

IADSA NEWSFLASH

October 2024

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Regulatory news



Japan

New rules starting September

Manufacturers of Foods with Function Claims (FFC) in Japan must now adhere to four newly introduced requirements. This latest regulatory move comes in the wake of the Kobayashi Pharmaceutical red yeast rice scandal, which highlighted the need for stricter oversight in the industry.

Mandatory adverse event reporting: One of the critical new requirements is the reporting of adverse events, particularly those confirmed by a doctor's diagnosis.

Mandatory Good Manufacturing Practices (GMP): The second requirement focuses on the implementation of Good Manufacturing Practices (GMP) for final products in supplement form. Manufacturers have a two-year transitional period to comply with this rule.

Guarantee of raw material quality: The notifier, typically the manufacturer or importer, must now guarantee the identity, equivalence, and/or homogeneity of the raw materials used in FFC products.

Introduction of the 120-day rule: Another significant change is the introduction of the 120-day rule for products using potentially new functional ingredients. This regulation requires that products are notified at least 120 days prior to marketing, as opposed to the previous 60-day requirement.

Improvement of labelling requirements: The new requirements include improved labelling requirements for FFC products, with a two-year transitional period for compliance.



EU

European Commission requests Member States' input on Article 8 priority substances

The European Commission is taking steps following a report from the Member States' Heads of Agencies that identified substances for priority

assessment under the Article 8 procedure. This could potentially lead to their prohibition, restriction, or increased scrutiny.

The Commission has requested that Member States provide detailed information on how these substances are currently regulated, whether national risk assessments have been conducted, and if there are concerns related to their safety or over-consumption. The Commission is particularly interested in whether these substances are classified as food or medicinal products in different Member States. This data will help an assessment of whether existing risk management measures are sufficient or if further actions are required.

Astragalus root extracts no longer considered as novel

The EU's Novel Food Catalogue no longer classifies astragalus root extracts as a novel food. This update provides much-needed clarity to the food supplement industry, which had faced uncertainty over the status of these extracts in products sold across the EU.

Previously, in November 2023, astragalus root extracts were listed as unauthorised novel foods, raising concerns about the legality of supplements containing this ingredient. Although the Novel Food Catalogue is not legally binding, an "unauthorised" designation could raise doubts on the compliance of supplements containing this botanical.

EU anticipates ban on HAD-containing plants

The European Commission is moving forward with its proposed regulation to ban hydroxyanthracene derivative (HAD)-containing plants in all food products, including supplements. The plants and substances in question, which were placed under scrutiny in 2021, are now set to be included in Part A of Annex III of Regulation (EC) No 1925/2006. This would result in the prohibition of their use due to potential health risks associated with their consumption. The legislation has not yet been formally adopted, but the European Commission has already notified the World Trade Organisation (WTO) of its intent to enforce this regulation.

The following plants are specifically targeted for prohibition due to their hydroxyanthracene derivative content:

- Rhamnus frangula L. and Rhamnus purshiana DC. (bark)
- Cassia senna L. (leaf or fruit)
- Rheum palmatum L., Rheum officinale Baillon, and their hybrids (root or rhizome)

It remains uncertain whether there will be a limit of quantification (LoQ), as was the case with Aloe vera, to identify the absence of HAD in these plants.

Austria proposes pullulan as a substitute for HPMC in organic supplement capsules

Austria has submitted a proposal to the European Organic Products Committee (GREX) to approve pullulan (E 1204), a naturally derived ingredient, as a substitute for Hydroxymethyl propyl cellulose (HPMC - E 464) in food supplement capsules. The Expert Group for Technical Advice on Organic Production (EGTOP) will review this request during its meeting on 4 October to assess its alignment with organic regulations.

French MEP calls for stronger EU oversight on supplements following French safety report

Member of the European Parliament, Catherine Griset has raised concerns about the import of food supplements containing banned substances, urging the European Commission to take swift action. This follows a report by the French National Agency for Food, Environmental and Occupational

Health and Safety (ANSES), which highlighted serious adverse effects, including fatalities, linked to supplements used by athletes and bodybuilders. The ANSES report detailed 154 new cases of adverse effects between 2016 and 2024, with 18 classified as very serious, including two deaths and several life-threatening cases. Many of these supplements were found to contain banned substances like anabolic steroids and sibutramine, which can lead to cardiovascular issues and are prohibited in France in 2010.

In her question to the Commission, MEP Griset asked whether the European Food Safety Authority (EFSA) is assessing the risk of these products, particularly their "cocktail effects," and if the Commission is considering amending current legislation to better address these risks.

