HVN Science of Food Programme

National Science Challenges
HIGH-VALUE NUTRITION
Ko Ngā Kai Whai Painga

Riddet Institute
ADVANCING FRONTIERS IN FOOD SCIENCE

Scanning the Horizons

Regulatory Update

June 2020

This document outlines changes to regulation of food labeling claims around the world, including novel foods to note.

Prepared by:

Drummond
Food Science Advisory Ltd

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1 Regulatory Updates – Health Claims and Functional Foods

Monitoring the regulatory environment provides information to enable compliance with local requirements when entering markets, it also provides information on emerging trends in new food and food ingredients that may contribute to foods with possible future health claims. This report provides an overview of relevant regulatory changes and health claim related approvals in the 12 months to June 2020 and identifies new, emerging and novel foods.

Whilst globally there have been no major updates to the architecture of regulations related to health claims, a number of jurisdictions, including China and Korea, have revised labelling and advertising laws in relation to health foods, with the intention of ensuring increased accuracy of claims and statement, and providing more robust regulatory structures to address misleading claims and advertising.

In the wake of COVID-19 this was especially pertinent as many countries actively reminded and policed claims and inferred claims of food and health food efficacy for the protection from and / treatment of COVID-19.

1.1 Food Standards Australia and New Zealand Update

1.1.1 Health Claims

There have been no updates to the health claim regulations (Standard 1.2.7 and Schedule 4) in ANZ in the past year. Currently the FSANZ has no 'high level health claim' applications in its workplan.

In contrast, the option for notification of a relationship between a food or property of the food and a health effect, or 'general level health claim', has been a popular choice for many food business operators. The ANZ Food Standard Code (FSC) (Standard 1.2.7 – 18.3 (b)) allows for the notification of food-health relationships that have been established by a process of systematic review, as described in Schedule 6 of the FSC. In the year to June 2020 sixty four (64) food health relationships have been notified to FSANZ. All are logged on the FSANZ website, with the food or property of food, the notified relationship and company who have notified the relationship details available:
(https://www.foodstandards.govt.nz/industry/labelling/fhr/Pages/default.aspx?page=1).

The following notified food-health relationships are aligned with the HVN research themes (Table 1-1). Other notified food health relationships cover a range of topics including but not exclusively , hydrolysed collagen & skin/joints (20 notifications); tart cherry for sleep and relaxation (2), protein for reduced energy intake, reduced hunger, satiety (3) thylakoids for suppression of hunger/satiety & weight management (2), and soy phosphatidylserine or cognitive function / brain health (1).

Pre- and probiotics and their role in gut health are by far the most common food-health relationships notified accounting for 36% of relationships notified.

Table 1-1 Notified food-health relationships (ANZ)

Food or property of food	Notified relationship
Digestive Health	
Probiotic. Ganeden BC30. *Bacillus coagulans* GBI-30 6086. When present at 1 billion cfu per serve.	Aids digestive health; Supports digestive health; Helps digestive health; Assists digestive health; Promotes digestive health; Boosts digestive health; Stimulates digestive health; Restores digestive health
Fermented dairy products containing *Bifidobacterium animalis* subsp. *lactis*	Supports digestive health by contributing to digestive regularity in adults
Probiotics	Probiotics contributes to healthy digestive system / intestinal function
Probiotics	Probiotics/ supports the health of the digestive/ intestinal flora/ microflora/ microbiome
Bifidobacterium (BB12) probiotic culture from CHR Hansen is used in Caldermeade brand Bowel Support Natural Yoghurt and *Bifidobacterium* (BB12) has been proven to support human bowel system	Support bowel system

Food or property of food	Notified relationship
Green kiwifruit and its freeze-dried fruit powder (Actazin®)	Supports normal bowel function by promoting bowel regularity
Bifidobacterium animalis subsp. *lactis*, BB-12®	Improves bowel function in adults.
Prebiotic Fibre	Nourish Good Bacteria
Lactobacillus acidophilus	Contributes to the maintenance of beneficial gastrointestinal microflora.
Lactobacillus acidophilus	Contributes to gastrointestinal health
Bifidobacterium lactis	Contributes to the maintenance of beneficial gastrointestinal microflora.
Bifidobacterium lactis	Contributes to gastrointestinal health
Bifidobacterium spp.	Contribute to the maintenance of beneficial gastrointestinal microflora
Bifidobacterium spp.	Contribute to gastrointestinal health.
Lactobacillus spp.	Contribute to the maintenance of beneficial gastrointestinal microflora
Lactobacillus spp.	Contribute to gastrointestinal health.
Bacillus coagulans	Supports digestive health
Prebiotic fibre	Promotes the growth of bifidobacteria and lactobacillus, which supports a positive change in the gut microbiota
Promitor(R) Soluble Corn Fiber	Supports a positive change in gut microbiota
Prebiotics	Prebiotics increase beneficial bifidobacterium to support digestive health
BarleyMax barley prebiotics	The effect of prebiotic fructans on stool frequency in humans support digestive health
Prebiotic fibre	Promotes the growth of bifidobacteria and lactobacillus, which supports a positive change in the gut microbiota
Fermented milk and yoghurt products containing *Bifidobacterium animalis* subsp. *lactis*	Supports gut health
Prebiotics	Prebiotics increase beneficial bifidobacterium to support digestive health
Immune Health	
Lactoferrin	Lactoferrin contributes to healthy immune system function
Lactobacillus casei 431 probiotic culture is used in Caldermeade brand Immune Support Natural Yoghurt and *Lactobacillus casei* 431 has been proven to support human immune system	Immune support
Lactobacillus rhamnosus, LGG®.	Strengthens the immune response.
Elderberry Fruit Extract (*Sambucus nigra)*	Contributes to normal immune system function
Bifidobacterium lactis	Contributes to immune function.
Bifidobacterium spp.	Contribute to immune function.
Lactobacillus spp.	Contributes to immune function.
Metabolic Health	
Low Glycemic Index (GI)	Provides Longer Lasting Energy

1.1.2 Novel Foods

Four (4) applications for novel foods are in process with FSANZ as of June 2020. These can be viewed in detail on the FSANZ website (https://www.foodstandards.govt.nz/code/applications/Pages/default.aspx) and on the workplan as per the link in the previous section.

Two applications are for the use of oligosaccharides in infant formula products (IFP) and formulated supplementary foods for young children (FSFYC). The applications have been submitted by different applicant companies. These oligosaccharides are more similar to oligosaccharides found in human breastmilk and have been evaluated in the EU and USA.

i. A1155 permission for the voluntary use of 2'-O-fucosyllactose (2'-FL) alone or in combination with Lacto-N-neotetraose (LNnT)produced by microbial fermentation using genetically modified *Escherichia coli* (*E. coli*) strains in IFP and FSFYC, was reviewed and notified to the Ministerial forum for final approval. The Forum requested further review which is currently in progress at June 2020.

ii. A1190 permission for the voluntary use of 2' -fucosyllactose (2'-FL) produced by microbial fermentation using genetically modified *Escherichia coli* (*E. coli*) strains in IFP and FSFYC, has been put on hold until A1155 review is completed.

Other active novel food applications include:

a. A1175 for the permission for the use of rapeseed protein isolate as a plant-based protein and,
b. A1186 to permit the use of soy leghemoglobin derived from the yeast *Pichia pastoris* as a component in meat analogue products to contribute "meaty flavour". The leghemoglobin was subject of a successful GRAS notification in 2018 (GRN737).

1.1.3 Warnings against exaggerated claims for exported products.

In response to potential mis-information regarding COVID-19 and food/ health food effects MPI issued a "For Your Information" Notice (F15/20) (April 2020) urging caution against the export of product with misleading information & claims:

Ministry for Primary Industries
Manatū Ahu Matua

F15/20: Caution against export of product with misleading information and claims

Food products

17 April 2020

For Your Information

1 Background

(1) MPI is aware that border and health authorities in a number of markets, such as Australia, China, Singapore and Vietnam are taking action to protect consumers from inadvertently purchasing products that claim to prevent COVID-19, treat COVID-19 or associated lung diseases, have anti-viral properties, suppress COVID-19, or strengthen the immune system against COVID-19.

(2) Exporters and manufacturers are reminded that claims on any food product labels or advertising (including websites) must not refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition. The above claims should not be made.

(3) Exporters and manufacturers should ensure that labels, websites or any form of advertising do not contain misleading information, images, trade names or dosage that could confuse consumers.

(4) Exporters and manufacturers are reminded any health claims associated with a food product must meet the requirements of Standard 1.2.7 Nutrition, Health and Related Claims of the Australia New Zealand Food Standards Code. Exporters and manufacturers should also check and comply with the importing countries requirements for health claims and product registration.

(5) Exporters and manufacturers are reminded that:

- the New Zealand Food (Supplemented Food) Standard 2016 prohibits the specific formulation or marketing of supplemented food for the purpose of sale for consumption by infants or children under the age of 4 years. As New Zealand has no such products permitted in New Zealand, no such products can be exported
- the Animal Products (Export Requirements – Dairy Products) Notice 2005 places obligations on Risk Management Programme (RMP) operators to ensure that a dairy product intended for export is not labelled or marked in any way that is likely to be misleading or deceptive in its nature, origin or composition.

(6) Exporters and manufacturers who do not comply with the above requirements may not be able to export or sell their products and are liable to penalties or other enforcement action under the Food Act 2014 and/or the Animal Products Act 1999.

Issued by the Ministry for Primary Industries

New Zealand Government

1.2 European Union Update

The EU is often referred to as the most stringent of all jurisdictions for the evaluation of health claims and novel foods. Review of the successes and failures of applicants in the EU offers insights into what foods and ingredients

are emerging and likely to be available in the future. Health claim applications provide insight into the requirements and processes required to establish evidence based health claims.

