IADSA NEWSFLASH

November 2022

Regulatory news

China

Process for new function claims

The State Administration for Market Regulation (SAMR) is consulting on its draft version of Detailed Rules on Implementation for Technical Evaluation of New Functions of Health Food.

This document clarifies that the proposed new functions shall belong to one of the three categories: supplementation of dietary nutrients, maintaining or improving body health, or reducing disease risk factors.

The evaluation methods and criteria for new functions must be verified and evaluated by at least one legally qualified food inspection institution before proposing new functions. During the post-marketing monitoring period, health food with new functions shall pass the verification and evaluation by at least two legally-qualified food inspection institutions.

The proposed new functions that have successfully passed the evaluation, will be sent to SAMR by the evaluation institution together with the related evaluation materials.

Once approved by SAMR, health food with the proposed new function can be put on the market conditionally. The post-marketing monitoring and evaluation of health food with new functions can be carried out for 5 years.

Ginseng, American Ginseng, and Lingzhi added to Health Food Raw Material Directory

China's State Administration for Market Regulation (SAMR) is consulting to add ginseng, American ginseng, and Lingzhi (also known as reishi) into the current "Health Food Raw Material Directory". The proposal includes the usage requirements, specific functional claims that products can bear, and the technical specifications for each ingredient:

- Ginseng manually planted for 5 years and below, 1 - 3 g, relieving fatigue and enhancing immunity
- American Ginseng, 1,5 - 3 g, relieving fatigue and enhancing immunity
- Lingzhi, 4 - 6 g, enhancing immunity

India

New requirements for export

Exporters to India are now being informed of additional requirements for certain food categories. These relate to the registration and inspection of foreign manufacturing facilities.

In the new order, the Competent Authorities of exporting countries are required to provide a list of existing manufacturers of food products, including nutraceuticals. Health supplements are not mentioned, and it is therefore not clear if they are also covered by the requirement. The new rules take effect from 1 February 2023.

Indonesia

Guidelines for health claims

Indonesia's Food and Drug Administration (BPOM) has recently released its Guidelines for Claims for Health Supplements in accordance with the ASEAN Guideline on Claims and Claims Substantiation for Health Supplement.

The publication covers the definition of health supplement claims, claim types, supporting documents for claims, and examples of permitted/forbidden claims, and applies to both Indonesian domestic and imported health supplements. It also includes a catalogue of known and registered claims for health supplements.

The Guidelines divide claims into three types: general claims, functional claims, and disease risk reduction claims. For each type of claim, different levels of proof and supporting documents is required for the approval from BPOM.

Japan

Tablets & capsules clarified as heath foods

The Consumer Affairs Agency (CAA) of Japan has recently released a draft version of Points of Attention Regarding Health Foods Under the Act Against Unjustifiable Premiums and Misleading Representations and the Health Promotion Act. This clarifies that products in the form of tablets and capsules are clearly included in the scope of health food.

The draft proposes a batch of newly permitted health claims (including Prevention of influenza/coronavirus; enhancing natural healing ability; anti-aging) and the requirements for advertising and labelling claims of health food.

Singapore

Voluntary notification

The Health Sciences Authority (HSA) is introducing a voluntary notification initiative for companies that deal with health supplements and traditional medicines. The aim is to establish a local database of safe and good quality complementary health products that consumers can refer to when they make their purchases. It will also allow for better traceability and follow-up actions by HSA if there are any safety or quality issues.

HSA will launch this initiative in phases from 1 August 2022, starting with commonly purchased products, such as vitamin and mineral supplements, and products at higher risk of adulteration, such as those for weight loss, pain relief and male vitality enhancement.

The notifications must be submitted by a locally registered company. The HSA reservers the right to refuse the notification of products that are not compliant with HSA's regulatory requirements, and to remove non-compliant products from the list of notified products. The acceptance of a notifications does not imply that the HSA endorses the product.

