IADSA NEWSFLASH

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Regulatory news

China

Consultation on new forms for Coenzyme Q10 and Melatonin

China's State Administration for Market Regulation (SAMR) issued a draft regulation to expand the dosage forms and excipients permitted for Coenzyme Q10 and Melatonin health foods under the filing system.

For Coenzyme Q10, powder and oral liquid would be added as new forms, with additional excipients such as fruit and vegetable powders, maltodextrin, fructose, and polyglycerol fatty acid esters depending on the formulation. For melatonin, oral liquid would also be allowed, with excipients including xylitol, citric acid, and potassium sorbate.

China updates GMP for Health Food

China's National Health Commission (NHC) and the State Administration for Market Regulation (SAMR) have jointly released an updated Good Manufacturing Practice (GMP) standard for health food, GB 17405-2025, replacing the previous version GB 17405-1998.

Effective from 2 September 2026, the revision represents a major modernisation of China's regulatory framework for the health food sector. It shifts from a hygiene-based approach to a comprehensive, risk-management system aligned with contemporary food safety principles. The new GMP standard strengthens regulatory oversight by introducing mandatory process validation, supplier qualification and management, material balance verification, and stricter controls over clean-room environments. These measures aim to enhance traceability, consistency, and product quality across the manufacturing chain.

Manufacturers are granted a one-year transition period to upgrade facilities, documentation, and operational procedures to meet the new requirements.

New draft regulation aims to strengthen food safety in live-stream sales

The State Administration for Market Regulation (SAMR) released for public consultation the Draft Provisions on the Supervision and Administration of Food Safety Responsibilities in Live-Stream E-Commerce. The draft sets out 25 articles to strengthen food safety responsibilities throughout the live-streaming supply chain.

Under the proposals, live-streaming platforms, operators, agencies and individual presenters will be required to establish food safety management systems, verify business licences and product information, retain records for at least three years, and ensure truthful advertising and transparent pricing. Platforms with annual food sales of RMB 5 million or more would be obliged to appoint a food safety director.

Service agencies must provide training and oversight of presenters, while live-streaming personnel are required to give accurate product descriptions and avoid misleading claims. Liability for violations will rest with the service agency or, where none exists, with the live-stream operator.

Market regulators at or above regional level will be empowered to supervise and enforce compliance, including through data checks, sampling and joint investigations with internet authorities.

India

Health supplements see tax cuts

The Goods and Services Tax (GST), introduced in 2017 as India's most significant indirect tax reform since Independence, has entered a new phase with sweeping "Next-Gen" changes approved by the GST Council at its 56th meeting.

The Council approved a simplified two-tier structure of 5% and 18%, together with extensive rate reductions covering more than 150

categories, including health supplements. The reforms are intended to ease pressure on households and stimulate economic growth.

Prime Minister Narendra Modi hailed the measures as a “Diwali gift” for farmers, micro, small and medium-sized enterprises (MSMEs), women, young people and middle-class families.

Indonesia

Indonesia enforces stricter safety rules for ingredients in supplements

Indonesia has introduced tougher controls on the raw materials used in health supplements, herbal medicines, quasi-drugs and certain cosmetics, following a series of contamination deaths linked to ethylene glycol (EG) and diethylene glycol (DEG) in 2022.

The country’s food and drug regulator, BPOM, has enacted Regulation No. 26 of 2025, which took effect on 3 October 2025. The new law makes risk assessments mandatory for all raw materials used in the affected product categories, whether produced locally or imported.

The regulation establishes a four-step scientific process designed to identify and minimise potential health risks:

- Hazard identification – assessing whether a substance may cause harm;
- Hazard characterisation – determining safe exposure levels based on toxicological data;
- Exposure assessment – estimating how consumers are likely to use and be exposed to the product;
- Risk characterisation – comparing exposure with safety thresholds to define acceptable risk levels.

If a material is found to pose a risk, it must meet pharmaceutical-grade quality standards set by the Indonesian Pharmacopoeia or an equivalent international benchmark.

South Korea

MFDS proposes expanded use of QR codes for Health Functional Food labels

The Ministry of Food and Drug Safety (MFDS) has released for public consultation a draft amendment to the Indication Standards for Health Functional Foods that would significantly expand the use of electronic labelling, including QR codes and barcodes, to deliver clearer and more accessible product information.

The revision aims to improve the legibility and accessibility of health functional food labels by allowing key product details to be provided electronically. Consumers will be able to scan a QR code to instantly access approved label content such as ingredient lists, nutritional and health claims, and other mandatory information, presented in an easy-to-read format.