1.2.1 EU Health claims

In the 12 months to June 2020 the EFSA Panel on Nutrition, Novel Foods and Food Allergens (EFSA NDA Panel) issued 5 opinions in response to article 13.5 (newly developed scientific evidence and/or which includes a request for protection of proprietary data) health claim applications submitted. Notably the opinions were all negative. The need for a plausible mechanism for the food /constituent linked to the physiological outcome was a recurring theme in the opinions. A brief overview of each application, the level of evidence submitted and the summary of the NDA Panel findings are provided below.

1.2.1.1 Combination of beta-sitosterol and beta-sitosterol glucoside and normal function of the immune system

(EFSA Panel on Nutrition Novel foods and Food Allergens (NDA), Turck, Castenmiller, De Henauw, Hirsch-Ernst, Kearney, Knutsen, et al., 2019a).

This application proposed that a specific combination of beta-sitosterol (BSS) and beta-sitosterol glucoside (BSSG) in a ratio of 100:1 would support immune defence against pathogens. The proposed effect was 'contribution to the normal function of the immune system by restoring balance between T_H1-T_H2 mediated immunity'. The target population was adults and children over 6 years of age. The NDA Panel confirmed the food/constituent was sufficiently well characterised. The applicants did not provide any recent evidence but relied on publications which looked at changes in a number of immune parameters.

The key rationale for the negative opinion was that the claimed effect 'contribution to the normal function of the immune system by restoring balance between T_H1- and T_H2- mediated immunity' does not refer to a specific function of the body which can be assessed in vivo in humans by generally accepted methods, but rather to a mechanism by which the food/constituent could exert the claimed effect. They noted that the health claims cannot be based solely on changes in outcome variables, but must be accompanied by evidence of a beneficial physiological effect or clinical outcome in the application as per the 2016 guidance (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2016). Thus, the final conclusion was "A cause and effect relationship cannot be established between the consumption of a combination of BSS and BSSG in a ratio 100:1 and a beneficial physiological effect" (EFSA Panel on Nutrition Novel foods and Food Allergens (NDA), Turck, Castenmiller, De Henauw, Hirsch-Ernst, Kearney, Knutsen, et al., 2019a).

1.2.1.2 GlycoLite™ and helps to reduce body weight

(EFSA Panel on Nutrition Novel foods and Food Allergens (NDA), Turck, Castenmiller, De Henauw, Hirsch-Ernst, Kearney, Knutsen, et al., 2019b).

GlycoLite™ is an aqueous extract from white kidney bean (Phaseolus vulgaris L.) standardised by its *in vitro* α-amylase inhibitory activity. The claimed effect was weight reduction in an overweight population 18 years old and over. The Panel confirmed that a reduction in body weight is a beneficial physiological effect for overweight individuals. Six (6) human intervention studies were submitted as evidence: three were performed under energy restriction and three were conducted when eating *ad libitum*. It was noted that two human intervention studies performed under moderate energy restriction (20% reduction in energy intake) showed an effect of GlycoLite™ on the reduction of body weight when 3g per day were consumed for 12 weeks. However, those studies were conducted in the same centres by the same research group and the results have not been replicated in a different setting. A third human intervention study conducted when eating *ad libitum* also showed an effect of GlycoLite™ on the reduction of body weight, however had methodological limitations. The one animal study submitted also had methodological limitation and used a high dose of the GlycoLite™.

Although the mechanistic studies submitted showed GlycoLite™ may induce a decrease in postprandial blood glucose responses when consumed in combination with meals containing high amounts of digestible carbohydrates there was no evidence for a mechanism by which a partial inhibition of the α-amylase activity could lead to a reduction in body weight in free-living humans. The Panel concluded the "evidence provided is insufficient to establish a cause and effect relationship between the consumption of an aqueous extract from white kidney bean (*P. vulgaris* L.) standardised by its in vitro a-amylase inhibitory activity (GlycoLite™) and a

reduction of body weight either under energy restriction or when eating *ad libitum*" (EFSA Panel on Nutrition Novel foods and Food Allergens (NDA), Turck, Castenmiller, De Henauw, Hirsch-Ernst, Kearney, Knutsen, et al., 2019b).

1.2.1.3 MenaQ7® and maintenance of the elastic properties of the arteries

(EFSA Panel on Nutrition Novel foods and Food Allergens (NDA), 2020).

MenaQ7® is a vitamin K2 as menaquinone-7 (96% w/w) produced by a specific manufacturing process, and the Panel concluded it is adequately characterised. Maintenance of the elastic properties of the arteries (as measured by arterial stiffness) is a beneficial physiological effect. The target population is the healthy general population.

Three human intervention studies were submitted to support the claim, however no conclusion could be drawn from one uncontrolled study for the scientific substantiation of the claim. The two other studies were carried out in the same centre and by the same research group. Both studies were randomised, two-arm, parallel, double-blind, placebo-controlled studies on MenaQ7® administration (during 1 and 3 years, respectively) and a number of vascular measures, however important methodological limitations (sample size calculation was not performed, unclear how primary outcome(s) were selected, no correction for testing of multiple primary outcomes was made, baseline was not included in the statistical analyses), meant that no conclusion could be drawn from those studies for the scientific substantiation of the claim.

Based on the absence of evidence for an effect of MenaQ7® on maintenance of elastic properties of the arteries in vivo in humans, the studies on the proposed mechanisms by which the food/constituent could exert the claimed effect cannot be used as a source of evidence for the scientific substantiation of the claim (EFSA Panel on Nutrition Novel foods and Food Allergens (NDA), 2020).

1.2.1.4 Coffee C21 and protection of DNA from strand breaks

(EFSA Panel on Nutrition Novel foods and Food Allergens (NDA), Turck, Castenmiller, De Henauw, Ildico Hirsch-Ernst, Kearney, Knutsen, Maciuk, Mangelsdorf, McArdle, Naska, Pelaez, Pentieva, Thies, Tsabouri, Vinceti, Bresson, & Siani, 2020).

Coffee C21, a coffee standardised by its concentration of caffeoylquinic acids (CQA), trigonelline and N-methylpyridinium (NMP), was considered by the Panel to be sufficiently characterised in relation to the claimed effect. The protection of DNA from strand breaks, is a considered a beneficial physiological effect (EFSA Panel on Nutrition Novel foods and Food Allergens (NDA), Turck, Castenmiller, De Henauw, Ildico Hirsch-Ernst, Kearney, Knutsen, Maciuk, Mangelsdorf, McArdle, Naska, Pelaez, Pentieva, Thies, Tsabouri, Vinceti, Bresson, & Siani, 2020).

Although the applicant proposed 2 mechanisms for the protection of DNA from strand breaks:

a) A direct pathway through scavenging of free radicals by antioxidants present in dark roast coffee and hence preventing oxidative damage to DNA strands.

b) Indirect pathways active through modulation of gene expression by coffee constituents leading to activation and upregulation of endogenous cellular DNA protective responses (mainly, but not exclusively, via activation of the nuclear factor erythroid 2-related factor 2 (Nrf2)/antioxidant/electrophile response element (ARE/EpRE) system);

The Panel concluded no evidence was provided for a mechanism by which coffee (including Coffee C21) would protect DNA from strand breaks. They commented that the literature on both the effects and the mechanisms of action of the different coffee constituents is incomplete, diverse and not consistent, and that inferences on the link with DNA integrity are in most instances reported in hypothetical and speculative terms.

Of the seven human intervention studies submitted, conclusions could only be drawn from 2. One of those studies provided some evidence that daily consumption of Coffee C21 (750 mL/day) for four weeks decreases DNA strand breaks in habitual coffee drinkers after coffee withdrawal over the previous four weeks. However, the statistically significant findings of that study were not replicated in another study performed under similar conditions in the same study centre. The Panel also noted no studies were undertaken in a different setting, from which conclusions could be drawn, are available.

Based on the weight of evidence submitted the Panel conclusion was that "A cause and effect relationship has not been established between the consumption of Coffee C21 and protection of DNA from strand breaks".

1.2.1.5 Orodispersible lozenges containing a combination of Lactobacillus reuteri DSM 17938 and Lactobacillus reuteri ATCC PTA 5289 and normal gum function

(EFSA Panel on Nutrition Novel foods and Food Allergens (NDA), Turck, Castenmiller, De Henauw, Ildico Hirsch-Ernst, Kearney, Knutsen, Maciuk, Mangelsdorf, McArdle, Naska, Pelaez, Pentieva, Thies, Tsabouri, Vinceti, Bresson, Sanz, et al., 2020).

Maintenance of normal gum function is a beneficial physiological effect, and the Panel determined that orodispersible lozenges containing *L. reuteri* DSM 17938 and *L. reuteri* ATCC PTA 5289 are sufficiently characterised.

The applicant submitted a number of clinical trials as evidence to substantiate the claim however only 2 of the trials investigated the effect of lozenges containing L. reuteri DSM 17938 and L. reuteri ATCC PTA 5289 on appropriate gingival outcomes in subjects with gingivitis but without periodontitis under the proposed conditions of use (twice daily). Other trials with the lozenges consumed twice daily, were acknowledged as providing support on gum function but either did not measure the same parameters or were conducted with participants with periodontitis. Mechanistic evidence was only available from studies with participants who had periodontitis. Of the 2 studies that aligned with the proposed conditions of use and claim, one showed a large effect on bleeding on probing and other gingival outcomes and the other (unpublished) study showed no effect. The inconsistent results obtained in these two studies could not be explained by differences in study design or sample size. These limitations outweighed the evidence provided.

Consequently, the Panel concluded the evidence provided was insufficient to establish a cause and effect relationship between the consumption of orodispersible lozenges containing a combination of *L. reuteri* DSM 17938 and *L. reuteri* ATCC PTA 5289 and maintenance of normal gum function.

1.2.2 EU Novel Foods

In the year to June 2020 EFSA assessed the safety of 15 novel foods / ingredients. All but one application (Viable embryonated eggs of the whipworm *Trichuris suis*) were deemed as safe for use, most under the proposed conditions for use and for the target population propsed in the applications. A summary of the applications finalised is provided in Table 1-2.