Vietnam

Aligning with ASEAN on contaminants

A draft regulation is under consultation that sets out contaminant limits (including arsenic, cadmium, lead and mercury levels), test methods, management requirements, and responsibilities for health supplement companies.
It is understood that the draft regulation was developed taking into account Annex III of the ASEAN Guidelines on Limits of Contaminants for Health Supplements and the test methods for specific indicators from the Association of Official Analytical Chemists (AOAC) and national standards in Vietnam among others.

EU

Titanium Dioxide not a carcinogen substance by inhalation

The EU General Court has annulled an EU decision to classify and label titanium dioxide as a carcinogenic substance by inhalation in certain powder forms.
"The (European) Commission made a manifest error in its assessment of the reliability and acceptability of the study on which the classification was based and, second, it infringed the criterion according to which classification can relate only to a substance that has the intrinsic property to cause cancer," said the Court.

The Court added that the requirement to base the classification of a carcinogenic substance on reliable and acceptable studies was not satisfied.

Ethylene oxide: Toughen the tone

Published late summer, a regulation toughens the tone regarding the presence of ethylene oxide in food additives.

'In order [...] to ensure a high level of protection of human health, it should therefore be provided that the presence of ethylene oxide, whatever its origin, is not authorized in all food additives"' says the new law.

No residues of ethylene oxide (sum of ethylene oxide and 2-chloroethanol, expressed as ethylene oxide) greater than 0.1 mg/kg, whatever its origin, may be present in food additives.

Not all GOS novel

According to latest discussions at the EU level, Galacto-oligosaccharides (GOS) produced by an enzymatic process using ß-galactosidases from Bacillus circulans were consumed in the European Union before 1997 and would therefore not be regarded as novel. Further discussions are foreseen to clarify the status of other GOS preparations

Belgium

Use of *Zingiber officinale* in supplements

The recent monograph for the oral use of the essential oil (E.O) of *Zingiber officinale* in or as a food supplement published by Health Belgium clarified that its use is permitted under the following conditions:

The use of old and oxidized E.O. has to be avoided;

The daily intake of camphene by *Zingiber officinale* essential oil and other sources thereof that may be present in the preparation should not exceed 37.5 mg/day;

Except for use as an aroma, the use of this E.O. is not suitable during pregnancy and lactation and for under 18 years;

The use of this E.O. in food supplements should be limited to a maximum of 14 days; medical advice is warranted if prolonged use is considered;

Unless otherwise indicated on the packaging, the weight of one drop E.O. is 40 mg.

Tackling greenwashing

In order to better frame environmental claims (commonly known as green claims) and tackle greenwashing, the Belgian administration has recently issued guidance on the use of environmental claims.

These Guidelines are designed to allow companies to assess and verify whether the environmental information they intend to provide to the consumer is accurate, truthful, not misleading, and sufficiently substantiated.

According to Articles VI.93 to VI.100 of the Economic Law Code (ELC) which focusses on unfair commercial practices, whenever an environmental claim is false, misleading or cannot be verified, it falls within the scope of unfair commercial practices. These claims are punishable by penalties up to 200,000 EUR. Dubious environmental claims can also be

reported to the economic inspection contact point by any citizen.

France

Vitamin D should not be labelled as endocrine disruptor

The National Agency for Food Safety (ANSES) has recently advised against including vitamin D3 in the list of substances to be mentioned as endocrine disruptors on food products.

In a recent expert report, ANSES considers that the display of vitamin D3 could aggravate existing inadequate intakes.

Unlike other vitamins, vitamin D also behaves like a hormone and as such, it acts on the endocrine system. If intakes are too high, the endocrine balance is disturbed, which then has harmful effects on health. ANSES points out that serious effects have already been observed in humans following vitamin D overdose.

Cholecalciferol was identified as an endocrine disruptor (ED) during its assessment by the European Chemicals Agency under the Biocides Regulation. However, ANSES stresses that the doses of cholecalciferol used in biocidal products to eradicate rodents are far higher than the doses of vitamin D provided by a normal diet, including foods fortified with vitamin D.

The anti-waste and circular economy law, known as the AGEC law, plans to inform the consumer of the presence in a product of any substance considered to be an endocrine disruptor.

ANSES considers that the identification of cholecalciferol as an endocrine disruptor would contribute to giving an erroneous perception of the risk and could discourage some people from consuming foods containing vitamin D and, as a consequence, increase the current inadequate intakes observed among the adult French population.