The Commission responded by acknowledging over 1,000 cases of non-compliance in the EU between January 2023 and July 2024, with 78 incidents involving unauthorised substances. While stressing that the current legal framework is "fit for purpose," the Commission admitted that enforcement remains a challenge. The Commission indicated that it will continue to support Member States' efforts through coordinated EU actions and by working with Europol to tackle organised fraud in the food supplement sector.

Updates from the EFSA Botanicals Working Group

EFSA has published the minutes of the Botanicals Working Group (WG) meeting on Toxicity Characterisation held on 3 July 2024. Key updates include the delayed release of the expanded 'COMBO database', which will feature additional plant and toxicological information. Additionally, the WG was informed about an ongoing EU initiative led by the Community of Knowledge on Food Supplements, coordinated by French ANSES, which aims to identify emerging risks in food supplements using Compendium data, particularly focusing on substances with predicted toxicity.

Current ULs for vitamin E will stay in place

EFSA has reaffirmed the current tolerable upper intake levels (ULs) for vitamin E, specifically α -tocopherol. The existing ULs remain unchanged: 300 mg/day for adults and lower

levels for children and infants. The Panel concluded that exceeding these ULs is unlikely in European populations, except for high-dose vitamin E supplement users. These ULs apply to all forms of α -tocopherol but exclude individuals taking anticoagulant or anti-platelet medications, those on secondary prevention for cardiovascular disease, or patients with vitamin K malabsorption.

EFSA call for data on malic acid & malates re-evaluation

As part of the re-evaluation programme on food additives, EFSA has issued a call for data to re-evaluate malic acid and malates (E 296; E 350-352) as food additives, permissible in food supplements and nutrient preparations at *Quantum Satis*. Key areas for data collection include additive identity and characterisation, risk assessment adequacy, manufacturing process details, production organism information, toxicological impurities, natural occurrence, and usage levels. I

Czech Republic

Changes for supplements

The Czech Republic has informed the European Commission about a draft Decree that aims to update regulations on food supplements and food composition. This notification is made through the Technical Regulations Information System (TRIS), which helps prevent regulatory barriers within the EU by allowing Member States to share their draft rules. The Decree aims to take effect on 1 January 2025, with no transition period foreseen.

Key changes:

Food Composition Requirements (§5): The current rule prohibits adding certain harmful substances directly to food. However, it doesn't cover cases where these substances might end up in food through ingredients. A new paragraph ensures that food containing harmful substances, regardless of how they get there, cannot be sold.

The Decree also updates rules on specific vitamins, minerals and other substances in food and supplements with the inclusion of:

- Chromium enriched yeast
- (6S)-5-methyltetrahydrofolic acid, glucosamine salt

- Organic silicon and calcium phosphoryl oligosaccharides
- Nicotinamide riboside chloride and magnesium citrate malate
- Measurement units for copper
- Ferric hydroxide adipate tartrate

Annex 1: Restricted plants and substances

Dioscorea sp. (genus Yam) and Schisandra chinensis, Monacolin K from Monascus purpureus and DMAE (dimethylaminoethanol) will be removed from the restricted substances list, allowing their unrestricted use as they are not added to the prohibited list.

Annex 2: Prohibited plants and substances

- Entire plant of Atropa spp. will be banned.
- Clematis spp. roots are banned only if they contain aristolochic acid.
- All bark of Tabebuia impetiginosa will be restricted.
- Melatonin, Dehydroepiandrosteron (DHEA), and 5-hydroxytryptofan (5-HTP) will be removed from the prohibited substances list.

Estonia

New upper limit for vitamin B6 following EFSA safety assessment

Estonia has set a new upper limit for vitamin B6 intake, which is nearly half of the previous value, effective from 1 September 2024. This decision follows the European Food Safety Authority's (EFSA) updated safety assessment. The new upper limit for adults, including pregnant and breastfeeding women, is 12 mg/day. Limits for children range from 2.2-10.7 mg/day, depending on age.

The Authority states that food supplements exceeding these safe intake limits (UL) cannot be considered safe. In such cases, food business operators (FBOs) must take action to ensure the products do not pose a health risk. Options include reducing the vitamin and/or mineral content per daily intake, lowering the recommended daily dose on the label, or discontinuing the product's marketing.