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Table 1-2 EU Novel Food Application Outcomes

Novel Food	Reference	Comment	Target population	Maximum daily amount	Status /Conclusion
Astaxanthin	EFSA Panel on Nutrition Novel foods and Food Allergens (NDA), Turck, Castenmiller, de Henauw, Hirsch-Ernst, Kearney, Maciuk, Mangelsdorf, McArdle, Naska, Pelaez, Pentieva, Siani, Thies, Tsabouri, Vinceti, Cubadda, Engel, Frenzel, Heinonen, Marchelli, Neuhäuser-Berthold, Poulsen, Sanz, Schlatter, van Loveren, Ackerl, Gelbmann, et al. (2020)	A re-evaluation safety based on revised ADI 0.2mg/kg bw /day Use in food supplements	All	8 mg /day	Safe for adults Adolescents (14 to <18 years) reaches ADI Exceeds ADI by 28% in children 10 to <14 years Exceeds ADI by up to 524% in infants aged 4-6 months
Phenylcapsaicin	EFSA Panel on Nutrition Novel foods and Food Allergens (NDA), Turck, Castenmiller, De Henauw, Hirsch-Ernst, Kearney, Maciuk, Mangelsdorf, McArdle, Naska, Pelaez, Pentieva, Siani, Thies, Tsabouri, Vinceti, Cubadda, Engel, Frenzel, Heinonen, Marchelli, Neuhäuser-Berthold, Pöting, Poulsen, Sanz, Schlatter, van Loveren, Amundsen, et al. (2019)	Use in food supplements and FSMP	General population > 11 years of age	2.5 mg /day	Safe under proposed uses and levels
Lacto-*N*-tetraose (LNT)	EFSA Panel on Nutrition Novel foods and Food Allergens (NDA), Turck, Castenmiller, De Henauw, Hirsch-Ernst, Kearney, Maciuk, Mangelsdorf, McArdle, Naska, Pelaez, Pentieva, Siani, Thies, Tsabouri, Vinceti, Cubadda, Engel, Frenzel, Heinonen, Marchelli, Neuhäuser-Berthold, Poulsen, Sanz, Schlatter, van Loveren, Colombo, et al. (2019)	Foods including infant and follow-on formula, foods for infants and toddlers, FSMP, and food supplements	General population Food supplements for general population > 1 year of age	Range of levels for different foods. For infants 0.8g/L does not exceed levels in breastmilk Food supplements 2 g/day	Safe under the proposed conditions of use for the proposed target populations
2'-fucosyllactose/difucosyllactose mixture	(EFSA Panel on Nutrition Novel foods and Food Allergens (NDA), Turck, Castenmiller, De Henauw,	Foods including infant and follow-on formula, foods for	General population	Range of levels for different foods. For	Safe under the proposed conditions of use for the proposed target populations

Novel Food	Reference	Comment	Target population	Maximum daily amount	Status /Conclusion
	Hirsch-Ernst, Kearney, Maciuk, Mangelsdorf, McArdle, Naska, Pelaez, Pentieva, Siani, Thies, Tsabouri, Vinceti, Cubadda, Engel, Frenzel, Heinonen, Marchelli, Neuhäuser-Berthold, Pöting, Poulsen, Sanz, Schlatter, van Loveren, Sun, et al., 2019)	infants and toddlers, FSMP, and food supplements	Food supplements for general population > 1 year of age	infants 1.6 g/L does not exceed levels in breastmilk Food supplements 4 g/day	
3'-Sialyllactose (3'-SL) sodium salt	EFSA Panel on Nutrition Novel foods and Food Allergens (NDA), Turck, Castenmiller, De Henauw, Hirsch-Ernst, Kearney, Maciuk, Mangelsdorf, McArdle, Naska, Pelaez, Pentieva, Siani, Thies, Tsabouri, Vinceti, Cubadda, Engel, Frenzel, Heinonen, Marchelli, Neuhäuser-Berthold, Poulsen, Schlatter, van Loveren, Colombo, et al. (2020a)	Foods including infant and follow-on formula, foods for infants and toddlers, FSMP, and food supplements 3'-SL food supplements are not intended for use when other foods containing it are consumed on the same day.	General population	For infants 0.2 g/L does not exceed levels in breastmilk Food supplements 0.5 g/day	Safe under the proposed conditions of use for the proposed target populations
6'-Sialyllactose (6'-SL) sodium salt	EFSA Panel on Nutrition Novel foods and Food Allergens (NDA), Turck, Castenmiller, De Henauw, Hirsch-Ernst, Kearney, Maciuk, Mangelsdorf, McArdle, Naska, Pelaez, Pentieva, Siani, Thies, Tsabouri, Vinceti, Cubadda, Engel, Frenzel, Heinonen, Marchelli, Neuhäuser-Berthold, Poulsen, Schlatter, van Loveren, Colombo, et al. (2020b)	Foods including infant and follow-on formula, foods for infants and toddlers, FSMP, and food supplements 6'-SL food supplements are not intended for use when other foods containing it are consumed on the same day.	General population	For infants 0.4 g/L does not exceed levels in breastmilk Food supplements: 1 g/day for >3 years 0.4 g / day for <11 months 0.3 g/day 12-35 months	Safe under the proposed conditions of use for the proposed target populations
Vitamin D_2 mushroom powder	(EFSA Panel on Nutrition, Allergens, Turck, Castenmiller, de Henauw, Hirsch-Ernst, Kearney, Maciuk, Mangelsdorf, McArdle, Naska, Pelaez, Pentieva, Siani, Thies, Tsabouri, Vinceti, Cubadda, Engel, Frenzel, Heinonen, Marchelli, Neuhäuser-Berthold,	Foods and food supplements. An ingredient produced from *Agaricus bisporus* mushrooms exposed to ultraviolet (UV) light to induce the conversion of provitamin D_2 (ergosterol) to vitamin D_2(ergocalciferol). It	General population	Levels within the daily UL for vitamin D Food supplements: 15 µg / vit D_2 for >1 year 10 µg / vit D_2 for 7-12 months Care required not to exceed vitamin D intakes	Safe under the proposed conditions of use for the proposed target populations

Novel Food	Reference	Comment	Target population	Maximum daily amount	Status /Conclusion
	Poulsen, Sanz, Schlatter, van Loveren, Roldán-Torres, et al., 2020)	contains concentrations of vitamin D provided by vitamin D_2 in the ranges of 1,000–1,300 μg/g.			
Dried whole cell *Euglena gracilis*	(EFSA Panel on Nutrition Novel foods and Food Allergens (NDA), Turck, Castenmiller, De Henauw, Hirsch-Ernst, Kearney, Maciuk, Mangelsdorf, McArdle, Naska, Pelaez, Pentieva, Siani, Thies, Tsabouri, Vinceti, Cubadda, Engel, Frenzel, Heinonen, Marchelli, Neuhäuser-Berthold, Poulsen, Schlatter, van Loveren, Ackerl, et al., 2020b)	*Euglena gracilis* is a single cell micro-alga common in freshwater habitats. The NF is produced by fermentation and its major constituent (> 50%) is a β-glucan polysaccharide.	General population. Except for food supplements and for foods for total diet replacement for which the target is the general population > 12 months of age.	564 mg/day for adults Food supplements: 375 mg/day adults 225 mg/day adolescents 150 mg / day 3-9 years 100 m g/day 12-35 months	Safe at the proposed uses and use levels.
Heat-killed *Mycobacterium setense manresensis*	(EFSA Panel on Nutrition Novel foods and Food Allergens (NDA), Turck, Castenmiller, De Henauw, Hirsch-Ernst, Kearney, Maciuk, Mangelsdorf, McArdle, Naska, Pelaez, Pentieva, Siani, Thies, Tsabouri, Vinceti, Cubadda, Engel, Frenzel, Heinonen, Marchelli, Neuhäuser-Berthold, Poulsen, Sanz, Schlatter, van Loveren, Sun, et al., 2019)	Intended to be marketed exclusively in food supplements	General population excluding children (including infants), pregnant and lactating women.	One capsule (with ≤ 10^5 heat-killed, freeze-dried *M. setense manresensis*) for 14 consecutive days and a minimum of 6 months with no consumption of the NF, before another intake for fourteen days	Safe under the proposed conditions of use
Selenium-enriched biomass of *Yarrowia lipolytica*	(EFSA Panel on Nutrition Novel foods and Food Allergens (NDA), Turck, Castenmiller, De Henauw, Hirsch-Ernst, Kearney, Maciuk, Mangelsdorf, McArdle, Naska, Pelaez, Pentieva, Siani, Thies, Tsabouri, Vinceti, Cubadda, Engel, Frenzel, Heinonen, Marchelli, Neuhäuser-Berthold, Poulsen, Sanz, Schlatter, van Loveren, Ackerl, & Knutsen, 2020)	Application for use as food supplement The dried and heat-killed selenium-enriched biomass of the yeast *Y. lipolytica.*	General population > 3years	0.2 g/day children 3 to 9 years 1 g/day >9 years	Is as safe as other dietary Se sources – no safety concerns Noted that at proposed levels Se intake could exceed recommended upper limits for intake.

