

Scanning the Horizons

Quarterly Update

CLINICAL TRIALS AND MARKETING

The primary purpose of clinical trials may be to substantiate a health claim but there are also opportunities to engage consumers.

Build consumer trust by communicating research plans and R&D programs. These can help demonstrate brand commitment to validating the health effects of different foods.

Consumers are looking to brands that have a high level of credibility throughout many aspects of their business.

Supporting evidence to demonstrate how foods can deliver tangible health benefits is a key part to this credibility.

Look for ways to communicate scientific information in a consumer-friendly manner.



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When is a clinical trial a good idea?

Food health claims must be substantiated by robust scientific evidence. Some markets allow for self-substantiation of claims while others require pre-market authorisation.

Regardless of the avenue for approval, one common requirement is the use of high-quality human clinical trials.

So, what constitutes a high-quality study for supporting a food health claim?

Good study design is imperative. This means **gold standard** randomised, double blinded, placebo-controlled trials. The study can be parallel or cross over, depending on the nature of the target health outcome. Cause and effect in humans cannot be established using non-human trials (*in vitro* and animal data), but these can be used as supporting evidence in some cases.

Participants are another important element. Food claims are for **healthy populations**, which means clinical trials for the purpose of health claims substantiation must use healthy participants. Including participants who are outside healthy parameters (e.g., obese, heart disease, diabetes) will result in the trial being disregarded from any claims substantiation dossier irrespective of the final results.

The **number of participants** must be sufficient to generate a **statistically significant result**. Health outcomes must be more pronounced when using small participant numbers which can be difficult to achieve in healthy volunteers. Some markets require the study participants to reflect the domestic population that can dictate the ethnicity of trial participants.

The **target health outcome** should be within the parameters of a food health claim. Claims for **supporting normal health** are the most common. Claims for higher states such as lowering cholesterol are also accepted as long as they are still within a healthy population context. **Claims to treat or cure disease states are not accepted and clinical trials that focus on these outcomes are not usable.**

Clinical trials require **significant financial investment and planning**. Expertise in conducting scientific studies must relate to the detailed requirements of food regulatory bodies. Look for **research partners** who understand the nuances of health claim regulation in the market(s) of interest. It may not be possible to get a one-size-fits-all trial design but there is opportunity to maximise efficiency to try and meet the needs of as many markets as possible.

EU / New Zealand Free Trade Agreement

On 30th June 2022 New Zealand and the EU finished negotiations on a free trade agreement¹. There is a range of proposed benefits that will be realised once the agreement comes into force which is estimated to be in 2024. One of the biggest is the removal of tariffs, which will mean significant cost savings for New Zealand businesses.

Another benefit is the inclusion of a Māori Trade and Economic Cooperation Chapter. As a result of this chapter, there is recognition that Mānuka is the Māori word exclusively for the plant *Leptospermum scoparium* and products derived from this plant including honey and oil.

The agreement also contains protection of geographical indications for both the EU and New Zealand. After a specified phase-in period, New Zealand producers must stop using terms such as port, sherry, and feta. Labelling will not be able to use expressions such as style or type (e.g., feta style cheese).



THAILAND: The Ministry of Public Health has announced new regulation which permits addition of hemp seeds and derivatives to food products². The maximum permitted THC content is 0.2%, which is consistent with food hemp regulations globally. Already products containing THC levels over the permitted threshold are being identified in the marketplace³. The inevitable result is there will be increased border testing in the future on food products containing hemp to ensure compliance.

INDIA: FSSAI has introduced new regulations for vegan food (Food and Safety Standards (Vegan Foods) Regulations 2021)⁴. The definition of vegan requires no use of components of animal origin. This not only encompasses food ingredients but also additives and processing aids⁵.

In addition, it is mandated that no animal products can be used in the food manufacturing process. A further extension to the vegan definition is animal testing. The Indian law states for food products to be labelled

as vegan, they shall not have involved animal testing for any purpose including safety evaluation, unless provided by any regulatory authority. Imported food products must be accompanied by a certificate from the exporting country's authorities⁶.

Food labelling must display a specific vegan logo (Image 1) and packaging must make it clear that the food product is vegan.

Image 1: FSSAI Vegan Logo



AUSTRALIA / NEW ZEALAND: FSANZ has received an application permit use of the combination of 2'-fucosyllactose (2'-FL) with galacto-oligosaccharides (GOS) and/or inulin-type fructans (ITF) in infant formula products⁷. Currently the ingredients are permitted to be added separately but the Code prohibits addition of 2'-FL to infant formulas containing GOS

Regulatory Updates

The application is to amend the Code to enable addition of the combination of these ingredients.

EU: Micro-organisms and contaminants continue to be the main sources of border alerts for 2022 in the EC Rapid Alert System for Food and Feed (RASFF)⁸. Primarily it is meat and fruit/vegetable products but also confectionery and beverages are popping up regularly.

