

IADSA NEWSFLASH

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Regulatory news



China

New functional ingredients

Coenzyme Q10, reishi shell-broken spore powder, spirulina, fish oil and melatonin are now officially considered as functional ingredients with their inclusion into the health food raw material positive list. In a communication from SAMR on 3 December, it has also been clarified that ingredients and related functions can only apply to the production of health food instead of ordinary food.

Coenzyme Q10 Daily intake 30-50mg Suitable group: Adults Unsuitable groups: Children, pregnant women, lactating women, those with allergies, people taking pharmaceutical drugs should consult the doctor before consuming the product Function: Enhance immunity; antioxidation

Melatonin Daily intake 1-3mg Suitable group: Adults Unsuitable groups: Children, pregnant women, lactating women, people who work on driving, mechanical operation and dangerous operation cannot consume this product before or during the operation, and

patients having autoimmune disease (like rheumatoid) or hyperthyroidism should take the product with caution. Function: Sleep improvement

Fish oil Daily intake: No more than 4.0g (among them, the usage amount of EPA+DHA should be no less than 1.0g). Suitable group: People with high blood lipids. Unsuitable groups: Children, pregnant women, lactating women; those with bleeding tendency and patients with bleeding diseases; those with hepatic insufficiency; those who are allergic to marine products. Function: Assist to reduce blood lipids

Reishi shell-broken spore powder Daily intake 1-4g Suitable group: Those with weakened immune systems Unsuitable groups: Children, pregnant women, lactating women Function: Enhance immunity

Spirulina Daily intake 3-4g Suitable group: Those with weakened immune systems. Unsuitable groups: Children, pregnant women, lactating women and those with allergic constitution. Function: Enhance immunity. Also note that beta carotene has also been added to the list of nutrients for health food filing as a source suitable for adults.

Update!

The State Administration for Market Regulation (SAMR), the National Health Commission ("NHC") and National Administration of Traditional Chinese Medicine have released the Health Food Raw Material Directory - Nutrient Supplement (2020) and Health Function Catalogue Allowed for Health

Claims - Nutrient Supplement (2020). Both regulations will come into force on 1 March 2021, replacing the Health Food Raw Materials Directory (1st Batch) and the Health Function Catalogue (1st batch) released in 2016. The new versions also provide new interpretation claims. It is clarified that it would be possible to include one or more sentences of the interpretation claims on a label. However, words cannot be deleted, added or modified.

Addressing variation

The China State Administration for Market Regulation (SAMR) has recently issued a notification on management of health food registration for variations made to existing applications. The variation can affect the product name, health functions, or change of label contents (limited to deleting the preface, removing health functions, reducing the scope of the "suitable for" or expand the scope of "unsuitable for", standardizing the expression of specifications or cautions, and specifying edible method). According to this notification, the changes made should not affect health food quality and safety, or invalidate the registration.

Series of changes

The China State Administration for Market Regulation (SAMR) has recently released a series of draft regulations related to health food functions for public consultation, namely:

- Health Function Catalogue Allowed for Health Food Claims Non-nutrient Supplement (2020 Draft)
- Interpretation of Health Functions (2020 Draft)
- Evaluation Guideline for Health Food Functions (2020 Draft)

- Ethical Review Guideline for Health Food Human Consumption Trial (2020 Draft)

Among the changes introduced:

- Three functions (Promoting lactation, Improving growth, Improving skin lipid) have now been removed, reducing the list of permitted functions from 27 to 24.
- 6 functions have also been reworded (e.g. Aiding blood lipid reduction replaced by Help maintain blood lipid health (cholesterol/ triglyceride)).
- It is understood that additional language that may now be used to further explain the function to consumers.

On the requirements of health food function evaluation, more information about the tested samples would be required. This also includes an analysis report of potentially harmful substances for the tested sample.

The Ethical Review Guideline for Health Food Human Consumption Trial (draft) is a new Regulation. It is understood that institutions conducting human trials should establish an ethical review committee, made up of professionals having multiple academic backgrounds.