Novel Food	Reference	Comment	Target population	Maximum daily amount	Status /Conclusion
Chromium-enriched biomass of *Yarrowia lipolytica*	(EFSA Panel on Nutrition, Allergens, Turck, Castenmiller, De Henauw, Hirsch-Ernst, Kearney, Maciuk, Mangelsdorf, McArdle, Naska, Pelaez, Pentieva, Siani, Thies, Tsabouri, Vinceti, Cubadda, Engel, Frenzel, Heinonen, Marchelli, Neuhäuser-Berthold, Poulsen, Sanz, Schlatter, van Loveren, Ackerl, et al., 2020)	Application for use as food supplement The dried and heat-killed chromium-enriched biomass of the yeast *Y. lipolytica.*	General population > 3 years	2 g/day children 3 to 9 years 4 g/day >9 years	Safe under proposed conditions of use
Viable embryonated eggs of the whipworm *Trichuris suis*	(EFSA Panel on Nutrition Novel foods and Food Allergens (NDA), Turck, Castenmiller, De Henauw, Hirsch-Ernst, Kearney, Maciuk, Mangelsdorf, McArdle, Naska, Pelaez, Pentieva, Siani, Thies, Tsabouri, Vinceti, Cubadda, Engel, Frenzel, Heinonen, Marchelli, Neuhäuser-Berthold, Pöting, Poulsen, Sanz, Schlatter, van Loveren, Fernandez Dumont, et al., 2019)	Application for use as food supplement	General population	15-mL bottle containing 250 viable embryonated eggs of *T. suis.*	No studies available that demonstrate the safety at proposed intake Safety cannot be established
Botanical extract derived from *Panax notoginseng* and *Astragalus membranaceus* (AstraGin™)	(EFSA Panel on Nutrition Novel foods and Food Allergens (NDA), Turck, Castenmiller, De Henauw, Hirsch-Ernst, Kearney, Maciuk, Mangelsdorf, McArdle, Naska, Pelaez, Pentieva, Siani, Thies, Tsabouri, Vinceti, Cubadda, Engel, Frenzel, Heinonen, Marchelli, Neuhäuser-Berthold, Poulsen, Schlatter, van Loveren, Ackerl, et al., 2020a)	Application for use as food supplement A combination of an ethanol extract of the roots of *A. membranaceus* and a hot water extract of the roots of *P. notoginseng* containing 1.5–5% total saponins, 0.1–0.5% ginsenoside Rb1 and 0.01–0.1% astragaloside I.	General population, excluding pregnant women	35 mg/day determined to be maximum (Note application originally for 350 mg/day max)	Safety established at 0.5 mg/kg per day for target population (equivalent to 35 mg/day)
Nicotinamide riboside chloride	(EFSA Panel on Nutrition Novel foods and Food Allergens (NDA), Turck, Castenmiller, de Henauw, Hirsch-Ernst, Kearney, Maciuk, Mangelsdorf, McArdle, Naska,	Application for use as food supplement	Healthy adult population	300mg / day	Safe under the proposed conditions of use for the healthy adult population, excluding pregnant and lactating women, and that an intake of the NF up to 230

Novel Food	Reference	Comment	Target population	Maximum daily amount	Status /Conclusion
	Pelaez, Pentieva, Siani, Thies, Tsabouri, Vinceti, Cubadda, Engel, Frenzel, Heinonen, Marchelli, Neuhäuser-Berthold, Pöting, Poulsen, Sanz, Schlatter, van Loveren Agnès de Sesmaisons-Lecarré, et al., 2019)				mg/day is safe for pregnant and lactating women
Chia seeds (*Salvia hispanica L.*) powders	(EFSA Panel on Nutrition Novel foods and Food Allergens (NDA), Turck, Castenmiller, de Henauw, Hirsch-Ernst, Kearney, Maciuk, Mangelsdorf, McArdle, Naska, Pelaez, Pentieva, Siani, Thies, Tsabouri, Vinceti, Cubadda, Engel, Frenzel, Heinonen, Marchelli, Neuhäuser-Berthold, Pöting, Poulsen, Sanz, Schlatter, van Loveren, Matijević, et al., 2019)	Composition similar to chia seeds previously recognised as safe novel food	General population	Intake estimates not required	Safe under proposed conditions of use

1.2.2.1 Allergen Labelling opinion

An interesting application was the request to exempt all foods manufactured using starch, modified starches, and glucose syrups that have been made from barley starch from allergen (gluten) labelling requirements for foods (EFSA Panel on Nutrition Novel foods and Food Allergens (NDA), Turck, Castenmiller, Hirsch Ernst, et al., 2020). The outcome was not in favour of the applicant.

Only one human intervention study was provided, however the Panel noted that study used glucose syrup manufactured from barley starch and importantly that this ingredient was already exempt from allergen labelling. All other studies submitted were based on the consumption of barley and other cereals in cereal-allergic individuals. Extensive scenarios and calculations were undertaken for the evaluation showing that in all the scenarios considered for the anticipated intake, the calculated total protein intake from barley starch was above the MED/MOED for wheat (expressed in mg of wheat protein) in adults (10 mg) and children (2 mg).

As a consequence the Panel concluded that the data available are insufficient to conclude on the likelihood of adverse allergic reactions in cereal-allergic individuals upon consumption of barley starch under the conditions of use proposed by the applicant, and that the consumption of foodstuffs produced from barley starch as starting (raw) material or foodstuffs containing barley starch as an ingredient is unlikely to cause an adverse reaction in individuals with coeliac disease who are not allergic to cereals, provided that the value of gluten for 'gluten-free' foods (20 mg/kg) is not exceeded. Therefore, allergen labelling must remain on products containing barley starch (native and modified) ingredients

1.3 Generally Recognised as Safe (GRAS) Notifications in the USA

Like the EU regulatory applications and approvals in the USA provide an insight into emerging foods, food ingredients and potential associated future health claims. GRAS notifications to the FDA require a more stringent level of evidence than perhaps to the self – affirmed GRAS evaluations, and are reviewed in detail by the FDA, who when satisfied issue a "no questions" letter response. All GRAS notices and the FDA response letters are publicly available at:

https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&sort=GRN_No&order=DESC&startrow=1&type=basic&search=

Successful GRAS notices that received a no questions response form the FDA in the year to June 2020 are listed in Table 1-3. Other notifications still pending can be reviewed in the GRAS Notice Inventory at the website above.

Table 1-3 GRAS Notices finalised

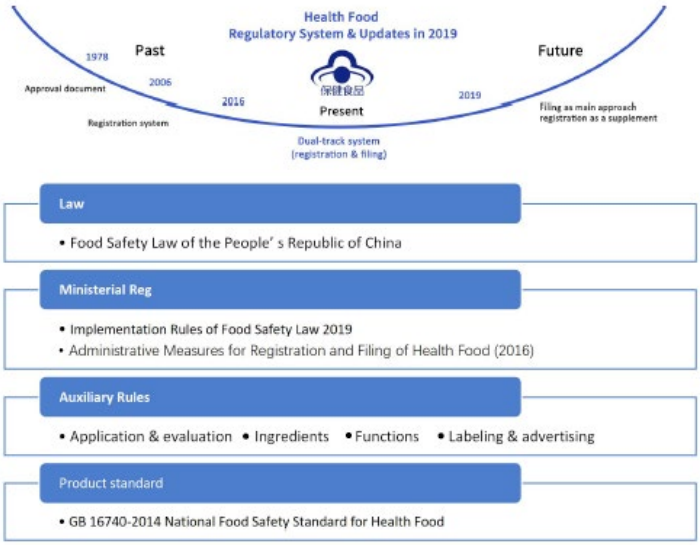
GRN No	Notice Title
883	*Ilex guayusa* leaf aqueous extract
879	Fava bean protein isolate
877	*Bifidobacterium longum* BB536
876	Hydroxytyrosol
873	Cranberry extract
872	*Bifidobacterium animalis* subsp. *lactis* UABla-12
871	*Lactobacillus acidophilus* DDS-1
870	*Ilex guayusa* leaf hydroethanolic extract
869	*Ilex guayusa* leaf aqueous extract
863	B-lactoglobulin produced by *Trichoderma reesei*
859	2'-fucosyllactose
858	Glucosylated steviol glycosides
856	*Bifidobacterium animalis* subsp. *lactis* strain BB-12
854	Agave mixed fructans from *Agave tequilana*
852	2'-fucosyllactose
851	Pea protein

GRN No	Notice Title
850	Olein from shea tree nut extract
849	Inulin from artichoke
848	Pea and rice protein fermented by *Shitake mycelia*
847	*Lactobacillus plantarum* ECGC 13110402
846	Rebaudioside M
844	Algal oil (55% docosahexaenoic acid) from *Schizochytrium sp.* strain FCC-3204
843	Algal oil (35% docosahexaenoic acid) from *Schizochytrium sp*. strain FCC-1324
840	*Lactobacillus paracasei* strain F19
839	Purified steviol glycosides
838	Purified steviol glycosides
837	Hydroxytyrosol
836	Algal oil (50-60% docosahexaenoic acid) from *Schizochytrium sp*. HS01
834	Preparation containing bacterial phages specific to shiga-toxin producing *Escherichia coli*
833	Lacto-N-tetraose
831	*Bacillus subtilis* DE111
829	Powdered *Aspergillus oryzae* grown with one or more added minerals
828	D-psicose
827	Preparation containing three bacterial phages specific to several *Escherichia coli* serotypes
825	Beta-galactosidase from *Kluyveromyces lactis*
824	Bacteriocin preparations specific to Salmonella
823	Rebaudioside E
822	Curcumin
819	Fatty acid ethyl esters from Alaskan Pollock
818	Isomalto-oligosaccharides
817	Serine endopeptidase from *Malbranchea cinnamomea* produced in *Trichoderma reesei*
816	Xylooligosaccharides from sugarcane
815	2'-fucosyllactose and difucosyllactose
814	*Bifidobacterium bifidum* BGN4
813	*Bifidobacterium longum* BORI
811	Phospholipase A1 produced by *Aspergillus oryzae*
807	*Streptococcus salivarius* M18
804	Pea protein
803	Pea protein
801	Chymosin enzyme from C*amelus dromedarius* produced in *Aspergillus niger*
798	*Saccharomyces cerevisiae* strain yBBS002

1.4 China

No major changes to the structure of the health food regulations have been introduced in China in the year to June 2020, however the major issue facing regulators remain fraudulent advertising misbranding, false functional claims and adulterated products (O'Brien et al., 2020) are starting to be addressed through labelling and advertising regulations, and a gradual refinement of existing regulations. Regulatory reforms are expected to continue throughout 2020 to address these issues together with increasing the ability to drive innovation.
The current status of the health food regulations in China is summarised in Figure 1-1:

Figure 1-1 Administration of Health Foods and Updates



1.4.1 Approval rates of health foods

With access to the authority databases, O'Brien et al. (2020) reported that through to 11 December 2019 China competent authorities (including the now SAMR, former Food and Drug Administration, former Ministry of Health) had granted blue hat certificates to 16,859 domestic health foods and 780 imported health foods, as shown in the database of China FDA. Since the dual-track system was initiated in 2016, over 3500 domestic health foods and 67 imported health foods obtained blue hat certificates through filing.