There is an equivalent situation for iodine. Like vitamin D, the Agency emphasises that other nutrients, such as iodine, are likely to have deleterious effects by disrupting the endocrine system at high doses, whereas they are beneficial for human health in nutritional doses. It is therefore against their inclusion in the list of substances which must be the subject of labelling for food products.

Melatonin: Consumers at risk are misinformed of side effects

Labels of food supplements containing melatonin which claim better sleep, too rarely remind consumers that they are not recommended for certain people, the Directorate General for Competition Policy, Consumer Affairs and Fraud Control DGCCRF has warned.

DGCCRF also made reference to an opinion from ANSES (French Agency for Food, Environmental and Occupational Health & Safety) in 2018 highlighting the risk of melatonin supplements for some people. The side effects reported by ANSES were diverse: general symptoms (headaches, dizziness, drowsiness, nightmares, irritability) and neurological (tremors, migraine) and digestive (nausea, vomiting, abdominal pain) disorders. These include people with epilepsy, asthmatics, people with mood, behaviour or personality disorders, children, pregnant or breastfeeding women.

The results of this survey must lead to a renewed vigilance of the most sensitive consumers, stated the DGCCRF, which strongly encourages these people to seek advice from a health professional before taking a melatonin-based supplement.

Piperine in the hot seat

Following several reports of hepatitis in Italy and France, ANSES is drawing attention to the risk of adverse effects occurring in association with the consumption of food supplements containing turmeric.

While the French Authority recognised that the exposure of the French population remains low with 27 mg for heavy consumers, the intake does not appear to exceed the ADI. However, ANSES points out that new formulations can pose a risk of adverse effects, notably by increasing the bioavailability of curcumin in the body by combining it with other ingredients such as piperine.

Recently, Italy has recorded around 20 cases of hepatitis involving food supplements containing turmeric. In France, ANSES's nutrivigilance scheme has received over 100 reports of adverse effects, including 15 reports of hepatitis, potentially related to the consumption of food supplements containing turmeric or curcumin.

To prevent cases of poisoning, ANSES advises companies marketing food supplements to provide detailed data on the bioavailability of their products so that a specific maximum daily intake level may be defined.

A similar line is taken by Luxembourg that has recently advised against the consumption of food supplements containing more than 2 mg of piperine, either as a pure substance or in the form of highly concentrated pepper extracts, and especially for people taking medication because of the risk of interactions, for children, pregnant women, and people with high blood cholesterol levels.

Denmark

First country in the world to develop climate label for food

Danish shoppers will soon be able to compare their food products on the basis of how environmentally friendly they are, thanks to a new initiative developed by the authorities.

The Danish Ministry of Food, Agriculture and Fisheries has announced plans to spend DKK 9 million on a state-controlled climate labelling system for food. The government expects to have made significant headway on the labelling system by the end of 2022 and is currently establishing a working group to lead the project.

The aim of this group will be to propose a label which is “unambiguous, simple and easy to understand” for consumers, according to the government.

B2B and Titanium dioxide

Denmark has revised in September its interpretation of the phase out period related to use of titanium dioxide in business to business (B2B) trade, clarifying that it is possible to sell food with titanium dioxide both wholesale and directly to the consumer until the shelf life expires if produced before 7 August 2022.

Germany

Dry Gingko biloba extract confirmed as medicine

Products containing Ginkgo biloba dry extract as the main active ingredient at 100 mg per day should be considered as medicines, not food supplements, Germany's federal administrative court has ruled.

The decision issued by Germany's federal administrative court (BVerwG) settles a longstanding dispute between the Federal Office of Consumer Protection and Food Safety (BVL), and a company that had applied for registration of such a product.

In 2012, the BVL rejected the company's application, a decision that the latter challenged unsuccessfully at lower court levels.

In its recent decision, the federal administrative court supported the conclusion of the Lüneburg Higher Administrative Court's which was of the view that 100 mg represented a health risk to consumers.