France

ANSES warns athletes of high risks associated with supplements

With the Olympics in Paris, the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) has issued a new warning to athletes about the significant health risks and potential doping issues linked to the consumption of food supplements and fortified foods. Despite a prior warning in 2016, the agency highlights ongoing concerns in this area. According to ANSES, athletes, both professional and amateur, frequently turn to supplements and fortified foods to enhance performance, develop muscle mass, or reduce fat mass, believing that regular nutrition might be insufficient to achieve their performance targets. These products are available online, in gyms, and in pharmacies and are used during training, competitions, or leisure activities.

However, from 2016 to February 2024, ANSES reported 154 new cases of adverse reactions, including 18 very serious cases, two deaths, and four life-threatening situations. Common issues included cardiovascular problems such as tachycardia, palpitations, and cardiac arrest, alongside symptoms like fatigue, fever, dizziness, digestive, and neurological effects. ANSES has raised concerns about the presence of dangerous ingredients in these products, such as anabolic steroids, clenbuterol, and ephedrine. These substances can cause severe cardiovascular effects and are associated with doping risks. Their presence in food supplements is considered fraudulent and can lead to an abnormal analytical result ("positive control") during an anti-doping check. Even if a product meets French regulatory requirements, it might still be banned by the World Anti-Doping Agency (WADA). To mitigate these risks, ANSES provides recommendations for athletes:

- Avoid combining supplements: Athletes should avoid mixing multiple supplements or combining them with medicines.
- Consult healthcare professionals: Before taking any sports supplements, athletes should seek advice

from healthcare professionals, doctors or sports dieticians.

- Focus on products that meet the European standard EN 17444:2021 on doping prevention and avoid making purchases online.

ANSES plans to conduct further research to update its 2016 risk assessment, aiming to provide more current and comprehensive guidance for athletes.

The Agency also reminds healthcare professionals and consumers of the importance of reporting to nutriviigilance any undesirable effect likely to be linked to the consumption of a food supplement or an enriched food.

France launches a new notification platform to help consumers make responsible purchases

In response to the rapid growth and accompanying challenges within the food supplements market, the Directorate General for Food (DGAL) has launched the "Compl'Alim" platform.

According to DGAL, with approximately 20% of adults incorporating food supplements into their daily routines, products have become widely available across many channels, including pharmacies (50%), supermarkets (16%), and e-commerce (8%). However, this growth has also resulted in significant challenges in ensuring the safety and regulatory compliance of the products accessible to consumers.

Distinguishing authorised food supplements from unauthorised ones is a major hurdle according to DGAL. Currently, information is scattered across multiple sources, making it difficult for the public to access reliable data. For manufacturers, specialised services are often required to ensure compliance with existing laws.

Compl'Alim is therefore being set up to replace the Télécare notification system. This initiative is part of a broader effort by the French Ministry of Agriculture to handle the 1,600 monthly submissions it receives while also addressing the concerning statistic that 50% of food supplements on the market are not notified (according to a survey of 30 randomly

selected products across supermarkets, pharmacies, and online platforms).

Key features of Compl'Alim are expected to include:

- A comprehensive ingredient database: A new database containing ingredients that can be used in supplements, along with their specifications (such as maximum dosage and required warning statements). This database will be accessible to businesses, enabling them to verify compliance with applicable requirements before making any submissions.
- Consumer reporting and inquiry system: Consumers will have the ability to report unlisted products and enquire about their status.

Voluntary QR codes: The platform will explore the implementation of voluntary QR codes on product labels, allowing consumers to verify product compliance directly from their mobile phones.

Germany

BfR highlights safety concerns for cannabinoid oils

According to BfR, various oils containing cannabinoids, commonly known as "CBD oil" or "CBD tincture" are commercially available. These products are often marketed as food supplements, but their classification and regulation are more complex.

BfR highlights that products containing CBD must receive approval as novel foods under Regulation (EU) 2015/2283 before they can be legally marketed in the EU. This regulation stems from the fact that such products were not consumed as food to a significant extent within the EU before 15 May 1997. To date, such products have not been authorised due to insufficient data, especially regarding CBD's effects on the liver, gastrointestinal tract, endocrine system, and nervous system, making it impossible to assess potential health impacts of the measured contents.

As part of a research project, a team from the German Federal Institute for Risk Assessment (BfR) investigated the

content of CBD, $\Delta 9$ -THC, and 17 other cannabinoids in such products. The study analysed 22 CBD oils, along with two oils each that had CBG and CBN as their primary components. The findings revealed that the actual concentrations of cannabinoids were often higher than those declared by manufacturers, posing potential health risks due to higher-than-expected intake.

Key findings:

CBD concentrations were on average 21% higher than stated.

92% of samples exceeded the UK FSA's provisional acceptable daily intake for pure CBD with just 2-7 drops per day.