Korea

General foods can now carry claims

General food can now bear "function claims" which were so far only permitted for health functional food. The Ministry of Food and Drug Safety (MFDS) has recently clarified in a Q&A that the use of such claims on general food would be permitted if the functional ingredient amount exceeds 30% of the recommended daily intake set in Health Functional Food Code. Currently 29 claims have been approved for use. These include Ginseng, Chlorella, Spirulina, Propolis extract, EPA, DHA oil, Probiotics. For domestic food products, the functional ingredients should be provided by factories in compliance with Health Functional Food Good Manufacturing Practice (GMP). However it is understood that if products are

manufactured in Korea with imported functional ingredients, HACCP accreditation would be sufficient.

Suspension of foods produced by ruminant and its by-products from 36 countries

The MFDS, the Korean Ministry of Food and Drug Safety, has recently banned the import of foods produced by ruminants and its by-products from 36 countries/regions. Under Korean law, MFDS can prohibit the import of foods that contain risk materials or are manufactured in a harmful environment.

The banned materials/foods are: Food and food additives using ruminants and their by-products as raw materials (milk, dairy products, and collagen casing excluded) with the exception of foods and products containing:

- Processed beef tallow products: The contains of insoluble impurities in products: less than 0.15% (certificate issued by the exporting country's government is required)
- Gelatin, Collagen: Made from raw skin or leather (certificate issued by the exporting country's government is required)
- Calcium Phosphate Dibasic: Containing no protein or fats (certificate issued by the exporting country's government is required)

This prohibition applies to Austria, Belgium France, Germany, Italy, Netherlands, Luxembourg, Ireland, Denmark, Greece, Spain, Portugal, Sweden, Finland, Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Hungary, Liechtenstein, Macedonia, Norway, Poland, Romania, Slovakia, Slovenian, Swiss, Serbia, Montenegro, Japan, Israel, Canada, United States of America, Brazil, United Kingdom.



European Union

New look at CBD

Following a recent EU Court judgment (Case C-663/18) reporting that a Member State may not prohibit the marketing of cannabidiol (CBD) lawfully produced in another Member State when it is extracted from the Cannabis sativa plant in its entirety and not solely from its fibre and seeds, the European Commission has officially changed its position relating to the status of CBD extracts. The Commission now considers that CBD extracted from hemp is not a drug and can be eligible for use in food and food supplements. All CBD extracts remain novel, requiring the submission and approval of a dossier before use. The Commission had received about 60 applications that were put on hold and will now proceed with checking their validity. If valid, they will send them to EFSA for the risk assessment. Parallel to this, the UN Commission on Narcotic drugs (CND) has voted to reclassify cannabis out of the most dangerous category of drugs by removing the substance from Schedule IV of the 1961 Single Convention on Narcotic Drugs.

Overruling national limits for selenium

The EU has recently extended the use of the novel food selenium-containing yeast (*Yarrowia lipolytica*) biomass in food supplements under the following conditions: Food supplements, excluding food supplements for infants and children under 4 years of age 50 mg/day for children from 4 to 6 years of age, resulting in 10 µg of selenium per day 100 mg/day for children from 7 to 10 years of age, resulting in 20 µg of selenium per day 500 mg/day for adolescents from 11 to 17 years of age, resulting in 100 µg of selenium per day 800 mg/day for adults, resulting in 160 µg of selenium per day.

Some Member States were however against this measure. Belgium indicated that the decision would overrule national limits applied in some Member States. The Netherlands considered the novel food to be a new source of selenium as this selenium-containing yeast biomass will be used to supplement the dietary intake of selenium. The Netherlands suggested to wait for EFSA's result of the re-evaluation of the safe upper level that

has been requested by the European Commission based on newly emerging data. Similar concerns were raised for a novel vitamin D2 mushroom powder to be used as a new source of ergocalciferol. The Commission decision on this novel food could be reviewed when the EFSA option will be available in July 2021.