The approval of health foods with function claim has been impacted significantly by the 2018 abolishment of Technical Standards for Testing & Assessment of Health Food means there is currently no standard to assess health food functional, physiochemical, and toxicological properties. The cancellation of this standard places a significant obstacle on companies looking to register health foods. The 454 (Table 1-4) approved domestic products were accepted mainly in 2010-2014 when the technical standards were still in place, which means their registration adheres to old standards. Since China's new health food regime was established in 2016, there have been no new health foods registered.

Table 1-4 Approval rates of Health Functional Foods

Year	No. of domestic products	No. of imported products
2016	4686	4
2017	834	17
2018	3	0
2019	454	0

In contrast approval for nutrient supplements managed by local authorities for domestic applications and SAMR for imported nutrient supplements, and 22 approvals were reported by SAMR in 2019.

1.4.2 Health food raw materials and functions

New “Administrative measures on Directory of Health Food Raw Materials and Directory of Health Functions” were published by in by China State Administration for Market Regulation (SAMR) in August 2019, becoming effective on October 1 2019. The measures apply to the formulation, adjustment, and publication of the Directory of Health Food Raw Materials and Directory of Health Functions. It specifies basic requirements for health food raw materials and function claims, prohibitions, procedures of expanding the lists, application documentation, etc. Under the old regulatory framework, SAMR would designate qualified agencies to conduct studies on certain raw materials or functional claims before approving or rejecting the claim or the ingredient. Under the new system, companies and individuals will be able to propose the addition of new ingredients to the health food raw materials directory and also expand the permitted functional claims (O’Brien et al., 2020).

1.4.3 Health food warning labels

In August 2019 SAMR published a “Health Food Labelling Warning Language Guide” which specifies the warning information that should be included on health food packages. This includes a warning statement ("Health foods are not medicines and cannot replace medicine to treat diseases"), production date and shelf-life, complaint contact telephone number and consumption advice ('health foods are not medicines and cannot replace medicine to treat diseases') in prominent positions – especially on e-commerce platforms. The rationale behind the release of this guide is to protect consumers and make sure consumers can differentiate between blue hat certified health foods, medicines, and general foods.

1.4.4 Health food naming guidelines

The Health Food Naming Guideline 2019 promulgated November 2019 by SAMR applies to all health food registered or filed China. This regulation stipulates that all product names must be accurate and cannot indicate any disease prevention or treatment function. Additionally, one registered/filed product formula can only be associated with one product name. Specifically the requirements for brand name, generic name and attribute name are defined.

- **Brand name:** The characters used shall conform to “Trademark Law”, and the brand name cannot explicitly or implicitly suggest disease prevention or therapeutic efficacy. For example, products with the function of eye fatigue relief are not allowed to be named as “Good Eyesight”.
- **Generic name:** Generally, the generic name of a registered drug cannot be used, with the exception of situations where the active ingredient is approved for use as both a drug and a health food and the drug has already been named after this primary active ingredient. Exceptions also apply in situations where the health food registration was granted prior to drug registration approval.
  If the product is made from a single active ingredient, then it shall be named after this active ingredient’s name or its abbreviation. If the product contains multiple active ingredients, the active ingredient with the highest concentration shall be used as the products generic name**.**
- **Attribute name:** Attribute name reflects the product’s dosage form or food classification, and its naming shall follow the corresponding national food safety standard, industry standard or local standard where applicable. Otherwise the “Chinese Pharmacopoeia” will be the reference used if the dosage form is similar to a drug dosage form as specified within the pharmacopeia.

1.4.5 Improved supervision of health food advertising

The “Interim Administrative Measures on the Review of Health Food, FSMP, Drug and Medical Devices Advertisements came into force in March 2020 and is applicable to the review of health food, FSMP, drug and medical devices' advertisements. It specifies the advertising requirements of health food and FSMP, advertisement prohibition, dossiers required, review procedure, penalties and etc. Health food advertisements cannot claim therapeutic/clinical efficacy or utility in the treatment of diseases. The advertised content must be consistent with the information submitted to authorities during registration or filing. Health food

advertisement shall indicate the disclaimer that “health food is not a pharmaceutical drug and cannot replace medicine to treat any disease." Additionally, the health food certification mark should be indicated, as too should the target population and any unsuitable populations.

1.4.6 Auxiliary Materials for Health Food

The “List of Auxiliary Materials for Health Food Filing and Terms of Use (2019) edition” came into force in December 2019. It included 17 new ingredients compared to the draft regulation of 2017.

1.4.7 Health claims in China under review

Consultation processes are still in progress that are reviewing:

a. The adjustment and cancellation of health food functional claims. This proposal seeks to change the terminology for 18 of the current 27 permitted claims as per Table 1-5.

Currently there is no time specified for the conclusion of this consultation process.

Table 1-5 Proposed health claim terminology changes

SN	Before revision	After revision
1	Immune regulation/ enhance immune function	Help to enhance immune function
2	Anti-fatigue/ relieve body fatigue	Relieve body fatigue
3	Anti-oxidation	Aid anti-oxidation
4	Increase/improve bone density	Aid bone health
5	Improve gastrointestinal function (laxative function)/ defecation	Help to reduce constipation
6	Improve gastrointestinal function (regulate enteric bacteria flora)/ regulate enteric bacteria flora	Help to regulate enteric bacteria flora
7	Improve gastrointestinal function (promote digestion)/ promote digestion	Help to facilitate digestion
8	Improve gastrointestinal function (have protective function against gastric mucosa injury)/ have protective function against gastric mucosa injury	Aid protecting gastric mucosa
9	Anti-hypoxia/ improve ability to anti hypoxia	Anti-hypoxia
10	Weight loss	Aid balance of body fat
11	Beauty (get rid of chloasma)/ get rid of chloasma	Aid alleviation of chloasma
12	Beauty (get rid of acne)/ get rid of acne	Aid alleviation of acne
13	Beauty (improve skin moisture/oil balance)/improve skin moisture	Aid improvement of skin moisture
14	Improve memory/ aid improvement of memory	Aid improvement of memory
15	Clear and nourish throat/ clear throat	Clear and nourish throat
16	Alleviate nutritional anemia/ iron-deficiency anemia	Aid alleviation of iron-deficiency anemia
17	Improve eyesight/ relieve eye fatigue	Relieve eye fatigue
18	Improve sleep	Help improving sleep

b. Cancel 3 of the 27 currently permitted claims (Table 1-6)

Table 1-6 Proposed health food function claims for cancellation

SN	Items to be removed
1	Beautify/balance skin lipid
2	Facilitate growth / improve growth
3	Stimulate lactation

c. Addition of new health food raw material ingredients. Currently 10 new materials are under consultation.

1.5 Japan

In Japan, Foods for Specified Health Uses (FOSHU or TOKUHO) claims, although shrinking in market value, are reported to represent the largest share of the health food and supplements market, however Foods with Function Claims (FFC) have been growing consistently since their introduction in 2015. A total of 2,887 FFC products have been approved by the Consumer Affairs Agency (CAA) since 2015, however in May 2020 NutraIngredients Asia.com reported only 1325 were currently available in the market.

Following the release and implementation (July) of the new Food Labelling Standard, the CAA updated the schema for the food labelling categories (Figure 1-1). In conjunction with the Standard an update to the Food Labelling Act has been published with implementation scheduled for June 2021. Changes are intended to provide more clarity and enable increased enforcement.