Italy

Tumeric claims prohibited

The Italian Ministry of Health is prohibiting all health claims related to turmeric and issuing a new warning to be displayed on product labels.

In light of the persistence of cases of hepatotoxicity linked to the intake of food supplements containing Curcuma longa extracts and preparations, the interdisciplinary group of experts decided to strengthen the regulatory action taken in 2019 and expand the wording of this warning statement as follows:

IMPORTANT WARNING In case of alterations in the liver function, biliary or gallstones of the biliary tract, the use of the product is not recommended. Do not use during pregnancy and lactation. Do not use for prolonged periods without consulting your doctor. If you are taking any medications, you should seek the advice of your doctor.

This group also concluded that there is no scientific evidence to support the physiological effects attributed to Curcuma longa in the ministerial guidelines. As a consequence, the physiological effects previously authorised can no longer be used.

The UK Committee of Toxicity seems to have, however, a different position on this issue. In its recent meeting, the committee concluded that consumption of conventional turmeric supplements should not pose a significant risk to the population

Poland

Negative list extended

The Polish Food Supplements Team of the Chief Sanitary Inspector (GIS) has recently updated its negative list of substances prohibited for use in food supplements (attached), by including 4 new substances:
Vodiamine, an alkaloid compound with a quinazoline carboline skeleton obtained from the dry, unripe fruit of the Evodia rutaecarpa plant, also known as Tetradiurn ruticarpum. Evodiamine has been found to be highly hepatotoxic and cardiotoxic, and therefore should be monitored in a clinical setting.

SARMs, a group of selective androgen receptor modulators, known as non-steroidal compounds with anabolic activity. These substances have been placed by the World Anti-Doping Agency (WADA) on the list of substances and methods prohibited in sport in the group S1 "Anabolic Agents" "Other anabolic agents."

Higenamine, a beta -2 agonist of plant origin. Since 2017, this substance has been on the List of Prohibited Substances and Methods of the World Anti-Doping Code in group S3 "Prohibited at any time (in and out of competition)". Higenamine occurs naturally in plants such as *Nelumbo nucifera, Tinospora crispa, Nandina domestica, Gnetum parvifolium, Asarum siebodii, Asarum heterotropoides, Aconitum carmichaelii and Aristolochia brasiliensis.*

Hordenine, N, N-dimethylthyramine is a phenethylamine alkaloid found in plants such as grains, germinating barley and cactus. Hordenine is also present in small amounts in bitter orange.

The authorities have also aligned their national regulation with EU rules by prohibiting the use of aloe leaf preparations (extracts, juice and gel) as ingredients in food supplements.

Switzerland

Aligning with EU

Following the third full revision of the Swiss food legislation which entered into force in July 2020 the Swiss Federal Council
opened a new consultation procedure, so called Stretto 4 package aligning further a number of Swiss ordinances with EU food
law provisions. A number of changes are foreseen in the following ordinances related to food supplements:

Ordinance on food supplements (Verordnung des EDI über Nahrungsergänzungsmittel (VNem)): Additional elements related to the designation "food supplement" and requirements on 15% ingredients content will be aligned with the EU provisions. As pointed out by the Swiss authorities the maximum levels stipulated in the legislation are based on health protection and not on a health need. In individual cases, a significant amount of a substance can therefore also be contained if less than 15% of the maximum amount is contained. The ordinance is therefore to be amended so that, in exceptional cases, a deviation from this provision is possible if it can be proven on the basis of generally accepted scientific data and information that the substance is present in an amount that achieves a nutritional or physiological effect. Evidence must be documented as part of the self-assessment.

With Regulation (EU) No. 2021/4185, magnesium citrate malate and nicotinamide riboside chloride were included in Annex II of Directive 2002/46/EC in the EU as permitted sources for magnesium and niacin respectively. These two will therefore also be included in Appendix 2 in Switzerland as permitted sources for magnesium and niacin in food supplements. A maximum level of 300 mg for food supplements for the general adult population (excluding pregnant and lactating women) and 230 mg for pregnant and lactating women will be included for niacin.