Malaysia

Update to list of permitted probiotic strains

The Ministry of Health (MOH) notified the World Trade Organization (WTO) of proposed amendments to the Food Regulations 1985, designed to bring the country’s probiotic list in line with latest scientific taxonomy and to open the door to a new strain.

What’s changing?

New taxonomy recognised: The probiotic known as L. casei Shirota will now also appear as L. paracasei Shirota / Lacticaseibacillus paracasei Shirota, reflecting current global scientific naming.

Lactobacillus plantarum 299v / Lactiplantibacillus plantarum 299v joins the official list of permitted cultures.

The amendments are set to take effect six months after publication. Comments are open until 5 December 2025.

EU

EFSA draft opinion confirms 1 g/day as safe level for DHA

The European Food Safety Authority (EFSA) has reviewed the latest science on docosahexaenoic acid (DHA). After examining new research, EFSA retains the safe level of intake of 1 g/day for all population groups, including pregnant and lactating women, originally set in 2012. The opinion clarifies that this safe level applies to DHA added to foods or consumed as food supplements, in any chemical form (triacylglycerols, ethyl esters or phospholipids), from sources containing DHA alone or predominantly DHA, defined as products with an EPA/DHA ratio below 0.3.

When DHA is combined with higher proportions of eicosapentaenoic acid (EPA), i.e. an EPA/DHA ratio of 0.3 or above, EFSA refers to the previously established safe level of 5 g/day for combined EPA and DHA, as set in its 2012 opinion.

No adverse effects were identified at intakes up to approximately 3 g/day in healthy adults for endpoints including bleeding risk, lipid profile, glucose homeostasis, lipid peroxidation, or immune function.

CBD: EFSA questions safety beyond 2 mg/day

The European Food Safety Authority (EFSA) has launched a public consultation on its updated statement concerning the safety of cannabidiol (CBD) as a novel food.

In its draft, EFSA’s Panel concludes that new literature published since 2022 does not close the data gaps previously identified. Uncertainties remain regarding potential hepatic, immunological and reproductive toxicity, as well as possible effects on neurological function and toxicokinetics. Data gaps on neurodevelopment between the ages of 18 and 25 are of particular concern. In addition, CBD is known to interact with drug-metabolising enzymes,

raising the risk of interactions with medicinal products.

On this basis, EFSA states that:
The safety of CBD cannot currently be established for intakes exceeding 0.0275 mg/kg body weight per day (around 2 mg/day for adults) until further data are available.

This provisional value applies only to CBD formulations with a purity greater than 95%, consumed as food supplements, provided there is no exposure to small or nanoparticles and genotoxicity has been excluded.

The safety of CBD cannot be established in individuals under 25 years of age, pregnant or lactating women, or people taking concurrent medications.

Belgium

Food supplements behind almost all adverse effect reports in Belgium's first year of Nutrivigilance

Belgium's new Nutrivigilance system, launched in January 2024 to track potential health problems linked to certain food products, has received 167 reports in its first year and almost all involved food supplements.

According to the Federal Public Service (FPS), 98% of admissible cases concerned supplements. In total, 130 reports were judged admissible, meaning the products fell under the system and the files contained enough information to be evaluated.

Nutrivigilance covers four categories of products: food supplements, novel foods, foods for specific groups and fortified foods.

The 2024 figures show that supplements dominated reporting: 84% of cases were notified by operators, 79% of products were bought in pharmacies, and most involved adults aged 19 to 70. The supplements most often linked to adverse effects were marketed for hair health, stress and fatigue, intestinal comfort and joint comfort. Undesirable effects ranged from digestive problems and headaches to more serious conditions such as liver or kidney issues.

Officials stress that most products are safe when used correctly, but misuse, prolonged consumption or interactions with medicines can carry risks. Citizens, healthcare professionals and operators are urged to continue reporting through the Nutrivigilance online portal.

New rules for green tea, mushrooms and other plants

Belgium has notified draft amendments to its Royal Decree on foodstuffs containing plants (2025/0342/BE). The update introduces new conditions of use and labelling requirements for certain botanicals, including green tea, revises the list of mushrooms with a distinction between wild and cultivated species, and updates the annexed lists of dangerous plants, mushrooms and plants authorised in supplements. A two-year transitional period is foreseen. The changes aim to improve consumer safety and reflect the latest opinions of the advisory committee for plant preparations.