$\Delta 9$ -THC was found in 77% of samples, with high concentrations in half of them.

Psychoactive $\Delta 8$ -THC and (R)-HHC were also detected in some samples.

Given these findings, BfR recommends close investigation and monitoring of CBD oil, for both CBD concentration and psychoactive $\Delta 9$ -THC.

Study

BfR raises concerns over safety of melatonin supplements

The German Federal Institute for Risk Assessment (BfR) has issued a comprehensive 114-page opinion concerning the use of food supplements containing melatonin. This report reflects the institute's significant concerns, especially when they are consumed without medical supervision. The BfR emphasises that food supplements do not undergo the same stringent quality controls as medicinal products, which increases the potential risks associated with their use.

In Germany, melatonin is legally recognised as an active ingredient in certain prescription medications. These are specifically approved for short-term treatment of sleep disorders in adults over the age of 55, as well as in children and adolescents aged 2 to 18 who suffer from autism spectrum disorder or Smith-Magenis syndrome. However, the report indicates that in recent years, melatonin has become widely available in food supplements in various forms sold in drugstores, pharmacies and online. The recommended daily doses for these supplements often match or exceed

the doses found in prescription medications.

The BfR's report warns that the long-term effects of regular melatonin supplementation are still largely unknown. The institute advises that certain population groups should avoid melatonin supplements entirely. These groups include children, pregnant and breastfeeding women, individuals with liver or kidney impairments, and those with autoimmune diseases or epilepsy. The report also highlights the potential for adverse side effects even at low doses. For instance, consuming as little as 1 mg of melatonin per day can lead to symptoms like drowsiness, headaches, reduced alertness, lowered blood pressure. The effects of melatonin can impair an individual's ability to perform tasks that require full alertness, such as driving or operating machinery, long after the supplement has been consumed. Furthermore, the report stresses the uncertainty surrounding the long-term impacts of melatonin use, particularly concerning growth hormone concentration, blood sugar levels, and hormonal or pubertal development. The report finds that these effects are especially concerning in children and adolescents, for whom the consequences could be more pronounced. Additionally, melatonin can interact with certain medications, such as antihypertensives and anticoagulants.

The BfR concludes that melatonin-containing food supplements should be approached with caution. They should not be used chronically, particularly by individuals in vulnerable groups. Instead, the institute recommends that people experiencing sleep disorders seek medical advice to determine the underlying causes.

This opinion is likely to influence ongoing regulatory discussions about whether melatonin should be covered under the EU's Article 8 procedure, a process that could lead to more stringent investigations into its safety and regulatory status.

Ashwagandha supplements: Potential health risks

After concerns raised by several Agencies in the EU, the German Federal Institute for Risk Assessment (BfR) has also issued its own warning about the possible health risks of Ashwagandha supplements. The BfR recommends that children, pregnant and breastfeeding women, and

individuals with liver disease avoid these products. Due to insufficient data, the BfR also advises caution for the general population. Reported side effects include digestive issues, dizziness, and liver damage, together with possible effects on blood sugar, hormones, and the immune system.

Ireland

Addressing probiotic safety in food supplements

The Food Safety Authority of Ireland (FSAI) has released a comprehensive report on the safety of probiotics in food supplements, aimed at guiding businesses in assessing the safety of live microorganisms in these products. FSAI recalls that probiotics are defined by the FAO/WHO as "live microorganisms which, when administered in adequate amounts, confer a health benefit on the host." Although EU law does not permit the term "probiotic" as a health claim on supplement labels—since no application has received a positive opinion from the European Food Safety Authority (EFSA)—the term is used in the report due to its common usage in the industry.

The report notes that adverse events associated with probiotics are rare, usually involving infections in physiologically at-risk individuals. A key aspect discussed is the Qualified Presumption of Safety (QPS) status, which can simplify the safety assessment process for products requiring pre-market authorisation. However, the report highlights that QPS status does not guarantee market approval or address the safety of high-concentration probiotics in supplements.

The report includes several recommendations, including conducting evidence-based risk assessments for each probiotic product and providing robust evidence of the microorganisms' safety. It also emphasises the need for accurate labelling in compliance with the Food Information to Consumers Regulation (Reg1169/2011). Labels should clearly state the type and number of microorganisms, provide storage advice, ensure viability throughout the shelf life, and indicate if certain strains are unsuitable for specific groups.