SOUTH KOREA: The Ministry of Food and Drug Safety (MFDS) has published guidance on requirements for a new hair health claim as a health functional food⁹. This guidance outlines permitted claim wording and human clinical trial requirements. This guidance is especially useful as it outlines minimum trial design including participant numbers and age range as well as accepted biomarkers for evaluation¹⁰.

QUARTERLY FOCUS: NUTRITION INFORMATION PANELS

Nutrition information panels (NIP) or nutrition facts panels are the way nutrition information is presented on a food label. They are also one of the most common ways that food labels vary around the world. There are numerous mandatory information requirements in food regulation with many different formats, which can vary significantly between countries

NUTRIENTS: In New Zealand, it is a requirement to declare the sodium content whilst in the UK/EU this should be the salt content.

The USA has brought in regulations that require the amount of **added sugars** to be declared separately to the total sugars content. Added sugars is generally defined as **the sugars added during the processing of foods.**

Some markets require energy to be declared in kilojoules (kJ) whereas other countries require energy to be declared in kilocalories (kcal or calories).

Another key difference is the nutrients that require mandatory declaration and the order in which they must be declared. Protein is often declared in different locations of the nutrition information. North American markets require mandatory declaration of a specific set of vitamins and minerals alongside other macro nutrients. For example, the USA requires mandatory declaration of Vitamin D, Calcium, Iron and Potassium whereas Canada requires Calcium, Iron and Potassium.

The EU and UK require use of the term 'of which' as part of their NIP for declaring saturated fat and sugars while other markets only require a dash in front of the word. The EU/UK also describe saturated fat as saturates in their NIP.

FORMAT: The size and shape of the panel is dependent on the minimum font size requirements and whether there are any minimum size requirements for the lines in the panel. These requirements can take up quite a bit of space on a label, so it is important to understand at the beginning of label design.

There can be allowances for small label sizes, which permit varied or smaller formats to be used. Check the definition of a small label as this can be quite different between countries.

LANGUAGE: Do not forget to consider mandatory language requirements when designing the nutrition information panel. It can be possible to design a multi-lingual panel in areas like Canada or the EU where there are many different official languages. But in other countries, this may not be feasible due to differences in the underlying format.

Due to the technical nature and large variation in nutrition information regulations, it is often not feasible to have a single label for a combination of markets. New Zealand and Australia share food regulations, so it is possible to have a single food label for both markets. The variation in language requirements and overall NIP format mean it is not possible to combine a New Zealand label with the EU.

A possibility is the use of over labelling that is commonly employed for labels going to several different markets in Asia. Regulations make it feasible to over label with the official language of the destination market which can allow for some flexibility with labelling. Overall, it is important to understand the full technical requirements of nutrition labelling when designing food labels.

Format Matters

USA

Nutrition Facts	
8 servings per container	
Serving size 2/3 cup (55g)	
Amount per serving	
Calories	230
% Daily Value*	
Total Fat 8g	10%
Saturated Fat 1g	5%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	13%
Dietary Fiber 4g	14%
Total Sugars 12g	
Includes 10g Added Sugars	20%
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 240mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

CANADA

Nutrition Facts	
Valeur nutritive	
Per 1 cup (250 ml)	
pour 1 tasse (250 ml)	
Calories 110	% Daily Value*
% valeur quotidienne*	
Fat / Lipides 0 g	0 %
Saturated / saturés 0 g	0 %
+ Trans / trans 0 g	0 %
Carbohydrate / Glucides 26 g	
Fibre / Fibres 0 g	0 %
Sugars / Sucres 22 g	22 %
Protein / Protéines 2 g	
Cholesterol / Cholestérol 0 mg	
Sodium 0 mg	0 %
Potassium 450 mg	10 %
Calcium 30 mg	2 %
Iron / Fer 0 mg	0 %

* 5% or less is a little, 15% or more is a lot
* 5% ou moins c'est peu, 15% ou plus c'est beaucoup

JAPAN

栄養成分表示 (100gあたり)	
エネルギー	252kcal
たんぱく質	0g
脂質	0g
炭水化物	62g
食塩相当量	0g

UK / EU

NUTRITION INFORMATION		per 100g
energy		kJ/kcal
fat		g
of which		g
— saturates		g
carbohydrate		g
of which		g
— sugars		g
protein		g
salt		g

What to Watch and Read?

Key HVN webinars and resources are available now to watch and read.

[*HVN Pānui | Poutu-te-rangi | June 2022 Newsletter*](#)

[*Scanning the Horizons: Alternative Proteins and Plant Bioactives June 2022*](#)

[*Scanning the Horizons: Innovation in Fruit*](#)

[*Commodities – Patent Landscape Snapshot May 2022*](#)

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2. Thailand Legalizes the Use of Cannabis in Food <https://food.chemlinked.com/news/food-news/thailand-legalizes-the-use-of-cannabis-in-food#:~:text=Starting%20from%20June%209%2C%202022,substance%20containing%20over%200.2%25%20T HC.>
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Smart Regulatory Solutions