France

Hexane in the Spotlight

France may launch a parliamentary inquiry into the use of hexane, a petrochemical solvent commonly used to extract vegetable oils and botanical ingredients, following a proposal submitted in March to the National Assembly.

The initiative, led by MP Richard Ramos, aims to assess potential health and environmental risks associated with hexane and to explore alternatives to its use in food and feed production. The inquiry would involve hearings with researchers, regulators, industry representatives, NGOs and citizens.

The move comes as EU-level scrutiny intensifies. In 2024, the European Food Safety Authority (EFSA) found that the 1996 safety assessment of technical hexane was outdated and called for a full re-evaluation, expected by 2026. Germany and Slovenian authorities have also proposed listing n-hexane as a Substance of Very High Concern under REACH, citing evidence of neurotoxicity.

The French proposal seeks to inform the public and may recommend precautionary actions such as warnings on affected products, restrictions in infant and institutional catering, and a phased ban. Under EU food and solvent legislation, France could temporarily restrict hexane's use nationally if new evidence suggests a public health risk.

Germany

BfR: No role for fluoride in supplements

Germany's Federal Institute for Risk Assessment (BfR) has reaffirmed that fluoride is not an essential nutrient and should not be added to food supplements. While appropriate doses protect against caries, BfR warns that intake from mineral water, tea and fluoridated salt can already approach safe limits. Extra supplementation risks excessive exposure. Instead, the agency points to topical use of fluoride in toothpaste as the most effective and safest form of prevention.

Netherlands

VWA tightens control on collagen supplement claims

The Netherlands Food and Consumer Product Safety Authority (NVWA) has released the results of a 2025 inspection into websites promoting collagen supplements. Thirty sites were reviewed, and 25 were found in breach of European law for making prohibited claims. Many advertised collagen as beneficial for joint and bone health, cartilage, or flexibility, while others went further by suggesting effects on diabetes, inflammation, wound healing and other medical conditions.

Under Regulation (EC) 1924/2006, no health claims for collagen are authorised in the European Union. Beauty claims, such as those relating to skin, hair or nails, are not covered by the Claims Regulation but must still meet the general requirement of not misleading consumers.

The NVWA has required companies to immediately remove unlawful claims and has imposed fines. Follow-up inspections are planned in the coming months, and companies that fail to comply face tougher sanctions. Consumers are urged to be cautious.

Romania

Broadcast daily: Supplements do not cure

The National Audiovisual Council of Romania (CNA) has adopted a new Audiovisual Content Regulation Code

that requires broadcasters to air mandatory “awareness messages” throughout the day. Among these is a compulsory consumer health warning: “Food supplements do not cure and cannot replace treatments prescribed by a doctor.”

Awareness messages are defined as short, one- or two-sentence statements designed to inform the public and promote positive, educational behaviours. They must be broadcast alternately between 06:00 and 22:00, with one message placed at the end of an advertising break every hour. Other examples include: “Vaccination prevents the occurrence of serious diseases. Vaccination is essential for your child’s health” and “Raise your child with love, without violence! Beating is not a method of discipline.”

The new Code also strengthens consumer protection rules for food supplements and other health-related products. Supplements will now be subject to the same advertising restrictions as over-the-counter medicines. Misleading claims are prohibited, including those made by pharmacies, and retailers may no longer promote offers on supplements, medicines, homeopathic products or medical devices under their own brand. In advertising and teleshopping for supplements, information must be limited to approved or notified content from the product label, packaging, or leaflet, along with authorised nutritional and health claims. Advertising for food aimed at minors may not feature celebrities, public figures, or doctors. The rules apply equally to television, radio, video-on-demand and video-sharing platforms.

Spain/EU

Micronised Creatine Monohydrate is not a novel food

The Spanish Agency for Food Safety and Nutrition (AESAN) has confirmed that micronised creatine monohydrate is not a novel food. The determination was made following an assessment under Article 4 of Regulation (EU) 2015/2283.

AESAN underlined that creatine monohydrate was already consumed in the EU before 15 May 1997, and that the process of micronisation is purely physical. This does not affect the substance’s composition, nutritional value, metabolism, or safety profile.

As a result, no novel food authorisation is required for micronised creatine monohydrate, ensuring that the ingredient can continue to be marketed in food supplements across the European Union.