Turkey

New botanicals

The Turkish authorities have published scientific opinions on the use of several plants in foods, including food supplements. These include:

- Buckwheat (*Fagopyrum esculentum*) sprouts: The sprout is added to the positive list (P), but its extract is excluded due to concerns over phototoxic compounds.
- Leaf of *Mentha arvensis* L.: Added to the positive list (P), but only allowed in teas, with extracts excluded due to high menthol content.
- Leaf of Holy basil (*Ocimum tenuiflorum* L.): Added to the positive list (P), excluding its extracts, as it shows no adverse effects in clinical studies.
- Fruit and Seed Parts of *Zanthoxylum piperitum* (Japanese pepper): Added to the positive list (P), restricted for use in alcoholic beverages only.

These amendments to the national Plant List reflect the outcomes of recent safety evaluations by the Plants Commission.

UK

TiO₂: Unlikely to pose a significant health risk to the UK population

The UK's Committee on Toxicity of Chemicals in Food, Consumer Products, and the Environment (COT) has concluded that the current dietary exposure levels of titanium dioxide (TiO₂), commonly used as a food additive, are unlikely to pose a significant health risk to the UK population. This conclusion comes after a series of comprehensive safety evaluations conducted worldwide, following concerns raised by the European Food Safety Authority (EFSA) in 2021.

Titanium dioxide (E171) has been extensively used in the food and supplement industry, particularly for its whitening properties. Despite its widespread use, the safety of TiO₂ as a food additive was called into question after EFSA's 2021 report highlighted potential health risks, including immunotoxicity, neurotoxicity, and particularly genotoxicity. These concerns led to the European Union's decision to ban

the use of TiO₂ in food and food supplements, prompting other global regulatory bodies to reassess the additive's safety.

In response to EFSA's findings, several international bodies, including Health Canada in 2022, Food Standards Australia New Zealand (FSANZ) in 2022, and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 2024, conducted their own evaluations of TiO₂. These reviews provided a more nuanced understanding of the potential health implications associated with TiO₂, ultimately supporting its continued use as a food additive. Additionally, the Codex Committee on Food Additives agreed earlier this year to maintain current provisions for TiO₂, including its use in supplements at levels deemed appropriate (quantum satis).

The COT's conclusion aligns with the broader global consensus that, despite the concerns raised by EFSA, the available data does not indicate a significant risk to human health at the levels of TiO₂ currently used in food and supplements.

This conclusion is particularly significant in light of the ongoing evaluations of other food additives, such as silicon dioxide (SiO₂).

Guidance on caffeine in food supplements

The Food Standards Agency (FSA) and Food Standards Scotland (FSS) have introduced new guidance to ensure the safe use of food supplements containing caffeine, following a fatal incident linked to excessive caffeine consumption in the UK. Surveys have also revealed that many consumers are unaware of proper caffeine dosing in supplements, highlighting the need for clearer guidance.

For consumers

The guidance encourages consumers to be mindful of safe caffeine intake limits, up to 400 mg per day for healthy adults and 200 mg for pregnant women. It advises caution when combining various caffeine sources (e.g. coffee, tea, energy drinks, and supplements) and highlights the importance of following instructions, especially with concentrated forms like caffeine powder. Risky practices, such as consuming powdered supplements without water are discouraged, and consumers are urged to use accurate measuring tools and consult

healthcare professionals when necessary.

For businesses

Businesses are reminded of the importance of transparent labelling of caffeine content in supplements, even though no legal maximum limit exists in the UK. They are encouraged to include measuring devices with their products. EFSA's 2015 opinion is referenced for guidance on safe daily and per-serving caffeine limits. Companies must also ensure the caffeine used is from reputable suppliers and report any harmful or non-compliant products to the authorities.



Argentina

Hydrolysed collagen approved for use in supplements

Argentina has officially approved the inclusion of hydrolysed collagen as a permitted ingredient in food supplements. On August 14, the Secretary of Health Quality and the Secretary of Bioeconomy issued Resolution 2/2024, amending Article 1417 of the Argentinean Food Code to define hydrolysed collagen and authorise its use exclusively in food supplements. The resolution does not specify a maximum usage limit, and unlike previous approvals granted on a case-by-case basis, hydrolysed collagen is now permitted for use by any company without the need for specific authorisation.

Argentina proposes health claims for supplements

The National Commission of Foods (CONAL) has initiated a public consultation regarding proposed modifications to Articles 235 and 1381 of the Argentinean Food Code. The key change introduced in Article 1381 stipulates that only health claims explicitly authorised by the national health authority may be used. This modification indicates that, for the time being, no predefined list of permitted health claims will be established. Instead, the approval of health claims will occur on a case-by-

case basis, requiring individual applications by companies seeking authorisation.