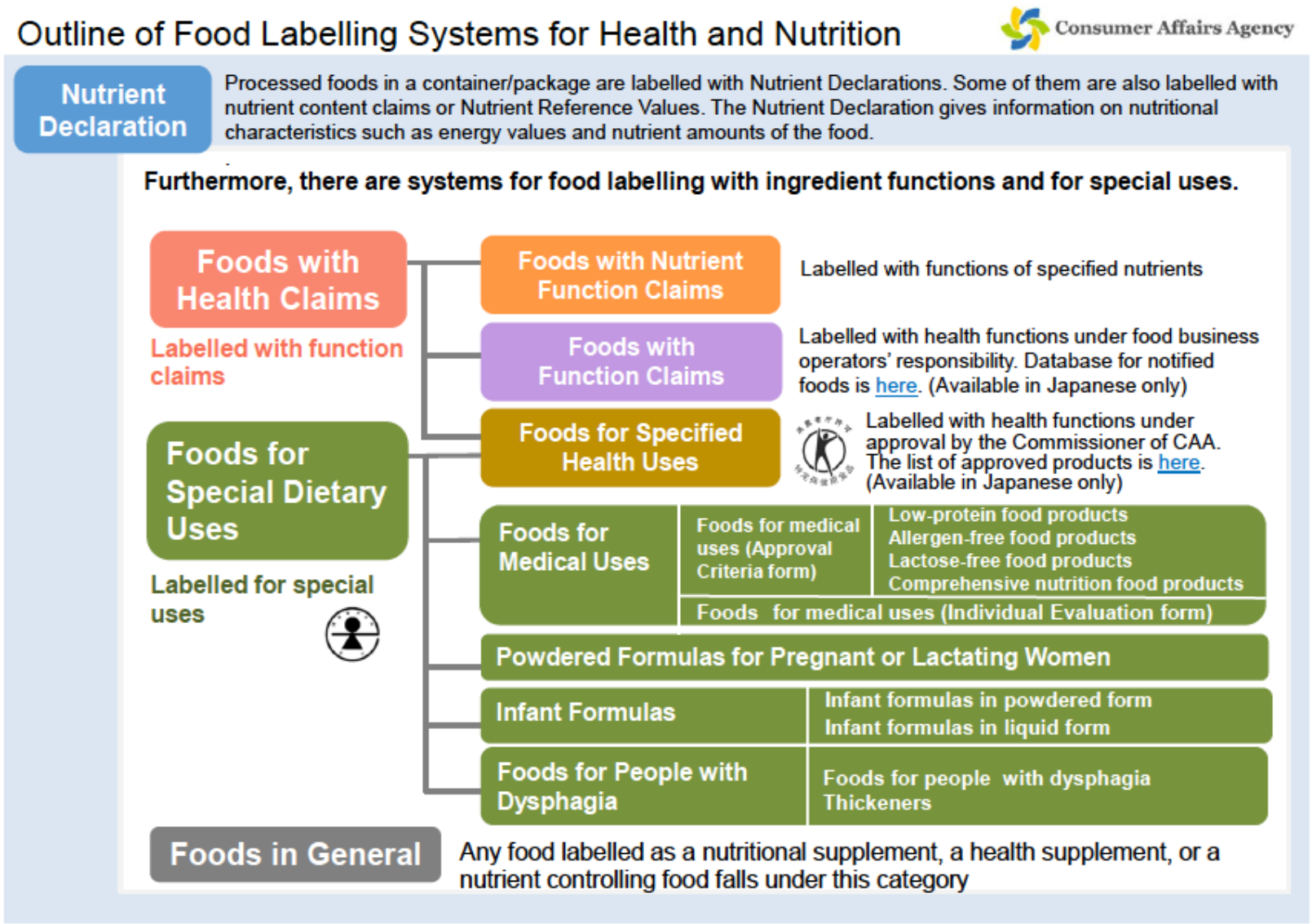
The updated Food Labelling Standard also included almonds in the voluntary allergen labelling scheme. The 21 allergens that may be labelled voluntarily are:
Almonds, orange, kiwifruit, peach, apple, banana, yam, matsutake mushrooms, cashew nuts, walnut, sesame, soybean, abalone, cuttlefish, salmon roe, trout, mackerel, beef, chicken, pork, gelatine. Compulsory allergen labelling is in place for e*gg, milk, peanut, wheat, buckwheat, shrimp/lobster, and crab.* Failure to label the compulsory allergens results in compulsory product recall.

1.5.1 Food with function claims (FFC) – quality of systematic reviews investigated

The registration of FFC in Japan, requires that stakeholders submit a notification to the CAA confirming that the products meet all safety standards and that any claims made are supported by a body of high-quality scientific evidence. Similar to the FSANZ standard the evidence base is required to include a systematic review. When first introduced in 2015, quality requirements for the systematic reviews were not detailed, however the CAA undertook a detailed verification in 2016, identifying several issues, including quality of data, which should be addressed by businesses wanting to register FFC. (https://www.caa.go.jp/policies/policy/food_labeling/about_foods_with_function_claims/pdf/food_with_function_report_0003.pdf)

Kamioka et al. (2019) undertook a review to assess the quality of SRs based on the FFC registered on the CAA website in Japan, and to determine whether the CAA's verification report in 2016 was associated with improvement in the quality of SRs. After the selection criteria were applied 108 systematic reviews were included in the quality appraisal, which followed strict protocols.
The researchers concluded:
"*Overall, the quality of methodology and reporting in after-SRs based on the FFC was poorer than that based on before-SRs. In particular, there were very poor descriptions and/or implementation of study selection, data extraction, search strategy, evaluation methodology for risk of bias, assessment of publication bias, and formulating conclusions based on methodological rigor and scientific quality of the included studies.*
To develop SRs of the FFC and launch a similar global food claim notification system, the following factors will be important: (i) applicants will need to use some global standard checklist such as AMSTAR 2, PRISMA, or PRISMA-NMA; (ii) applicants will need to critically examine the quality when using another applicant's SR; (iii) academic researchers should support the food industry in order to perform an SR and/or clinical trial properly; and (iv) country authorities should confirm that the notification SR is above a certain level of quality" (Kamioka et al., 2019).

Figure 1-2 Updated schema of food labelling systems for health and nutrition in Japan



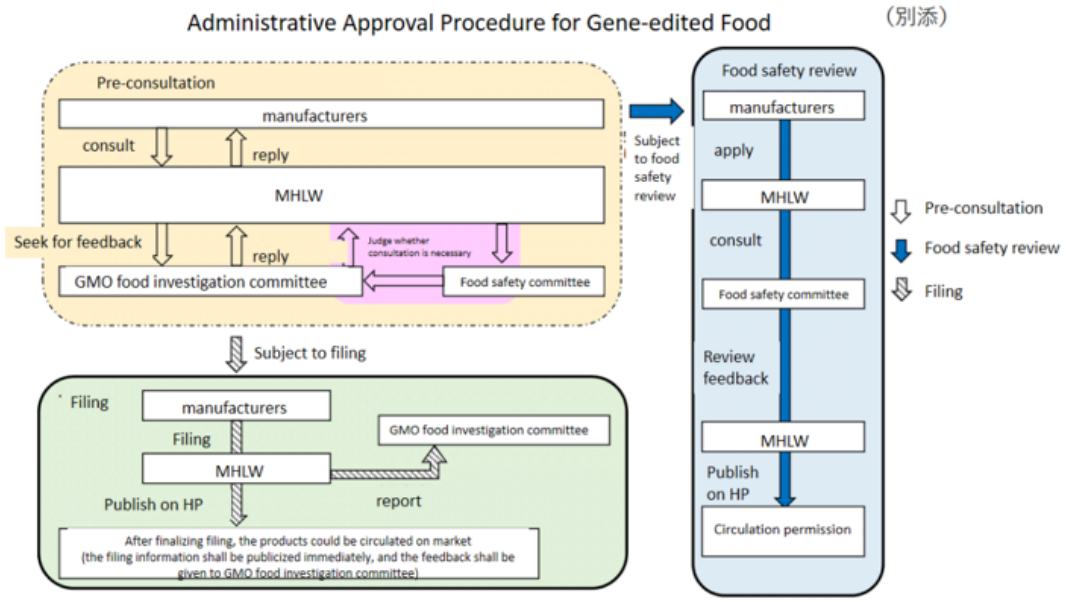
1.5.2 Gene edited foods

A number of new sources of "health foods/ ingredients" are being developed using gene-based technologies, some of which make production of the foods more economic and ensure security of supply. New regulations introduced in Japan in September 2019 require that all food products (both domestically manufactured and imported) containing gene-edited ingredients must apply for official pre-consultation before administrative approval.

Gene-edited food products will be subject to filing or food safety review (which is stricter than filing) after going through pre-consultation. Filing applies to products satisfying one of the following conditions:

- The food product is obtained through gene-edit technology
- The food product is produced through gene-edited microorganism

Figure 1-3 Administrative approval procedure for gene-edited foods



1. Food products defined as GMO and require food safety review are subject to No. 233 announcement issued by MHLW in 2000
2. Enterprises could consult with food safety committee for the new food and new technology, and the authority will give a final decision

1.6 South Korea

Agencies in Korea have updated and released a significant number of regulations that impact functional, health and special purpose foods, particularly labelling requirements.
In addition, in April 2020 the Korean Ministry of Food and Drug Safety (MFDS) released an updated "Food Code". The Food Code includes the following Chapters and is scheduled for progressive introduction through to October 2020:

- Chapter1. General Provisions
- Chapter 2. General Standards and Specifications, which consists of material standards, manufacturing and processing standards, standards and specifications of general food, standards of storage and distribution
- Chapter 3. Standards and Specifications of Food for Infants and Young Children
- Chapter 4. Standards and Specifications of long-preserved food
- Chapter 5. Standards and Specifications for Each Food Category
- Chapter 6. Food Cooking Standards and Specifications of Restaurants, etc.
- Chapter 7. Sampling Method

Much of the updated legislation in Korea will also support the MFDS announcement in December 2019 of the intention to encourage growth in food development in 5 specific areas before 2022. The announcement included plans for the staged changes, both regulatory and consumer-focussed needed to achieve the objectives to grow these initiatives.
(https://www.mfds.go.kr/brd/m_99/view.do?seq=43846&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=1) (O'Brien et al., 2020).

Table 1-7 MFDS Initiatives to support emerging food development.

Initiative	Specific Target	Background	Activities to support
1. Foods designed for specific groups	Foods for special medical purposes (FSMP)	Global market for FSMP increasing 6.9% per annum Increase in aging population and incidence of chronic disease suggests demand FSMP will continue to increase	- MFDS will separate FSMP food from the current food classification hence FSMP will become an independent food category; - Further standards and specification will be formulated for FSMP foods designed for specific diseases; - Promote the industry development of the FSMP sector
	Aging- friendly / senior foods	By 2025 Korea is predicting 20.3% of the population will be > 65 years. Due to lack of specific policy, consumers do not recognise the value of aging-friendly foods.	- To stimulate the development of the senior food market, South Korea will implement the KS (Korea Industrial Standards) certification system on senior food to increase consumption recognition. - At the same time, the government will provide senior food to the old through public authorities, such as the welfare home.
	Alternative foods (including organic & plant-based alternatives)	- Plant-based alternatives were first developed for vegetarians and vegans. - Due to the enhanced awareness of health and environmental protection, Korean consumers are tending to purchase more alternative products such as	- Preferential policies will be launched to encourage investment e.g. enterprises that research the technology to develop plant-based alternatives can enjoy the "tax-free" policy. - Regulations of its labelling, specification, safety management