As regards amino acids, the maximum levels for the amino acids L-isoleucine, L-leucine and L-valine will be adjusted based on the BfR opinion 052/2019 on the isolated intake of the branched-chain amino acids

On botanicals: With the revision of the Swiss Ordinance on foods of plant origin, mushrooms and table salt (Verordnung des EDI über Lebensmittel pflanzlicher Herkunft, Pilze und Speisesalz (VLpH, SR 817.022.17)) the Ordinance has been amended accordingly. Notably, the list of prohibited plants will include plants, parts of plants and preparations made from them that are banned in food in Switzerland in accordance with Annex 1 and expanded to include herbal substances and individual specific preparations with these substances.

Annex 1 will also be expanded by an addition of a significant number of plants which have been included in the 2nd edition of "The substance lists of the federal and state governments with the participation of experts from Germany, Austria and Switzerland" because of their risks for use as or in food regardless of the dosage.

On claims: Health claims approved in the EU will be added to the Annex 14 list of approved health claims in Switzerland, including claims on carbohydrate solutions, chitosan, DHA, DHA and EPA, meal replacement for a weight control and sugar substitutes.

Novel Food: The Annex of approved novel foods is now being expanded to align with EU novel food legislation

Food supplements are popular with the Swiss population

A government survey shows that almost a third of the Swiss population takes at least one food supplement: Vitamins, preparations combining vitamins and minerals and minerals form the top three most popular products.

These supplements are mainly purchased from pharmacies, drugstores or doctors' surgeries. More than a quarter are purchased on the internet or by mail order, and nearly a fifth in retail or supermarkets.

Statistically, consumers are more often women, live in German-speaking Switzerland and in cities, and have a medium or high level of education and a high income.

More than 50% of dietary supplement users have a lifestyle largely influenced by health considerations, compared to only about 30% of the population who do not take supplements. The trend is much the same for the importance given to a balanced diet. People who are committed to a healthy lifestyle take dietary supplements more often.

UK

Further investigation for high dose ginger during pregnancy

The UK Committee on Toxicity (COT) has recently conducted a review of the potential effect that ginger supplements may have during pregnancy and lactation.

The Committee concluded that there was no clear indication that ginger is detrimental to consumers. Some concerns were however raised regarding the use of highly concentrated products.

Libya

Ban of titanium dioxide

A decision to ban the use of titanium dioxide has now been taken in Libya. A 6-month transition period is given for non-compliant products.

Saudi Arabia

Tablet & Capsules as supplements

The SFDA has recently published a Draft Document " Food Supplement Registration Guideline".

In this document tablets and capsules have been included as permitted forms of food supplements.

Canada

Canadian report on titanium dioxide on EFSA table

Minutes of an EFSA working Group on toxicology reported that " the WG was informed of the publication of a 'state of science' report on titanium dioxide (TiO2) as a food additive by Health Canada's Food Directorate.'

The minutes do not say more on whether EFSA will reconsider its opinion.

Last June, Health Canada's Food Directorate joined the UK Standards Agency in concluding that titanium dioxide was safe for human consumption. This was based on the evaluation of new scientific evidence that addresses the EU uncertainties identified by the European Food Safety Agency (EFSA) and which was not available at the time of the EFSA review.

New labelling requirements

New labelling requirements have recently been announced by Health Canada. The purpose of these amendments to the label requirements is to better align Natural Health Products (NHPs) with comparable Canadian non-prescription drug labelling requirements. In 2021, an audit by the Commissioner of Environment and Sustainable Development (CESD) found that product label information, such as safety warnings, are difficult to read without magnification, which may lead to incorrect product use. The findings were also confirmed for natural health product labels.

The new labelling requirements will come into force in three years and product licence holders will have an additional three years from that date to re-label their NHPs in accordance with the new requirements. Among the key changes:

The text on the label of the NHP must be clearly displayed and accessible for the customer. The new requirements specify the type of font (sans serif), the position and style of the headings, the spacing of the words, the contrast between font and background (font

must be dark and the background must be light with minimal transparency), and the size of the font (no smaller than between 5.5 and 6 points.