Vegetable carbon: Call for particle sizes data & limits for PAHs

The European Commission has published a new call for data regarding the re-evaluation of vegetable carbon (E 153) authorised in supplements at *Quantum satis*. This request includes information on particle size and particle size distribution for the food additive, and data on the lowest technologically achievable levels for 16 priority PAHs. Deadline: 14 August 2021

α-Lipoic Acid at risk

According to the European Food Safety Authority (EFSA), the consumption of Alpha Lipoid Acid added to foods, including food supplements, is likely to lead to an increased risk of developing Insulin Autoimmune Syndrome (IAS) in individuals with certain genetic polymorphisms.

Based on the limited data available and the low prevalence of IAS in Europe, it was also reported that the risk associated with the development of IAS following consumption of <meta>Alpha Lipoid Acid cannot be quantified precisely neither for the general population overall nor for sub-groups or individuals with genetic susceptibility.

Such conclusions could lead the European Commission to impose restrictive measures or even a prohibition.

The publication of this scientific opinion is based on a request of the European Commission to initiate the procedure under Article 8 of Regulation (EC) No 1925/2006 for the intake of alpha-lipoic acid in food supplements because of the potential risk to health associated with the intake of this substance raised by the Danish National Food Institute (DTU) and the Belgian Superior Health Council.

France

Extension of TiO2 ban

France has extended its national ban of the use of the additive titanium dioxide (E171) in foods and supplements for another year. No decision has been taken yet at the EU level. The final EFSA opinion on the safety of E171, based on further studies that have been carried out, is foreseen by end March 2021.

Vitamin D: Take medicines not supplements

The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) has recently published an article recommending the use of vitamin D medicines rather than food supplements to prevent the risk of overdose in children.

According to the Agency, cases of vitamin D overdose have recently been reported in young children following the use of food supplements. In response to this, ANSES, the French Health Products Safety Agency (ANSM), paediatric scientific societies, the National College of Midwives and French poison control centres are alerting healthcare professionals and parents to the risk of overdose associated with giving vitamin D supplements to children, especially infants (link) To prevent this risk, they are asking healthcare professionals and parents to:

- Opt for medicines rather than food supplements;
- Check the doses administered (verify the amount of vitamin D per drop);
- Avoid combining different products containing vitamin D.

ANSES also note that some of the potential risk issues relating to food supplements are linked sometimes to very high (up to 10,000 IU) vitamin D concentration per drop, the presence in the food supplement of other vitamins (example: vitamin K, for which there is no recommendation for daily administration to children) or high dose calcium (increased risk of renal damage such as lithiasis / nephrocalcinosis).

Germany

Stoffliste v2 published

The new working Group Bund-Länder-Arbeitsgemeinschaft Stoffliste (AG Stoffliste) has recently published its revised list of Plants (Pflanzen) developed 6 years ago. The new version that was open to public consultation in September has been developed by representatives of various authorities [the German federal Authorities (BVL, BfR, BfArM), the authorities of the German Länder, the Swiss Federal Office for Food Safety and Veterinary Affairs FSVO, the Austrian agency AGES], as well as experts in the respective fields not under any authority.

Over 100 monographs and more than 250 plants have been added. In addition, a “list of mushrooms” has been created. The lists are not legally binding and do not claim to be complete. The lists will be updated periodically to take into account new scientific knowledge and market developments.

The lists also serve as a guide in Austria and Switzerland for botanicals and mushrooms used as food or food ingredients.

Status of highly bioavailable curcumin

A recent publication of a German Joint Expert Commission has examined how products containing curcumin with improved bioavailability and placed on the market as food supplements are to be classified. While the Joint Expert Commission reported that there was no basis for classifying such products as functional medicines or traditional herbal medicinal products, no food preparations containing curcumin with improved bioavailability had been consumed to any significant extent within the European Union before 15 May 1997. It was reported that no application for approval as a novel food has been submitted. The Joint Expert Commission concluded that the evaluation of the safety of curcumin-containing products with improved bioavailability should therefore be recommended in each individual case due to the heterogeneity of the specific manufacturing processes

Norway

Focus on MSM and melatonin

The Norwegian Food Safety Authority (Mattilsynet) has requested its Scientific Committee for Food and Environment (VKM) to investigate a potential health risk associated with a daily intake of food supplements containing methylsulfonylmethane (MSM) at a dose of 3 g/day and those containing melatonin at a dose up to 1 mg/day. VKM was also asked to consider how long a food supplement with 1 mg of melatonin can be taken daily without causing negative health effects. The conclusion of these risk assessments must be completed by 12 May 2021.

