



F47/23: China Health Food

Animal Products, Plant Products, and Processed Food

18 December 2023

For Your Information

1 Background

- (1) This FYI replaces and revokes F10/22 China Health Food.
- (2) This FYI has been prepared using information available at the time of publication. The information in this FYI is current at the date of publication but may change in the future.
- (3) This FYI provides guidance for 'health food' products intended for export to China, including nutritional or dietary supplements and foods that use health claims and are considered functional health foods in China.
- (4) The key regulatory measures used for health food are product registration or filing with China's State Administration for Market Regulation (SAMR), standards for raw material requirements, and health function claims, in addition to China's General Administration of Customs (GACC) Decree 248 requirements for establishment registration.
- (5) This FYI should be read in conjunction with the current FYIs for China Registration of Food Establishments, and F09/22: Guidance for Cross-Border E-commerce Trade to China.

2 Definitions for health food products in China

- (1) **Health food** is defined in China (in the GB Standard for Natural and Health Foods GB16740-2014) as foods which claim to have specific health functions or can supplement certain vitamins and/or minerals and are suitable for certain people to help them improve body functions. They are not for the purpose of therapy and will not bring harm to the human body.
- (2) In China, **health food** is regulated as special food and is classified under the following two sub-categories:
 - a) **Nutrition supplement** (also known as **dietary supplement**) refers to products whose purpose is to supplement or replenish nutrients such as vitamins and minerals rather than supply energy. Vitamins and minerals are the major ingredients and products may be single-ingredient or multi-ingredient nutritional supplements.
 - b) **Functional health food** refers to products that share common properties with food that claim specific health functions or physiological effects on the human body. They are suitable for consumption by specific groups of people and have the effect of regulating human bodily functions, but are not used to provide treatment of diseases, or make claims of such nature.

3 China regulations on health food products

- (1) Exporters intending to export health food to China should be aware of the relevant laws, regulations and standards that apply to health food in China, including but not limited to the following:
 - a) GACC establishment registration (refer to [F36/23: China Registration of Food Establishments](#)), noting that GACC requires MPI to recommend registration for the final manufacturing establishment of a health food that is exported from New Zealand to China.

- b) China's requirement is that products included in GACC manufacturing establishment registration applications for health food also have China health food product filing/registration. Refer to Section 5 for further information.
 - c) China's list of nutrients that are permitted to be used as ingredients in health foods, and list of nutrient supplements permitted to have health claims (also referred to as the 'directory of health food raw materials' and 'directory of health functions' respectively).
 - d) China's announcement on regulating health claims for dietary supplements, which requires products to indicate whether it has undergone 'human consumption testing' or 'animal testing' on the label, depending on the health claim being made.
 - e) China's guidelines for labelling warnings on health foods.
 - f) China's notice on health food functions approved by the National Health Commission (NHC).
 - g) China's notice on further regulating the management of raw materials for health foods, which outlines raw materials permitted for use in health foods, and those which are prohibited.
 - h) China's notice on dosage forms and technical requirements for health food filing (2021).
 - i) Relevant laws and regulations such as China's Food Safety Law, Advertising Law and national GB (*guobiao*) standards.
- (2) Exporters and processors should seek further guidance from an importer or in-market agent for additional information and guidance on compliance with China's health food regulations.
 - (3) MPI understands there is regular monitoring and surveillance of health food products in China by authorities to ensure compliance with Chinese regulations, including the use of health claims and health food labelling. Exporters and manufacturers should ensure labelling on products is truthful, accurate and not misleading for consumers.

4 China health food product filing and registration

- (1) China's measures for health food registration and filing have been in force since 1 July 2016 and requires all imported health food products to be approved via filing or registration before being allowed to be sold in China.
- (2) Exporters can check if products are listed or registered via China's special food database - <http://ypzsx.gsxt.gov.cn/specialfood/#/food>
- (3) Whether a product requires filing or registration depends on the type of health food category it falls under (as outlined in Section 2), and whether it meets relevant Chinese regulations. It is understood that:
 - a) nutritional or dietary supplements are subject to product filing
 - b) functional health foods (eg products that claim specific health functions) are subject to product registration.
- (4) The following information is relevant to both product filing and registration of health foods in China:
 - a) Application for filing and registration should be authorised by the processor, translated into Chinese, and notarised by a notarisation agency in China.
 - b) Imported health food products should be marketed or sold in the country of production for at least one year before being eligible for health food filing or registration in China.
 - c) Testing and clinical trials by China-approved laboratories are likely to be required as part of the filing and registration process. MPI understands this can be a lengthy and expensive process, depending on the health claim being sought, and that laboratories may have a waiting list of between 6–18 months or longer.
- (5) MPI understands the product filing process may take 8–12 months or longer and requires product testing such as for hygiene, stability, composition etc by approved Chinese laboratories.
- (6) MPI understands the product registration process may take 1–5 years or longer and requires product testing such as for toxicology, efficacy, composition, hygiene etc by approved Chinese laboratories.