Turkey

Concerns over rules on GMO bacteria in nutrient manufacturing

Turkey’s food supplement sector could face disruption as the government prepares to publish new rules on novel foods. The regulation, submitted to the Presidency earlier this month, may lead to a ban on the use of genetically modified (GMO) bacteria in the production of vitamins and minerals.

GMO bacteria are widely used in fermentation processes to manufacture essential nutrients. If they are no longer recognised as food processing aids, as the Ministry has indicated, industry warns that many supplements could face supply shortages.

A similar issue previously affected the enzyme and food additive industries. That issue was resolved when the Biosafety Board ruled that GMO bacteria could be accepted as processing aids. Officials have suggested that the supplement sector should also seek guidance from the Board.

But the Biosafety Board is not currently operational. It has no chair and would need to be re-established through new parliamentary legislation.

Turkey to require source declarations for ingredients

The Turkish Ministry of Agriculture and Forestry has announced that the new Turkish Food Codex Novel Foods Regulation will require companies to provide detailed information on the sources of active substances used in food supplements.

The Regulation, now in its final drafting stage, will classify as novel foods all active substances and sources not already in use in supplements prior to 31 December 2025. These will need to undergo a separate evaluation process managed by a newly established Commission, independent from the current Food Supplement Commission.

To ensure clarity and avoid disruptions, the Ministry has launched a process to collect source declarations for active substances already present in approved supplements. With more than 23,000 approved products and over 100,000 source declarations expected, companies are asked to submit this information via the dedicated online portal.

The Ministry has clarified that the collection of declarations is intended solely to establish statistical data, not to alter existing approvals. The aim is to prevent approved products from falling under the scope of novel food legislation and facing potential delays of up to nine months at customs clearance.

The digital submission system has been designed with strict safeguards to protect data security, including unique notification codes and measures against duplicate entries. Access to the system will close once the submission deadline passes.

Argentina

National Food Commission dissolved

The Argentine government has dissolved the National Food Commission (CONAL) under Decree 538/2025, transferring responsibility for updating the Argentine Food Code to ANMAT and SENASA. The move aims to speed up decisions, strengthen technical oversight, and keep regulations up to date.
Oversight will now be split between the Ministry of Health, via ANMAT, and the Ministry of Economy, through SENASA. While provincial and Buenos Aires authorities remain involved, municipalities will no longer have access to the central database, a

change expected to simplify national procedures.

New system to modernise food regulation updates

Argentina's National Administration of Medicines, Food and Medical Technology (ANMAT) has launched a new digital platform to streamline how companies and individuals request updates or modifications to the Argentine Food Code (CAA), the country's core framework governing all foods, including food supplements.

The move forms part of the government's wider modernisation drive under Decree No. 538/2025, aimed at making the regulatory process more transparent, traceable, and scientifically grounded.

Through the new system, users can:

- Submit requests to amend the Food Code (for example, to add new permitted substances);
- Track progress of submissions in real time;
- Access archives from the now-dissolved National Commission of Foods;
- Review recent updates and official resolutions related to the CAA.

ANMAT has issued detailed guidance outlining the data required for applications.

The National Institute of Foods (INAL) will now review all proposals, validate them, and, where appropriate, develop draft resolutions for public consultation.

Chile

Chile strengthens "Gluten-Free" labelling rules

Chile has introduced new provisions to tighten controls on the use of the "gluten-free" claim for foods. The updated regulation keeps the gluten limit at 5 ppm but now requires manufacturers to have a Good Manufacturing Practice (GMP) programme in place to prevent cross-contamination.

The new definition of gluten-free applies to foods that have been processed to remove or maintain the absence of gluten and that, through proper GMP controls, contain no prolamins from wheat, rye, barley or oats (if present).

The Ministry of Health will later specify the required elements of the GMP programme. Products meeting these conditions may continue to display the "Gluten Free" claim alongside the strikethrough spike symbol on the front of the pack. The new requirements will take effect on 18 March 2027.

Honduras

Updated regulation for nutritional supplements

ARSA issued Communication C-009-ARSA-V1, updating the list of permitted ingredients and their limits, together with the criteria for assessing and classifying nutritional supplements. The regulation revises the definition of supplements (now including gummies and excluding therapeutic effects), removes the synonyms "nutritional complement" and "food supplement", introduces new definitions for a wide range of substances, and establishes procedures for notifying changes to existing registrations.