United Kingdom

Post Brexit: Not much change

Overall, the rules applying to food supplements remain mostly unchanged, but with national procedures instead of EU ones. The most relevant links have recently updated by the UK Department of Health:

Food Supplements Guidance documents

<https://www.gov.uk/government/publications/food-supplements-guidance-and-faqs>
<https://www.gov.uk/government/publications/food-supplements-guidance-and-faqs/guidance-notes-on-legislation-implementing-directive-200246ec-on-food-supplements>

Scientific applications concerning the safety and bioavailability of an individual substance for consideration for use in the UK market must until further notice continue to be completed in line with administrative guidance produced by the European Commission. Submission should be by email to: nutritionlegislation@dh.gsi.gov.uk
 Nutrition and health claims

Guidance document

<https://www.gov.uk/government/publications/nutrition-and-health-claims-guidance-to-compliance-with-regulation-ec-1924-2006-on-nutrition-and-health-claims-made-on-foods/nutrition-and-health-claims-guidance-to-compliance-with-regulation-ec-19242006>

The register of authorised claims

<https://www.gov.uk/government/publications/great-britain-nutrition-and-health-claims-nhc-register>

For applications of new health claims

<https://www.gov.uk/government/groups/uk-nutrition-and-health-claims-committee#making-an-application-for-authorisation-of-a-health-claim>



Argentina

Revision of FS regulation

The National Food Institute (INAL) has considered it necessary to update Article 1381 of the Argentine Food Code (CAA) that defines dietary supplements. The new Resolution published at the end of December establishes, in addition to the definition and particular labelling requirements, the requirements that supplements must meet in terms of composition. Different regulations such as those of the United States, European Union, Canada, Brazil, Chile, Australia and New Zealand, as well as the recommendations of the Codex Alimentarius, were considered.

Main changes include: The increase of the minimum level for vitamins and minerals, from 20% to 30% of the recommended daily intake. The Tolerable Upper Intake Levels were updated for the following vitamins and minerals: vitamins A, C, D, E, K, thiamin, B6, iron, magnesium and iodine. A maximum level has now been established for boron. It is specified that Tolerable Upper Intake Levels (UL) are established as the maximum safe daily intake for vitamins and minerals for dietary supplements. The establishment of limits for amino acids and other nitrogenous substances, components of the products. The list of permitted botanicals has been reduced from 35 to 27 species. Requirements for the use of probiotics have also been included. Enforcement date: 30 December 2020. Companies will have a period to adapt until 30 December 2021.

Fees for market access

Due to continuing inflation, Argentina has updated its fees to register food supplements from \$11.120,00 Argentinean Pesos to \$16.240,00. The Provision 705/2021 was published on 22nd January 2021 which modifies administrative fees for the National Administration of Medicines, Foods and Medical Devices (ANMAT) and the National Institute of Foods.

Enzymes & Processing aids

Argentina has recently revised its list of enzymes. The revised list contains 108 enzymes for use as processing aids in food products, including food supplements, and their conditions of use. Although the previous list contained 106 enzymes, some enzymes have been removed and are not allowed, and some others have been added. This Resolution has been developed by the working group on enzymes from the National Commission of Foods. The new list is valid from 29 January 2021.

Brazil

Guidance for food additives

The sanitary authority ANVISA has issued the second edition of the Q&A document on food additives and processing aids, aiming to clarify common questions about the regulation. This includes 70 questions and answers with updated guidance on the applicable regulation for food additives and processing aids, including clarification on how to declare food additives on labels, the use of botanical species as flavourings, the safety assessment of food additives, and information on use of the INS number.