Initiative	Specific Target	Background	Activities to support
		organics and/or plant-based meat alternatives.	procedures, etc. will be formulated before 2022.
	Pet food	Due to an increase in the number of pets, the pet food market in Korea is expanding. In 2016, imported pet food took over 65.3% of the whole market.	Pet food will be separated from the animal feed and will own its pet food-management code in 2020.
2. Health Functional Food	All health functional foods	The global functional food market is increasing at approximately 5.9% per annum and the production value of health functional foods in Korea increased 16.7& in 2018 to a value of 1728.8 bn SKW.	- Further grow the market through developing a regulatory and business support systems - By revising relevant code, substantiated pharmaceutical ingredients can be used in the manufacture of health functional food; the functional labelling system can be applied to ordinary food once it is with substantiated evidence; - Permission to sell health functional foods in large scale supermarket and to sell mix-packaged health functional - To set up a functional ingredient database to support product development.
3. Convenience foods	Foods that are convenient for all age groups	The convenience food market is growing at an average of 11.8% per annum & is expected to continue growing	- Reorganise regulatory structure to support innovation and access to development - Review of tax support for research and development of rapid cooling and thawing technology, which is a basic technology for high-quality convenience food, and support R&D for development of premium products. - Develop global standards for convenience foods such as instant rice, RTE meals and processed seaweed.
4. Environmentally-friendly foods	Sustainability of food cycles	This market is expected to grow with the increasing awareness of Environmental protection	- To implement the certificate system of “Processed with pesticide-free ingredients"; optimize the labeling standard of “organic food”; - Build up zones for compound organic agriculture service - Project to produce agricultural products that are suitable for pregnant women
5. Export foods	All potential export markets including UN procurement markets.	Exported foods as Korean (K)-Food's global preferences increase: - Global preference for K-food increases due to the spread of Korean Wave and the increase of foreign tourists - Number of overseas tourists visiting Korea: 2010: 8.8 million → 2015: 1,323 → 2018: 1,535 - Overseas Korean food awareness: 2011: 24.2% → 2016: 64.4%	- Support for online and offline sales - Support for new markets such as new and southern markets, halal and UN procurement markets - Strengthen marketing support using Korean Wave and Korean culture - Expansion of non-tariff barrier consultations between countries

1.6.1 Updates to Korean Labelling and Advertising legislation

Many regulations, including the labelling and advertising regulations, in Korea are based on a hierarchical structure. Updates to the Act on Labelling and Advertising of Foods and the Health Functional Food Act, together with subordinate legislation are summarised in Table 1-1 and Table 1-2.

Table 1-8 Structure & updates of Korean Labelling and Advertising regulations

Hierarchy	Name of Regulation	Revision Date	Main Content
Main Act	Act on Labelling and Advertising of Foods	April 2020	This act is applicable to all kinds of food in South Korea. This act includes the definitions and terminology, relationship to other statutes, labelling standards, advertising standards, prohibition of false labelling or advertising, substantiation of claims in labelling or advertising, voluntary review of labelling or advertising, advice on labelling or advertising policies, suspension, penalty and etc.
Enforcement decree	Enforcement Decree of Act on Labelling and Advertising of Foods	March 2019	This enforcement decree is applicable to all kinds of food labelling and advertising in South Korea. It includes the regulations on improper labelling and advertising, standards of review on labelling and advertising, registration of voluntary review committee, raising of an objection to the review result, regulations on administrative penalty and etc.
Enforcement rule	Enforcement Rule of Act on Labelling and Advertising of Foods	April 2019	This enforcement regulation is applicable to all kinds of food labelling and advertising in South Korea. It includes partly labelling items in specific cases, general labelling items, responsible person for food labelling, labelling method, nutrition facts label, sodium content comparison label, advertising standards, substantiation of claims methods, food subject to voluntary review of labelling or advertising, fee, registration for voluntary review committee, education, administrative penalty standards, etc.
Subordinate regulations	Health Functional Food Labelling Standard	June 2019	This standard is applicable to all kinds of health functional Food in Korea. This standard includes the detailed information of term definition, labelling content, method, exceptions, allowable weight error, etc.
	Food Labelling Standard	May 2020	This standard is applicable to labelling matters of food, livestock products, food additives, containers or packaging. It includes the definition and terminology, general labelling standard, individual labelling items and the relevant labelling standards, etc. to be implemented progressively through to January 2022

Table 1-9 Structure & updates of Korean Health Functional Food regulations

Hierarchy	Name of Regulation	Revision Date	Main Content
Main Act	Health Functional Food Act	April 2020	This act is applicable to all kinds of food in South Korea. This act includes the definitions and terminology, relationship to other statutes, labelling standards, advertising standards, prohibition of false labelling or advertising, substantiation of claims in labelling or advertising, voluntary review of labelling or advertising, advice on labelling or advertising policies, suspension, penalty and etc.
Enforcement decree	Enforcement Decree of Health Functional Food Act	June 2020	This enforcement decree is applicable to all kinds of health (functional) foods in Korea. This enforcement decree defines the entrusted affairs and other affairs thereof. It includes the information of terminology and definition of business types, permission for business, standard for qualification of quality controller, inspection affairs, operation details, rewards and punishments and etc.

Hierarchy	Name of Regulation	Revision Date	Main Content
Enforcement rule	Enforcement Rule of Health Functional Food Act	June 2020	This enforcement regulation is applicable to all kinds of health (functional) foods in Korea. This regulation includes the entrusted affairs and other affairs thereof in Health Functional Food Act and Enforcement Decree of The Health Functional Food Act. It includes detailed information of terminology and definition of health food, business types and facility standards, permission for business, reporting, criteria and standards, recognition of raw materials, label, advertisement, inspection, good manufacturing practice regulation etc.
Subordinate regulations	Health Functional Food Good Manufacturing Practice (GMP)	December 2019	This regulation is applicable to all kinds of health functional foods in Korea. This standard includes requirement of workplace, storage/manufacturing/quality control equipment, manufacturing/manufacturing management/manufacturing hygienic management/quality control standard document, etc.
	Food Traceability Management Standard	December 2019	This standard is applicable to the traceability management of food, livestock products, health functional food and imported food in Korea. This standard includes the detailed information of food trace registration number application, registration assessment, attaching method of food traceability management number, verifying food traceability management information, etc.
	Requirements on Food, etc.	February 2020	This requirement is applicable to food subject to inspection order under Korea food relevant regulations and food designated by MFDS. This requirement includes the scope of the food subject to inspection order, procedure of inspection, report of non-compliance product, submission of inspection result and management, etc
	Subject to an Inspection Order	February 2020	This requirement is applicable to food subject to inspection order under Korea food relevant regulations and food designated by MFDS. This requirement includes the scope of the food subject to inspection order, procedure of inspection, report of non-compliance product, submission of inspection result and management, etc.
	Food, Food Additives, Livestock Product and Health Functional Food Shelf Life Determination Standard	March 2019	This standard is applicable to food, food additives, livestock product and health functional food in Korea. This standard includes the general principle of food, food additives, livestock product and health functional food shelf life determination standard, like basic information, shelf life determination test, testing method, etc.

The Korean MFDS also updated the regulations on:

- Health Functional Food Code (December 2019) Health Functional Food Code is to stipulate the standards and specifications of manufacture, processing, importation, distribution and storage of health function food products in South Korea. It includes:

  Chapter 1. General Provisions
  Chapter 2. General Standards and Specifications
  Chapter 3. Standards and Specifications for Each Food Category
  Chapter 4. Test Method

  Key changes in in the updated Code include:

  - Newly approved functions of already approved active ingredients will not be listed in South Korea's positive list of active ingredients and associated approved functional claims for three years;
  - Newly added the permitted and forbidden food additives for Children's health functional foods;
  - When using 2 or more active ingredients, provided that there are some overlaps in production requirements or specifications, manufacturers can choose to follow the appropriate specification requirements based on the usage ratio of active ingredients;
  - Labelling precautions for taking health functional foods containing Vitamin D, EPA, DHA, saw palmetto extract, glucosamine and fructo-oligosaccharide are added; International units were newly added to describe the daily intake of vitamin A, D and E. E.g.: "3∼10 ㎍ " was revised as "3∼10 ㎍ (120 ∼ 400 IU)"; The fructo-oligosaccharide functional claim "helps inhibit bacterial growth and contributes to calcium absorption," was deleted due to uncertainty related to functional efficacy; Functional terminology permitted to be used on "garcinia cambogia" and "marigold" products was changed to "could" help to lose body fat.
  - Residual solvent testing of evening primrose seed extract was revised; Rancidity management standard and testing method for products containing EPA and DHA have been formulated;
  - The testing methods of glucosamine was revised. Revision of the heavy metal specification of glucosamine has been stipulated under which total arsenic content shall be less than 4.0mg/kg. The daily intake of glucosamine was changed from "1.5~2g" to "1.5g".

- Inspection of Imported Health Functional Foods in March 2020. This regulation is applicable to imported health functional foods in Korea. This regulation includes the detailed information of import notification, management of distribution, inspection, verifying labels and advertisement, minimum importation amount and related document.