A standardized product facts table is now also required to display certain important information about a product, including medicinal ingredients, uses, warnings, directions for use, recommended storage information and contact information. This table must be on the outer label of the packaging or, if there is no outer label, on the inner label of the product. The table will have to reflect the product's terms of market authorization that were approved by Health Canada as part of the licensing of the product.

USA

New definition for "healthy"

The U.S. Food and Drug Administration (FDA) has published a proposed rule which would change the criteria for foods to carry the "healthy" claim.

Currently, there are specific criteria based on limits for total fat, saturated fat, cholesterol and sodium as well as minimum amounts of at least 10% of the Daily Value (DV) for one or more of the following nutrients: vitamin A, vitamin C, calcium, iron, protein and fibre. These standards were set in 1994 and, according to FDA, in some respects they are now inconsistent with current nutrition science and Federal dietary guidance.

Under the proposed new rule, the food would need to: a) Contain a certain meaningful amount of food from at least one of the food groups or subgroups (e.g., fruit, vegetable, dairy, etc.) recommended by the 2020-2025 Dietary Guidelines for Americans; and b) Adhere to specific limits for certain nutrients, such as saturated fat, sodium, and added sugars.

According to the agency, such "healthy" claims would provide information to consumers that allow them to quickly identify foods that can be the foundation of a healthy dietary pattern.

Australia

Products containing fennel, targeted compliance reviews

The TGA will be initiating targeted compliance reviews of selected listed products that require the below safety warnings because they contain the herbal ingredients *Foeniculum vulgare* (fennel), fennel bitter seed dry, fennel sweet seed dry and/or fennel oil.

- 'Do not use if pregnant or likely to become pregnant' (or words to that effect)
- 'Do not use while breastfeeding'
- 'Use in children under 12 years is not recommended'

The absence of these warning statements in products that contain fennel or fennel oil may pose a risk to the health of pregnant women, breastfeeding women and/or children under the age of 12.

Dual name labelling transition

The Therapeutic Goods Administration (TGA) is seeking views on medicine ingredient names that must be displayed as both the old and new ingredient name ('dual labelled') on labels and Product Information (PI) and Consumer Medicine Information (CMI) documents until 30 April 2023 as part of International harmonisation of ingredient names (IHIN).

In relation to listed complementary medicines, only products containing mecobalamin (comethylcobalamin) are affected.

New Zealand

Titanium Dioxide: No safety concerns.

Based on the data currently available, there is no evidence to suggest that dietary exposure to food-grade TiO2 is of concern for human health, concluded Food Standards Australia New Zealand FSANZ

FSANZ has reviewed key evidence relating to the safety of TiO2 when used as a food additive. The review was initiated following the release in 2021 of an updated safety assessment of TiO2 by the European Food Safety Authority (EFSA) which concluded TiO2 could no longer be considered safe when used as a food additive.

In line with the outcomes of recent reviews conducted in the United Kingdom (UK) and Canada, FSANZ found no safety concerns.

Argentina

Vegan / vegetarian claims

The Secretariat of Food, Bio-economy and Regional Development has issued Resolution 5/2022 which introduces to the Argentinean Food Code a definition for the terms vegan and vegetarian and the conditions for claiming a product as such. The term "vegan" is reserved for products that do not contain ingredients of animal origin and/or their derivatives (including additives and processing aids) and whose manufacturers and importers certify that their processes and management system guarantee compliance which may be verified by an officially recognised body. These products may include the following on their labels: "VEGAN PRODUCT" or "VEGAN FOOD".

The term "vegetarian" is reserved for products that do not contain ingredients of animal origin and/or their derivatives (including additives and processing aids), except for the following ingredients and/or their components or derivatives: milk and dairy products; eggs or egg products obtained from live animals; honey or bee products. The labels of these products may include: "VEGETARIAN PRODUCT" or "VEGETARIAN FOOD". In addition, products that do not contain ingredients of animal origin can claim "Made only with vegetal ingredients", "100% vegetal" or "Plant-based".