Correcting errors

In December, an amendment of Administrative Order 76/2020 was published which lists the permitted ingredients in food supplements, their respective maximum limits, and the list of claims, in order to amend Annexes II, IV and V, where some information were incorrect: - Annex II relating to the permitted ingredients in food supplements intended for infant and young children, where proteins were missing from the list. - Annex IV relating to the maximum limits for bioactive substances, enzymes and probiotics, for each age group, where a footnote for folic acid has been added - Annex V relating to the list of

permitted claims, where some wording has been changed for the permitted claim for *Bifidobacterium animalis* subsp. *lactis* BB12 (DSM 15954)

Colombia

Registration fee up

In January Resolution 2020046413 was published which updates Resolution 2020027137 which establishes INVIMA's fees, including fees for the registration of food supplements. The new fees have been updated considering the minimum wage and the current 'Unit of Tax Value'. The new fees are the following:

- Food supplements in solids forms: the fee has been increased from 4,554,638 to 4,997,071 Colombian Pesos
- Food supplements in liquid form: the fee has been increased from 4,333,808 to 4,754,533 Colombian Pesos
- Food supplements in semi-solid form: the fee has been increased from 4,361,411 to 4,785,032 Colombian Pesos

The new fees are already in force.

Nicaragua

First legal framework

Nicaragua has issued its first regulation for food supplements.

In short :

- The enforcement authority will be the Department of Natural Artisan Products and Nutritional Supplements, which will be linked to the Ministry of Health
- The import of supplements registered with the Department of Natural Artisan Products and Nutritional Supplements will be authorized by the Department of Pharmacy of the Ministry of Health
- Registration must be issued within 60 working days. Part of the documentation to be presented includes a free sale certificate, GMP certificate, composition, analytical methodology, stability studies (for products with a shelf life greater than 24 months). All

documents must be submitted in Spanish.

- Maximum limits of vitamins and minerals are established.
- There is no positive list of ingredients, although the definition foresees vitamins, minerals, amino acids, carbohydrates, proteins, fats, combinations of substances with extracts from plant or animal origin and enzymes (except for hormones)
- Labelling requirements including warning statements



Belarus

Dietary supplements & medicines can no longer have identical trade names

The Belarusian Health Ministry's Resolution 78 on criteria for trade names of medicines of 24 September 2020 came into force in November 2020. Importantly, one of the criteria bans the use of names fully replicating the names of dietary supplements as trade names of medicines.

Separate shelves

The Health Ministry has ruled medicines and dietary supplements should be displayed on separate shop shelves. The Belarusian national internet portal published the Health Ministry's Resolution 86 on amending the Health Ministry's Resolution 120 of 27 December 2006 of 23 November 2020. It states that medicines in a pharmacy must be displayed separately from other products, including dietary supplements. Dietary supplements must be marked appropriately as a product category on the dedicated shelf.

Change of rules for supplement adverts

Following a new law published in January, dietary supplements can only be advertised if the advertiser has received approval from the Ministry of Health of Belarus. This requirement does not apply to outdoor and transport advertising. Dietary

supplements and medications may not be advertised during children's programmes, including movies aimed at children.

Russia

Distribution channel restrictions lifted

Following the approval of the new rules of goods sales and revocation of sanitary norms and rules of production and sales of food supplements (Government Decree N2463 of 31 December 2020), all restrictions for retail sales of food supplements are lifted from 1 January 2021. In particular, the Decree allows E-commerce trade of dietary supplements, as well as lifts restrictions for retail sales of food supplements only in pharmacies, dedicated stores selling preventive and medical nutrition products, and department stores.

Ukraine

Language law comes into force

16 January 2021 marked the enactment of Article 30 of Ukrainian Law 2704-VIII on facilitating the use of Ukrainian as the official language for consumer services. All market operators are obligated to service customers and provide information about products and services in Ukrainian. The requirement is also valid for online information about products.

As per the law, information about products and services may be included in other languages.

Uzbekistan

Draft regulation covering supplements

Uzbekistan's Academy of Sciences has proposed a draft resolution on safety of food additives, flavouring agents, dietary supplements and processing aids. The draft document introduces requirements for their manufacture, storage, sale, disposal and labelling. The document has a number of appendices which contain detailed safety requirements and hygienic norms. The public discussion phase closed on 26 December 2020. Based on its results, the draft resolution may now be amended or rejected.