zealand or Australia for 10-20 years or 2-3 generations depending on nature of use	Common use in food in the USA before 1958	Consumed as an ongoing part of diet by a significant human population for more than 20 years	Manufactured or sold in China for more than 30 years	Evidence of safe use in Japan	Evidence of safe use in South Korea
Application Timeframe	6-18 months	Self-substantiation of GRAS – prior to placing the product on the market. FDA GRAS notification – 1 year	3-6 months	2-4 years	1-2 years	1-2 years

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	NZ/AUS	USA	SINGAPORE	CHINA	JAPAN	SOUTH KOREA
Assessment Fee	No fee – sit on the waiting list. Fee (exact amount determined by the complexity of application) – go to the top of the waiting list.	No assessment fee	No assessment fee	Determined by the complexity of the application	Determined by the complexity of the application	Determined by the complexity of the application
Data Requirements	Toxicology Nutrition analysis Efficacy Manufacturing process Dietary exposure and use levels Specification Intended function Labelling	Toxicology Nutrition analysis Efficacy Manufacturing process Dietary exposure and use levels Specification Intended function Labelling	Toxicology Nutrition analysis Efficacy Manufacturing process Dietary exposure and use levels Specification Intended function Labelling	Required to have testing completed at government-approved laboratories located in China. Similar types of tests are required to that for NZ novel food. Additional government certification can be required from the country of origin.	Toxicology Nutrition analysis Efficacy Manufacturing process Dietary exposure and use levels Specification Intended function Labelling	Toxicology including data on toxic or adverse effect causing substances Nutrition analysis Efficacy Manufacturing process Dietary exposure and use levels Specification Intended function Labelling
Approvals from Other Countries	Approvals in other countries are taken into consideration	Approvals in other countries are taken into consideration	Approvals in other countries are taken into consideration	Expected to have approval in another country before seeking approval in China	Approvals in other countries are taken into consideration	Approvals in other countries are taken into consideration
Intellectual Property	Possible to gain exclusive permission for 15 months. Further IP protection should be considered through patents and trademarks.	No exclusivity through the application. IP protection should be considered through patents and trademarks.				

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Advisory Committee on Novel Foods (NZ/AUSTRALIA)

The ACNF is chaired by FSANZ and representatives from Australian state and territory jurisdictions and the New Zealand Ministry for Primary Industries (MPI). The Committee meets regularly to review applications made for ACNF view on whether a food is novel or not. The recommendations made by ACNF are not legally binding but are designed to assist with understanding whether a novel food application should be considered by the applicant.

The process for making an application to ACNF firstly requires the applicant to make an assessment using the published guidance tool to determine what information needs to be supplied. After that, the applicant needs to complete a questionnaire which is submitted to ACNF for consideration. The questions fall into 2 main groups. The first group is the history of use which is used to determine whether the food is a traditional or non-traditional food.

Questions on the history of consumption include:

- Length of use – is it generations or a small number of years.
- Extent of use – has it been used by the general population in New Zealand or by a specific sub-population group.
- Level of intake – are large or small amounts consumed and is it available in a small or wide range of foods.
- Purpose or context of use – is it primarily medicinal or regular part of the diet.

The second group is public health and safety considerations. These questions are reviewed if the answer to the previous history of consumption questions is that the food is non-traditional. If a food is deemed to be traditional, then further considerations of public health and safety are not necessary as there is significant evidence of safe consumption of the food in the population.

Questions on public health and safety considerations include:

- Potential for adverse effects in humans – reports of any adverse effects, animal toxicity studies, human clinical trials
- Composition or structure of the food – are the components that are known to cause adverse reaction or illness and are they present at a level in the food where this is likely to cause an effect.
- The process by which the food has been prepared – does the process alter the composition or structure of the foods.
- The source the food is derived from.
- Patterns and levels of consumption – is the expected level of intake likely to cause an adverse effect or does it exceed any medicinal use levels.

If ACNF decides an assessment of public health and safety considerations is required for a non-traditional food, it will be considered a novel food. To be able to use a novel food in a food product that is regulated under the Food Standards Code, permission must be obtained through FSANZ to amend Standard 1.5.1 – Novel Foods.