Brazil

ANVISA reaffirms safety of Titanium Dioxide in food, contrasting with EFSA's precautionary approach

ANVISA, Brazil's health regulatory authority, has reaffirmed the safety of titanium dioxide (TiO₂) for use in food, which contrasts with the European Food Safety Authority's (EFSA) more cautious approach. Brazil's General Food Management (GGALI) stated that current safety concerns are based on studies that do not reflect real usage of food-grade titanium dioxide.

With a long history of safe use, research has shown extremely low absorption of titanium dioxide and no adverse effects, even at high doses in animal studies. Furthermore, no concerns have been found regarding its reproductive, developmental, carcinogenic, immunotoxic, inflammatory, or neurotoxic effects.

In light of ANVISA's findings, several actions are proposed: Organise a virtual dialogue to share findings with stakeholders, present conclusions to other Mercosur States, remove titanium dioxide from the 2024/2025 Regulatory Agenda, monitor new scientific and regulatory developments, reassess titanium dioxide's safety if new evidence emerges.

New food supplement notification rules effective 1 September 2024

As of 1 September 2024, Brazil requires all food supplements to be notified to ANVISA (Resolution RDC N° 843/2024). The required documents include: Notification form; a copy of the valid health license for the manufacturer responsible for production, quality control, and storage activities within the national territory, or, for foreign manufacturers, a document verifying compliance with the health authority of the country of origin; stability study reports; product analysis report or certificate confirming compliance with technical regulations.

A transitional period extends until 1 September 2025 for products already in production or importation. Registered enzyme and probiotic supplements can be marketed until their registration expires, provided they comply with the new notification rules before that.

Mexico

New additives, enzyme, and flavouring

The Federal Commission for the Protection Against Sanitary Risks (COFEPRIS) has updated its annexes to the Agreement on permitted additives and processing aids in foods, beverages, and food supplements. This update includes the following two new additives for supplements:

- Cross-linked Polyacrylic Acid Polymers (INS 1210) :
Functions: Volume increasing, stabilising, and thickening, Maximum limits: Solid and semi-solid forms: 200,000 mg/kg, Liquid forms: 30,000 mg/kg
- Class III Caramel (INS 150c)
Function: Colouring agent
Maximum limit: 20,000 mg/kg

And for general use, including supplements:

- New enzyme: Lipase
Produced by *Saccharomyces cerevisiae*, This enzyme includes a gene from *Fusarium oxysporum*.
- Natural-identical Flavoring: Eucalyptus Oil

All updates are now in effect.



USA

U.S. Senator Durbin proposes dietary supplement listing act of 2024

On 29 July, Senate Majority Whip Dick Durbin (D-IL) introduced the Dietary Supplement Listing Act of 2024. The proposed legislation requires dietary

supplement manufacturers to register their products with the FDA, providing detailed product information including names, ingredient lists, electronic copies of labels, allergen statements, and health and structure/function claims. This information would be publicly accessible through an electronic database. The Act also mandates that manufacturers submit all website claims for new products. This proposal builds on Durbin's earlier initiative, the Prohibiting Tianeptine and Other Dangerous Products Act, aimed at banning harmful ingredients like tianeptine from dietary supplements.



Australia

Temporary new arrangements for GMP inspections to address COVID-19 backlog

The Australian Therapeutic Goods Administration (TGA) has implemented temporary new arrangements for GMP inspections of domestic and overseas manufacturers of medicines, APIs, biologicals, and blood products. These inspections, introduced to address the COVID-19 pandemic backlog, will be in place for a period up to two years. These inspections, termed 'surveillance inspections,' will be full-scope but reduced in duration by approximately 50%. For instance, a typical 4-day inspection will be reduced to 2 days. Surveillance inspections can be conducted on-site, remotely, or as a hybrid, and will only be used once per eligible manufacturing site. GMP certificates issued will indicate that a surveillance inspection was used.

Eligibility for these inspections is limited to manufacturers with good compliance ratings (A1 or A2) from previous inspections. Sites with lower ratings, ongoing compliance issues, or requiring initial licensing/variation inspections are ineligible. TGA will issue GMP certificates with an extended validity from 3 years to 4 years for licensed sites that have not had a re-inspection in the last three years.

Consultation on changes to permissible ingredients determination

The Therapeutic Goods Administration (TGA) has announced its annual public consultation regarding proposed changes to the Permissible Ingredients Determination. The update focusses on ingredients with lower to negligible risks and includes new warnings and changes in ingredient nomenclature. The proposals include pregnancy warnings for *Petroselinum crispum* (Parsley), a liver warning for *Garcinia* species, hydroxycitric acid, hydroxycitrate complex and salts. Additionally, the ingredient name 'Rutoside' will change to 'rutoside trihydrate' and the removal of two ingredients is proposed for *Xanthium* species.