The process may also require animal testing or human trials depending on the health claim being sought.

- (7) Registration is understood to be valid for five years, and should be submitted and approved at least six months before its expiry if product is to continue being sold in market. Additional information and testing may be requested as part of the registration renewal process.

5 Decree 248 of China's General Administration of Customs

5.1 Background of Decree 248

- (1) China's General Administration of Customs (GACC) Decree 248 came into effect on 1 January 2022. The Decree requires that all overseas establishments that manufacture/process specific foods that are exported to China (from all countries) obtain GACC establishment registration, which is separate to the product filing/registration by SAMR. Food additives and food-related products (eg food packaging) are exempt from this requirement.
- (2) Under Decree 248, there are two methods to apply for registration with GACC. The registration method depends on which product category the food product that the operator manufactures/processes for export to China comes under.
- (3) Health food is one of the 18 product categories that need to apply for registration via MPI. Health food that is intended for human consumption (including trade samples) and that is intended for export from New Zealand to China, is only to be sourced from manufacturing establishments registered with GACC.
- (4) Exporters can check if establishments are registered with GACC via China's Registration information of overseas manufacturers of imported food website - <https://ciferquery.singlewindow.cn/>.
- (5) It is important to note, SAMR product filing or registration is a pre-requisite for GACC's registration of health food manufacturing establishments, and establishments will not gain GACC registration if the product intended for export to China do not have SAMR filing or registration.

5.2 GACC Registration Validity

- (1) GACC manufacturing establishment registrations for health food are valid for 5 years. For product categories where registration needs to be recommended by MPI, operators will need to apply for registration renewal via MPI, at least 6 months before the registration expiry date. Failure to apply for registration renewal within the expected timeframes will result in GACC revoking the registration.
- (2) Registration expiry dates for establishments on the new GACC health food register can be found by using the GACC registration website: <https://ciferquery.singlewindow.cn/>.
- (3) Further information regarding the application processes for new registration, registration modification, registration renewal and registration cancellation processes can be found in [F36/23: China Registration of Food Establishments](#).

6 Health claims and health food labelling in China

- (1) Health claims refer to a relationship between a food and health (eg 'calcium is good for bone density') and differs from nutritional content claims, which are claims about the content of certain nutrients or substances in a food (eg 'low in fat', 'good source of calcium'). Further information on understanding health claims that can be made in New Zealand is available on the Food Standards Australia New Zealand (FSANZ) website.

- (2) Nutritional content claims are not considered health claims and are allowed to be used on food labels in accordance with GB Standard for Nutrition Labelling of Pre-packaged Foods (GB 28050- 2011) and GB Standards for Uses of Nutritional Fortification Substances in Foods (GB 14880-2012).
- (3) Health foods imported to China should comply all with relevant labelling requirements, including using health claims which fall within the scope of China's list of approved health functions permitted to be indicated in health food labelling (refer to Section 3).
- (4) MPI understands that recent amendments to China's Advertising Law further restrict what can be used to market health foods. This includes restrictions on:
 - a) assertions or guarantee of efficacy and safety,
 - b) mentioning disease prevention or cures,
 - c) claiming or implying the product is essential for ensuring health,
 - d) comparing it with drugs or other health food, and
 - e) using endorsements.
- (5) China also released guidelines for labelling warnings on health foods, that came into effect on 1 January 2020. The guidelines set out the type of information required on health food labels, including having:
 - a) appropriate disclaimers and warnings, including the statement that "health foods are not medicines and cannot replace medicine to treat diseases",
 - b) clearly marked production and expiration dates, and
 - c) a customer service line or phone number for handling complaints.
- (6) Exporters are advised to liaise with their importer on the applicable standards and requirements for health food labelling.

7 Other information

- (1) It should be noted that health food in China is considered to be separate from **Traditional Chinese Medicines (TCMs)**, which have their own set of standards and requirements. The Chinese Pharmacopoeia sets out approved TCMs and other medicines.
- (2) MPI understands that deer velvet and ginseng (grown for a certain length of time) can be considered as TCMs in China.
- (3) China also regulates raw materials for health food and has a list of approved raw materials that can be used as the active ingredients in health foods. This list includes ginseng, bee propolis, deer antler (frozen and dried) and deer bones.

Contact for further information

Ministry for Primary Industries (MPI)
Policy and Trade Branch
Market Access Directorate
PO Box 2526
Wellington 6140
Email: market.access@mpi.govt.nz

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