For a product to be classified as a nutritional supplement, at least one active ingredient must fall between the minimum and maximum permitted levels; if all active ingredients are below the minimum, the label and insert must indicate the suggested dose to reach the minimum. Minimum and maximum levels for numerous vitamins and minerals have been adjusted, while levels for additional substances such as amino acids, fatty acids, coenzyme Q10, melatonin, and others are now specified. A positive list of 206 plant species and a negative list of 61 species have also been adopted, and labelling must follow both Central American Technical Regulations and Codex guidelines.

Mexico

COFEPRIS procedures simplified

The Ministry of Health of Mexico has published an agreement establishing actions to simplify administrative procedures managed by the Federal Commission for the Protection against Sanitary Risks (COFEPRIS).

The measures are designed to reduce administrative burdens, eliminate duplication of requirements, and strengthen efficiency in the authorisation of imports of medicines, medical devices, and other health-related products. They include the removal of obligations to submit physical copies of documents already held by the authority, the consolidation of several permit procedures, and the introduction of clearer timelines for decision-making.

Canada

Version 4.0 of the GMP guide for Natural Health Products Health

Canada has released Version 4.0 of the Good Manufacturing Practices (GMP) Guide for Natural Health Products (NHPs), which will take effect on 4 March 2026 after a six-month transition period.

It is understood that the updated guide does not introduce a new framework but sets out clearer, more detailed expectations for manufacturers, importers, packagers, and distributors.

Key changes include: stronger quality systems, senior management accountability, expanded stability and recall requirements, stricter obligations for importers, and enhanced records management, including electronic and bilingual documentation.

Companies are encouraged to begin preparations now to ensure readiness by March 2026.

USA

FDA U-turn on NMN

The U.S. Food and Drug Administration (FDA) has reversed its previous provision on beta-nicotinamide mononucleotide (NMN), confirming that NMN is not excluded from the definition of a dietary supplement. In letters dated 29 September 2025, the Agency stated that NMN was marketed in the United States as a supplement before it was authorised

for drug investigation. Under the federal "race-to-market" rule, this means NMN can remain on the market as a supplement ingredient. FDA clarified that proof of lawful marketing is not required, only evidence that marketing occurred before the key drug authorisation date.

NMN, however, remains a New Dietary Ingredient (NDI). Companies must file a New Dietary Ingredient Notification (NDIN) to the FDA before marketing NMN products, unless the ingredient is sourced from the same supplier/manufacturer that previously filed an NDIN.

FDA proposes mandatory GRAS notification rules

The U.S. Food and Drug Administration (FDA) has announced that it will introduce a proposed rule in spring 2026 requiring the mandatory submission of Generally Recognized As Safe (GRAS) notices for substances used in both human and animal food.

At present, companies may self-affirm the GRAS status of a substance and voluntarily submit supporting evidence to the FDA. If the agency has no objections, it issues a "no questions" letter. The proposed rule would end this voluntary approach by requiring all companies to submit GRAS notices directly to the FDA. The draft regulation also seeks to:

- Formalise the FDA's responsibility to maintain and regularly update the public GRAS inventory.
- Clarify the process under which the FDA may determine that a substance does not meet GRAS criteria.
- Exempt substances that are already listed as GRAS or for which the FDA has issued a "no questions" letter.

This step follows a directive issued in March 2025 by the U.S. Department of Health and Human Services, which instructed the FDA to develop a pathway to phase out self-affirmed GRAS status.

Russia

Russia plans to restrict doctor-prescribed supplements to domestic products

Russia's Ministry of Health has proposed new rules that would limit the prescription of dietary supplements by doctors to those made in Russia, under a draft governmental decree released for public consultation on 15 August 2025.

The proposal sets out stringent quality and efficacy criteria that only domestically produced supplements are expected to meet. The move builds on Federal Law No. 150-FZ, adopted in June, which for the first time allowed doctors to prescribe supplements alongside conventional medicines.

Under the draft rules, eligible products must comply with Eurasian Economic Union (EAEU) safety standards verified by Russian-accredited laboratories, undergo batch-by-batch testing of active ingredients, and hold certification under GOST R ISO 22000-2019. The first three production batches would require mandatory analysis and annual inspections by laboratories overseen by the Health Ministry, Roszdravnadzor, or Rospotrebnadzor.

To prove efficacy, supplements would need to meet at least two of three demanding criteria:

- Publication of a scientific review in a Russian-indexed journal;
- Inclusion in official clinical or preventive guidelines;
- Manufacturer-backed studies demonstrating physiological effects or interactions with food or drugs.

If adopted, the measure will take effect on 1 March 2026.