Key regulatory considerations for HVN programmes

All food for sale in New Zealand and for export must meet the relevant regulatory requirements under the Food Act 2014. Of particular importance to the HVN programmes are the requirements that relate to the composition and classification of a food, and to how information on the food is included on labels and promotional material. These are primarily covered in the Australia and New Zealand Food Standards Code (the Code) (link here: http://www.foodstandards.govt.nz/code/Pages/default.aspx). In addition, a New Zealand only standard that is likely to be relevant to the HVN programme is the New Zealand Food (Supplemented Food) Standard 2016 (link here: https://www.mpi.govt.nz/dmsdocument/11365-new-zealand-food-supplemented-food-standard-2016).

While HVN products are mainly developed for export, the Food Act 2014 requires that all food for sale exported from NZ must comply with NZ requirements unless exemptions have been granted. These exemptions are granted by way of a Regulation and/or a Notice under the Food Act.

MPI is very happy to help clarify implementation of these regulations and provide additional information on particular importing country requirements.

Some important considerations prior to proceeding with product development and clinical research within each of the HVN work streams include:

1. How is the food classified?
Different 'classifications' of foods have different requirements related to composition (e.g. what vitamins and minerals can be added, and at what levels) and also how they can be promoted. These are found in Chapter 2 of the Code.
For example is it a formulated supplementary food for young children? Is it a supplemented food? Is it a food for special medical purposes? Is it a food for infants? Is it a formulated supplementary sports food? Is it a food with a compositional standard (eg ice-cream, yoghurt, milk, meat, non-alcoholic beverages)? Is it a general purpose food (ie, no particular classification)?

2. Does the food composition adhere to the relevant compositional standard?
Ensure that the food meets the relevant compositional standard under Chapter 2 of the Code. For example, foods classified as "foods for infants" have certain compositional requirements. For non-cereal based foods such as vegetable products, vegetable juice, fruit drink or fruit gels, they must contain no less than 25 mg/100 g of vitamin C (refer to Australia and New Zealand Food Standards Code Standard 2.9.2). Other foods may also have relevant compositional standards – the above is just an example.

3. Are any ingredients/foods novel?
The Code prohibits the use of a nutritive substance or a novel food (as a food or ingredient in a food) unless there is express permission to do so. Extracts from food that is commonly eaten in New Zealand may still be considered novel because the extract and new food matrix are not traditionally eaten and is present in higher amounts than naturally found in food. This means that some bioactive compounds may not be permitted as an ingredient in foods, and an application to FSANZ may need to be made before the food can be sold or exported. More information on the regulation of novel foods can be found here: http://www.foodstandards.govt.nz/industry/novel/Pages/default.aspx
Some useful questions in identifying whether a food/ingredient is novel include: Is it traditionally used in New Zealand or in Australia? Is it extracted from one food matrix and concentrated and added to a different food matrix? Is the food or ingredient(s) new to the population in New Zealand or importing market?

4. Are fundamental safety/toxicology data available for a novel food?
In determining whether or not a food or ingredient is suitable for use, a key consideration is whether or not it is safe to consume. This will involve assessing any safety/toxicological data that is available.

5. Is there approval to add specific components for a nutritive purpose?
The Code specifies what vitamins/minerals/amino acids can be added to particular foods. There needs to be careful consideration as to whether the final food matrix that is developed is able to comply with these requirements.
For example, a food that is able to meet the requirements under the New Zealand Food (Supplemented Food) Standard 2016 can be classified as a supplemented food. The Supplemented Food Standard has broader permissions on the use of nutritive substances and novel foods compared to the Code. However, there are still some restrictions in the Supplemented Food Standard. For example, the age prohibition for under 4 year olds may be an issue for the infant foods.

6. Assuming compositional requirements are met, how will the proposed research programme meet the needs for health claim justification in NZ and in the intended importing countries?
MPI have compiled material to help understand the regulatory requirements for health claims: https://www.mpi.govt.nz/food-safety/labelling-and-composition/health-claims-for-high-value-foods/.
General level health claims can be self-substantiated with appropriate evidence (see #7 below). High level health claims require the compilation of evidence and an application to FSANZ. Therapeutic claims are prohibited on any foods.
Complying with all New Zealand regulations about Nutrition and Health claims (Standard 1.2.7 and Schedules 4-6 of the Code) is a requirement before any foods with claims can be exported. If specific claims are approved in importing countries but not in New Zealand, an exemption may be sought. The nutrition and health claims requirements in different countries are different. .
https://www.mpi.govt.nz/food-safety/labelling-and-composition/health-claims-for-high-value-foods/international-regulatory-environment/
Some useful questions in identifying how Standard 1.2.7 applies include: How will the health benefit be promoted? Is it a general level, high level or therapeutic health benefit? How can the programme of clinical trials be planned to show reproducible results in the target population group(s), and fill any gaps in existing published evidence?

7. By the end of the science programme will it be possible to undertake a systematic review of all randomised controlled trials examining the food-health relationship?
Standard 1.2.7 and Schedule 6 of the Code sets out the requirements to make a self-substantiated general level health claim. If there is a business decision to compile a systematic review to self-substantiate a health claim from the HVN research programme, the research work should build in consideration of the regulatory requirements from an early stage to ensure the outcomes facilitate a systematic review.
The main question in identifying how regulatory requirements for self-substantiated claims can be met is: Will there be enough human clinical evidence available from this programme and other published research about the food/property and the specific health effect, to undertake a systematic review of all high quality studies that exist, and together do they all establish a causal association?

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