Two new substances for use in food supplements

The Argentinean Food Code has recently been updated to include ß-

hydroxy-ß-methylbutyrate (HMB) and beta-alanine (ß-ALA) for use in food supplements. For both ingredients the purity and identity specifications must follow Food Chemical Codex, USP and other pharmacopeias. In the case of ß-hydroxy-ß-methylbutyrate (HMB) the maximum daily intake must not exceed 3 g/day, and for beta-alanine (ß-ALA) it must not exceed 2 g/day.

Both ingredients were previously approved on a case-by-case basis.

Enforcement date: 22 November 2022.

Brazil

0% tax

In August, a 0% tax was announced for imported food supplements containing whey protein, creatine, amino acids and vitamins. In addition, a reduction from 11.2% to 4% for other items like dairy proteins and albumin were announced. The measures were enforced from 1 September.

Bolivia

New standard for supplements

With a lack of clear rules in place, food supplements have been ruled under pharmaceutical regulations, but in practice, some products were classified under food regulation.

The Bolivian Institute for Standardization and Quality (IBNORCA) has consulted on a new draft standard for food supplements. This would be the first standard for the category in the country.

The proposal considers:

- A definition for food supplements that foresees the use of vitamins, minerals, carbohydrates, proteins, fatty acids, probiotics, prebiotics, postbiotics, plant extracts, bioactive substances, vegetal or animal hormones, enzymes, among others

- Additives to be used according to Codex Alimentarius rules

- Botanical ingredients to be permitted, including those approved by the US FDA, Germany, BELFRIT, Health Canada, among others

- Minimum levels for micronutrients: 15% of the RDI from FAO/WHO

- Maximum levels for micronutrients: Upper levels from the US Institute of Medicine

New limits for tocopherols

On 17 August Resolution RDC 740/2022 was issued which modifies the limits for the use of tocopherols as antioxidants in food supplements. In liquid food supplements the limits are:

- Maximum limit for D-alpha-tocopherol (INS 307a), mixed concentration of tocopherols (INS 307b) and DL-alpha-tocopherol (INS 307c) in liquid food supplements containing bioactive or fat-soluble substances of 0.2g/100 ml (except for those containing fish or algae oil)

- Maximum limit for D-alpha-tocopherol (INS 307a) in liquid food supplements containing bioactive or fat-soluble substances of 0.6g/100ml only in fish or algae oil, alone or in combination with other authorised antioxidants

- Maximum limit for DL-alpha-tocopherol (INS 307c) in liquid food supplements containing bioactive or fat-soluble substances of 0.6g/100ml only in fish or algae oil, alone or in combination of other authorised antioxidants In solid food supplements

- Maximum limit for D-alpha-tocopherol (INS 307a), mixed concentration of tocopherols (INS 307b) and DL-alpha-tocopherol (INS 307c) in solid food supplements containing bioactive or fat-soluble substances of 0.2g/100ml

Enforcement date: 1 September 2022.

Chile

Change to food additives legislation

The Ministry of Health has opened for public consultation a proposal to revise the food additives regulation. It seeks to update the section on food additives in the Sanitary Regulation of Foods, taking into account the Codex Alimentarius categories and maximum limits and also the opinions of the European Food Safety Authority, Food Chemical Codex and the US FDA.

The descriptors of the food categories established in the proposed Technical Standard for Food Additives are not intended to be legal names of the products for labelling purposes, but they serve to validate the additives and limits that are allowed in those categories. Likewise, the Food Classification System is hierarchical, which means that when the use of an additive is recognized in a general category, its use is recognized in all subcategories, unless otherwise indicated. If approved, it would be enforced 24 months after its publication.

Guatemala

Updating regulation

Guatemala has recently issued a revised Technical Standard (14/2022) which updates and replaces the previous one regulating dietary supplements.

In this new version, the changes include:
Definitions for primary and secondary packaging, complementary labels, instructions of use and daily reference intakes have been introduced

An updated definition for dietary supplements:
"Substance or mixture of substances intended to supplement the nutrients normally present in food, such as vitamins, minerals, amino acids, herbs or other substances or extracts of plant and even animal origin (gland extracts), even when their nutritional value has not been checked." Replaced by *"Products especially formulated and destined to supplement the intake of nutrients in the diet of daily persons, who present unsatisfied basic dietary needs or greater than usual contain any of the following nutrients, proteins, lipids, amino acids, carbohydrates, vitamins, minerals, dietary fibre and herbs".*

Different daily reference intakes for children with different age groups.