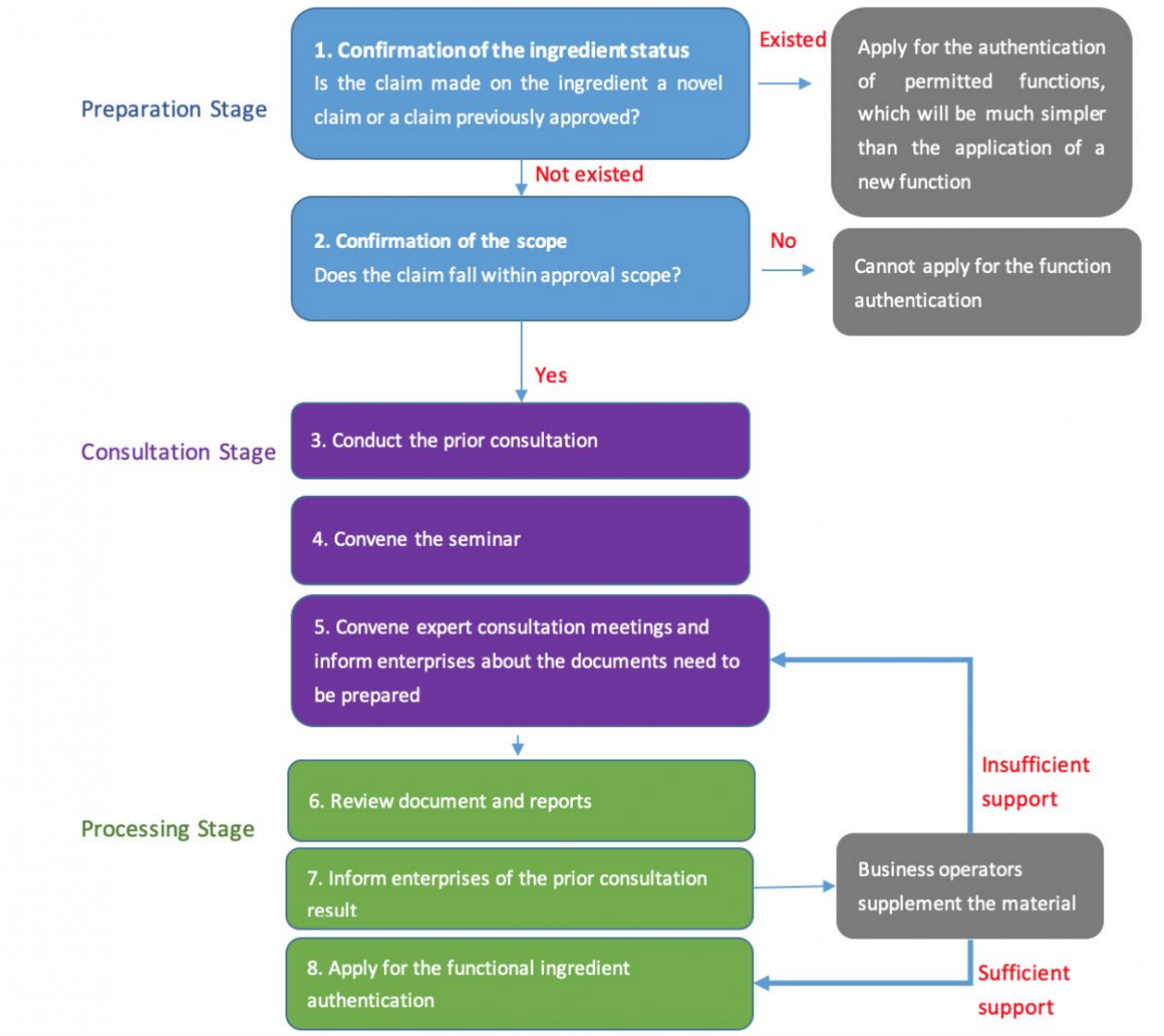
- Prohibited Materials in Health Functional Food Products (December 2019). This inventory is listed in the Health Functional Food Code, it is applicable for all kinds of health functional food products in South Korea. This inventory includes the Korean names, scientific names and variant names of the prohibited plant raw materials and prohibited animal raw materials and category of other materials.

- Guidance on Preparing Data for Certification of Health Functional Raw Materials (February 2020). This guidance is to illustrate the method of preparing data needed for applying the certification of health functional raw materials. This guidance includes the outlines of applying for certification, data prepared for the application of certification.

In November 2019 the MFDS released a guideline referring to a new consultation service to help business enterprises expedite the approval of functional foods in Korea (Figure 1-1). Together with assisting enterprises to expedite the registration process, MFDS will also conduct more rigorous investigations of all applications and ensure therapeutic or clinical efficacy claims are not used, in order to ensure consumer protection. Previously it has typically taken about 120 days to assess functional food ingredients and issue results (this step excludes time

required to conduct safety review, etc.). However, if the scientific evidence supporting the application is deemed insufficient during the review the application is rejected; requiring applicants to start the whole process again. This results in significant time and resources wasted for both the applicant and the government.

Figure 1-4 Schematic for consultation for new health functional foods



1.6.2 Korean MFDS enforcement of labelling and advertising violations of foods during Covid-19

Sales of functional foods in Korea due to COVID-19 related anxiety grew significantly , with health-related food sales increasing by 579% , and vitamin sales increasing by over 2000% in the period between 27 January and 11 February 2020 (https://www.statista.com/statistics/1101727/south-korea-impact-of-coronavirus-outbreak-on-online-functional-foods-sales/#statisticContainer). This was accompanied by an increase in illegal and misleading advertising of foods and supplements reporting to be effective against COVID-19. With the recent revisions of the Act on Labelling and Advertising of Foods and related legislation response the MFDS responded forcefully with targeted review of goods online. The Act, like similar legislation in many other countries prohibits the use of misleading advertising (Figure 1-2) that leads consumers to believe the food is effective in treating, curing or preventing disease. Administrative penalties under the Act include the potential for suspension of business licenses, revocation of business license or registration, cessation of business, or fines. As a first step MFDS requires closure of the web- pages. As of 21 May 2020, 824 illegal practises associated with the violations of the Act on Labelling and Advertising of Foods were identified and addressed

(https://food.chemlinked.com/news/food-news/south-korea-cracks-down-on-health-related-false-advertising-of-food-sold-online)

Figure 1-5 Article 8 of the Act on Labelling and Advertising of Food

Prohibition of False Labeling & Advertising
(Article 8 of Act on Labeling and Advertising of Foods)
The ban on false labeling or advertising includes:
(1) Labeling or advertising food to **mislead consumers into believing that the food is effective in preventing, treating, or curing any disease**;
(2) Labeling or advertising food to mislead consumers into believing that the food is a drug;
(3) Labeling or advertising a food mislead consumers into believing that the food is a functional health food;
(4) Labeling or advertising food in a false or exaggerated manner;
(5) Labeling or advertising food in a deceptive manner;
(6) Labeling or advertising any company or its product in a slanderous manner;
(7) Labeling or advertising a company or its food, by means of false comparison with another business entity or its food without objective evidence;
(8) Labeling or advertising in a manner that seriously disturbs public order or social morality using an expression which encourages speculation or is obscene;
(9) Labeling or advertising without a review as required.

1.7 Taiwan

Regulation of claims
In Taiwan the Taiwan FDA issues several new regulations relevant to health and functional foods:

i. "Regulations on Nutrition Labeling for Prepackaged Vitamin and Mineral Tablets and Capsules"

This regulation is applicable to pre-packaged vitamin and mineral tablets and capsules mean which are adding nutritional additives as vitamins or minerals sources.
It includes:

- Information required on the nutrition labelling
- Ways of labelling of contents of vitamins, minerals and other nutrients
- Labelling of daily nutrient intake reference values and measure units
- Data formatting of pre-packaged vitamin and mineral tablets and capsules nutrition labelling units

ii. "Regulations Governing of Criteria for the Label, Promotion and Advertisement of Foods and Food Products Identified as False, Exaggerated, Misleading or Having Medical Efficacy" (June 2019)

This regulation applies to food and food products such as food additives, detergents for food, food containers, packages, etc.
The compliance of labelling claims, promotion and advertising content will be identified from the overall evaluation of product name, product description, photos, signs, videos, sounds and other forms of information. The content related to food and food products will be identified as false, exaggerated or misleading when it

1. is contrary to established scientific consensus or other facts
2. lacks sufficient evidence
3. purports functionality in maintaining or changing human organs, tissue, physiology or appearance
4. cites the Notice No. released by the government

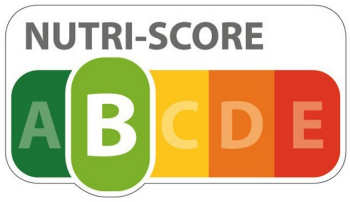
The content related to food and food products will be identified as claiming medical efficacy when it includes content related to:

1. the prevention, improvement, alleviation, diagnosis or treatment of disease, disease syndrome or symptoms

2. purports to decrease a substance in the human body involved in a pathological process
3. purports to have Chinese traditional medicinal efficacy

1.8 Singapore

To help address the high rates of diabetes in Singapore, the Singapore Ministry of Health introduced legislation that requires mandatory nutrition level labelling on the package front side for all pre-packaged sugar-sweetened beverages. The label requirement is based on the French system of 5 levels where A is the healthiest (green) and E the least healthy (red). In addition Singapore banned the advertising of E-level beverages on mass media including television, network, paper media and outdoor public places.



In an internet co-ordinated investigation (3 – 10 March 2020) co-ordinated with Interpol, the Singapore Health Sciences Authority (HAS) removed > 2,500 listings of adulterated products or products making false claims from local Singapore e-commerce platforms. The HSA also detected a significant number of product listings claiming to prevent or treat COVID-19 (Coronavirus Disease 2019). These fraudulent products included health supplements, herbs, traditional medicines and "clip-on" products. The false and misleading claims made include "strengthen the immune system against the coronavirus" or "prevent and cure coronavirus". There is currently no evidence that such products can prevent or treat COVID-19. HSA also detected rapid test kits which claimed to be able to diagnose COVID-19 within 10 minutes. Testing for COVID-19 can only be done by clinical laboratories or medical professionals in clinics and hospitals to ensure an accurate test result and diagnosis. Product listings with false claims related to COVID-19 made up about half the total number of listings taken down by HSA. Such fraudulent claims are not allowed and HSA advised it will take action against the sellers of these products.

1.9 India

On May 6, 2020, a list of FAQs with FSSAI clarifications on the Food Safety and Standards (Health Supplements, Nutraceuticals, Foods for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016, was published. This is a comprehensive document that addresses many items in the regulation. It is available (in English) from the FSSAI website at the above link.

The FFSAI extended the registration of companies making/ marketing complementary foods through to June 2020 in order to enable adequate transition. All future complementary foods must comply with the 2018 regulation "Formulated Supplements for Children" (https://fssai.gov.in/upload/advisories/2019/10/5db293180c21bDirection_Standard_Supplements_Children_25_10_2019.pdf)

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