TGA proposes pharmacist-only access for Vitamin B6 supplements

The Therapeutic Goods Administration (TGA) has announced a proposed amendment to the Poisons Standard aimed at supplements containing Vitamin B6 (pyridoxine, pyridoxal, and pyridoxamine). This proposal comes in response to a growing number of reported cases of Vitamin B6 toxicity. The proposed changes, scheduled for review in November 2024, would limit the availability of Vitamin B6 supplements that deliver between 5 mg and 200 mg of pyridoxine, pyridoxal, or pyridoxamine per recommended daily dose. If implemented, these products would be reclassified as Schedule 3 (Pharmacist Only) medications, requiring pharmacist oversight for purchase.

In its consultation paper, the TGA highlights the increasing number of patients experiencing Vitamin B6 toxicity, often resulting in progressive and sometimes irreversible nerve damage. The TGA highlights that many are unaware of the potential dangers posed by excessive intake, particularly when self-medicating with multiple supplements.

Although supplements containing more than 10 mg of Vitamin B6 are required to carry warnings about the risk of peripheral neuropathy, the TGA is concerned that many consumers—particularly the elderly—may overlook or disregard these labels.



Azerbaijan

Redefining dietary supplements and clarifying new advertising requirements

Azerbaijan has passed Law No. 1169-VIQD which revises the legal definition of dietary supplements and updates advertising rules. The term "food additives with biological activity" is now replaced by "biologically active foods", defined as foodstuffs intended to enhance dietary intake, comprising one or more nutritional or biologically active substances with nutritional and physiological effects, with specific daily doses and various forms available (capsules, tablets, ampules, drops, or similar). These products must adhere to the country's food safety laws (No. 523-VIQ On food safety dated 5 May 2022). Additionally, new advertising regulations require that advertisements clearly state that these products are not medicines and do not possess therapeutic properties. They must also include their registration number under food safety law.

Belarus

Government lifts ban on distance selling of dietary supplements

The Belarus government has lifted the ban on distance selling of dietary supplements. In July, the Council of Ministers unveiled Decree No. 489 to implement amendments to the law governing state regulation of trade and the catering industry.

This decree updates:

Decree No. 1537 (dated 2 December 2004) outlining the procedure for the manufacturing and marketing of dietary supplements. Decree No. 31 (dated 5 January 2009) establishing the rules for distant selling.

Under the new regulations, the classification of dietary supplements into two distinct categories remains:

Supplements that support bodily functions: These include products

containing biologically active substances, vitamins, micro-elements, minerals, amino acids, live microorganisms, and/or their metabolites that have a normalising impact the composition and biological activity of the gut flora in the human gastrointestinal tract; Supplements for the enrichment of foods : These supplements provide additional sources of proteins, fats, carbohydrates, and dietary fibre.

The Ministry of Health's Commission on State Registration of Dietary Supplements will continue to classify each product brought to market. Significantly, the decree now allows dietary supplements to be sold not only in specialised stores or sections within food stores but also through e-commerce platforms. However, online sellers must have a physical retail location and/or warehouse facility.

Kazakhstan

Health ministry bans advertising of dietary supplements outside of retail locations

Kazakhstan's Ministry of Health has revised and re-published for comment a draft order approving rules of official control of advertising of foods that are subject to state registration. The previous version of the document was discussed in January 2024. The new version considerably expands the list of foods covered by the advertising rules, stating that the rules apply to all foods that are subject to mandatory state registration.

The rules introduce specific requirements for the advertising of dietary supplements. Adverts presenting dietary supplements as unique, safest, effective, or comparable to medicine are not allowed, as well as claims about their therapeutic properties.

Dietary supplements may also not be advertised in public transport or any places other than those where supplements are prescribed, used, or sold.

If adopted, the order will become effective ten days after official publication. The enactment of the order will invalidate the Ministry of Health order No. KR DSM-160/2020 dated 27 October 2020, which approved the current rules for advertising of dietary supplements (registered under No. 21544 in

Kazakhstan's register of laws and regulations).