Maximum levels have been established for 15 bioactive substances, including omega 6 and 3 fatty acids, inositol, lycopene, lutein, coenzyme Q10.
The creation of a 5 year period for the sanitary registry.

For registration purposes, in addition to the full formula, information must also include the colorants and pigments and for plant extracts the scientific name and the part of the plant used must be declared.

Mandatory labelling information has been clarified.

EAEU

Dietary supplement amendments to Union's food safety regulation ready for approval

In October, Member States of the Eurasian Economic Union held consultations aimed at finalising draft amendments to the Union's food safety regulation regarding special requirements for dietary supplements, their manufacture, sale and labelling. The EAEU Commission's Department for Business Development has completed all formalities required for the approval of the draft by the Member States.

Following the consultations, it was agreed to:
- Define the term of a vitamin and mineral premix as "a mixture of biologically active substances with or without other components, intended for commercial manufacturing of foods, including enriched and/or specialized foods, including dietary supplements";
- Reinstate the ban on the use of hemp oil in dietary supplements;
- Add a provision that dietary supplements are used only as sources of biologically active substances.

The draft amendments are now under review by the Eurasian Economic Commission's Consultative Committee which should then send the document to the member states for approval.

Ukraine

Ukrainian MPs propose empowering health ministry to control dietary supplement market

In October, the ruling faction of the parliament tabled a bill on improving the safety of foods.

The draft law is designed to regulate marketing of foods with ingredients which, by their impact on human health, can be classified either as medicines or as dietary supplements, therapeutic foods, or weight management foods. It has been reported that recent market inspections revealed numerous violations that pose a threat to the lives and health of consumers, including:

-Addition of active pharmaceutical substances to dietary supplements and FSDU;

-Presence of substances that are deemed dangerous to humans;

- Absence of the biologically active substances claimed in product labelling.

The bill calls to establish a single government oversight system that covers all markets, including dietary supplements.

The proposal is to task the State Service on Medicines and Drugs Control (Ministry of Health) with in-market control over dietary supplements, foods for special medical purposes, and foods for weight management.

Also, the bill offers a new definition of a dietary supplement to be added to the law on key principles and requirements to safety and quality of foods:

"Dietary supplement is a food which is consumed in small amounts complementing a conventional diet; They are concentrated source of nutrients, including proteins, fats, carbohydrates, vitamins, and minerals (this list is non-exhaustive) within the limits of standard physiological requirements to achieve a nutritional or physiological effect, and is manufactured in the form of tablets, capsules, dragees, powders, liquids or other forms".

Uzbekistan

Uzbek government ready to adopt umbrella regulation covering dietary supplements and food additives

Uzbekistan's government is reviewing a national regulation that applies to dietary supplements, food additives, processing aids, and flavours. The document was developed by the Academy of Sciences to replace the existing regulatory framework based on outdated sanitary rules introduced in Soviet Union and CIS in 80s-90s. A short commenting period was opened to the public in December 2020 with no further revisions announced.

The draft document contains 26 appendices including:
- Annex 24: Safety requirements for dietary supplements. This lists maximum limits (MLs) for critical contaminants including heavy metals, mycotoxins, nitrites, and melamine. The Annex copies MLs from technical regulation of the Eurasian Union TR TS 021/2021 On safety of foods. Part 2 of the Annex lists botanicals that are not permitted in dietary supplements and essentially duplicates the list in the Sanitary Requirements of the Eurasian Economic Union.
- List of food additives that can be used in food production, and their MLs in food categories;
- Customs harmonization codes for dietary supplements, food colours, food additives, auxiliary substances, and flavours

The draft groups dietary supplements into two broad categories:
Nutraceuticals – supplements that contain alimentary substances (macronutrients, vitamins, minerals, and fibre) and used for correction of diet.
Parapharmaceuticals – supplements that are used for the functional support of systems and organs in the human body, complementary therapy and disease prevention.
It is not specified further how these two categories should be regulated.