Health Ministry restricts supplement ads to retail locations

The interim Minister of Health issued Order No. 36, amending the advertising rules for dietary supplements. These revised rules, now called the Advertising Rules for Foods Subject to State Sanitary and Epidemiological Supervision and State Registration, apply to all foods requiring state registration. The new regulations set general advertising standards for foods and specific guidelines for dietary supplements (unlike the initial version, which contained requirements for specialised foods in general). Notably, the rules ban ads that present supplements as unique, safest, or effective, prohibit comparisons to medicines, and disallow claims of therapeutic properties. In addition dietary supplements may not be advertised in public transport or any locations other than those where supplements are prescribed, used, or sold.

Russia

Parliament to allow doctors to prescribe supplements and authorise consumer authority to block websites that sell unregistered supplements

On 8 July 2024, the State Duma approved in the first reading the government bill (No. 638771-8) that seeks to improve market regulation of dietary supplements. The amendments are to be introduced to the following laws:

- On quality and safety of foods;
- On information, information technologies and protection of information;
- On basics of citizens' health protection in the Russian Federation.

Article 6 of the federal law On quality and safety of foods is to include additional clauses on new powers of the government to introduce:

- Quality criteria for dietary supplements and their ingredients;
- Specific directions of use of dietary supplements;
- Specific terms of registration of dietary

supplements made by Russian manufacturers.

Additionally, the law also includes a new article stating that health professionals can prescribe dietary supplements to certain population groups provided they comply with guidelines of the Ministry of Health.

Similar amendments are proposed to article 37 of the federal law On basics of citizens' health protection in the Russian Federation. Compliance with new requirements related to prescribed use of dietary supplements subject to official control in the area of healthcare quality and safety. The federal law on information, information technologies and protection of information is to be amended to read that the federal register of prohibited websites will include websites containing information on sales (including distant sales) of unauthorised dietary supplements. The Federal Service for Surveillance on Consumer Rights Protection (Rosпотребнадзор) is to be responsible for monitoring and reporting all violating websites.

Parliament considers Bill allowing doctors to prescribe supplements and empowering Market Watchdog to block websites

The Russian State Duma has adopted in the first reading a draft bill (No. 638771-8) that introduces significant changes to the regulation of dietary supplements. Filed by the government on 31 May, the bill proposes amendments to federal laws, including the introduction of quality criteria for dietary supplements, specific specify directions of use, and registration terms for domestically produced supplements.

Notably, the bill allows health professionals to prescribe dietary supplements to certain population groups, following guidelines from the Ministry of Health. However, concerns have been raised, including the lack of a requirement for clinical trials for these supplements and the potential impact of allowing the market watchdog to block websites without a court order, which could severely affect e-commerce businesses. Additionally, the proposed quality criteria for supplements may conflict with international laws and the regulations of the Eurasian Economic Union.

Parliament rejects supplement education bill

Members of the State Duma (Russia's parliament) voted against proposed amendments to the federal law on education in the Russian Federation. The draft law would have required government approval for all educational programs and events related to the promotion of dietary supplements. Initially introduced to the State Duma in April 2023, the bill aimed to prevent the misuse of seminars and training on food supplements by unscrupulous actors and to provide the public with greater protection. In April 2024, the government issued a negative opinion on the bill, and it was subsequently rejected after its first reading.

Ukraine

Ukraine aligns supplement regulation with EU

The Ukrainian government has introduced a bill to update the regulation of food supplements. The proposed legislation seeks to close gaps in the in-market control of supplements, a requirement under the EU Association Agreement. Key provisions of the draft law include:

- Amending the definition of food supplements in line with EU Directive 2002/46/EC;
 - Replacing the requirement for state registration with a notification system for food supplements, including maintaining and publishing a list of notifications on an official website;
 - Delegating the Ministry of Health to establish a list of approved nutrients or substances and their maximum doses for use in food supplements;
 - Enhancing liability for the manufacturing and sale of food supplements that fail to comply with statutory requirements.
- The law also aims to establish the procedure and methodology for assessing the health impact of vitamins, minerals, and other bioactive substances.

Uzbekistan

Uzbekistan requires Ministry of Health approval for supplement ads on TV and radio

From 1 July 2024, all television and radio advertisements for dietary supplements in Uzbekistan must be approved by the Ministry of Health before they can be aired, according to Presidential Order No. UP-20, issued on January 23, 2024.

The approval process is outlined in Appendix 18 of the Unified Administrative Procedure for Providing Public Services to Individuals and Legal Entities, as established by Cabinet of Ministers Decree No. 169 on 29 March 2024. Advertisers can submit their applications through the my.gov.uz portal, with the service being provided free of charge within five business days. Notably, businesses will not need to reapply for approval if they change their legal form, name, or location (postal address).

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IADSA

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