

IADSA NEWSFLASH

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Regulatory news



China

Simpler pathway for lycopene supplements

The State Administration for Market Regulation (SAMR) has released a draft proposal to include lycopene in its Health Food Raw Material Directory, with public consultation open until 10 May.

If adopted, the measure would allow lycopene products to move from the registration system to the simplified filing pathway, reducing both time and cost for market entry.

The draft sets out detailed conditions of use. It covers different forms of lycopene, including tomato-derived extracts and synthetic sources, with defined compositional requirements. Proposed daily intake levels range from 15 to 30 mg for adults, with use not recommended for children and for pregnant or lactating women. Permitted health functions include antioxidant effects, immune support and lycopene supplementation. The proposal also includes technical specifications, such as purity criteria, limits for heavy metals and residual solvents.

China updates registration rules for foreign food exporters

China's General Administration of Customs of China has released detailed guidance under Decree 280, setting out how overseas food manufacturers will need to register ahead of the new system taking effect on 1 June 2026.

The new framework also introduces automatic five-year renewals for most products, but maintains stricter controls for higher-risk categories such as meat and bird's nest products, which will require active renewal. Products made during a valid registration period can still be imported after expiry if they are within shelf life under the recommended pathway. For self-registration, a valid registration is required at the time of import. Shipments sent before a registration is suspended, cancelled or revoked may still be accepted.

India

Single window approval system for food products and claims

India's Food Safety and Standards Authority (FSSAI) has announced the launch of a new Single Window System for product approvals and risk assessments through the electronic Product and Claim Approval Application System (ePAAS). From 1 June 2026, all applications requiring prior approval must be

submitted exclusively through the ePAAS portal. This includes applications for non-specified foods and ingredients, claims approvals, Ayurveda Aahara products, FSMPs, vegan endorsement, r-PET authorisations and notifications for certain vitamin, mineral and amino acid forms.

According to FSSAI, the system aims to improve transparency, consistency and efficiency in the approval process by creating a unified digital platform for submission, review and monitoring of applications.

The notification also confirms that manual, offline or email-based submissions will no longer be accepted after implementation

India clarifies ashwagandha use

The Indian government issued a communication in April on ashwagandha, with statements from both the Food Safety and Standards Authority of India (FSSAI) and the Ministry of Ayush

The Ministry of Ayush has reiterated that only the root should be used in Ayush products and that the use of leaves is prohibited. This has been followed by FSSAI stating that only ashwagandha root is permitted in food products and that leaves are not allowed in any form. Both statements confirm that only the root is acceptable. This does not introduce a new rule, but reinforces the existing position, indicating that it may now be applied more strictly.

The Indian authorities have referred to evidence that leaves of ashwagandha may contain higher levels of certain compounds, such as withanolides like Withaferin A, which may raise safety concerns.

While the announcement has taken many by surprise, the authorities are positioning it as a national clarification.

Ashwagandha is coming under closer scrutiny globally. In the United Kingdom, regulators are asking for more data to define safe use. Across the European Union, authorities are also reviewing its safety. In France, warnings have been issued for certain groups, and in Denmark the ingredient has already been restricted. Other countries are also looking at possible risks, including effects on the liver and use during pregnancy.

This was also reflected at the WHO Global Traditional Medicine Summit in New Delhi in 2025, where there was a focus on the need for stronger scientific evidence, better quality standards and improved safety monitoring for traditional ingredients. India's decision is likely to have effects beyond India and may lead other countries to review their approach.

Indian High Court temporarily suspends FSSAI Ashwagandha leaf restriction

In mid-May, the Bangalore High Court has granted an interim stay on the recent Indian restriction prohibiting the use of ashwagandha leaves in food products, following legal challenges from a group of manufacturers.

The court's decision temporarily suspends enforcement of the Food Safety and Standards Authority of India (FSSAI) advisory of 16 April 2026 for the petitioning companies until the next hearing scheduled for 8 June 2026.

The case relates to the FSSAI advisory issued following concerns raised by the Ministry of AYUSH regarding the safety of ashwagandha leaves, particularly the presence of higher concentrations of reactive withanolides such as withaferin A. Authorities had directed manufacturers to use root material only and to clearly identify plant parts used on labels.

However, the petitioning companies argued that such a prohibition could

not legally be introduced through an advisory alone and would instead require a formal amendment to India's 2016 nutraceutical and health supplement regulations. The petition also challenged the scientific basis and proportionality of the restriction, highlighting that ashwagandha leaf extracts have been produced and exported for decades without objection.

Move to improve ease of doing business

India's Ministry of Health and Family Welfare (MoHFW) has approved a set of regulatory reforms aimed at reducing compliance burdens for food businesses while strengthening food safety oversight.

One measure is the introduction of perpetual validity for registrations and licences issued by the Food Safety and Standards Authority of India (FSSAI), removing the need for periodic renewals. Authorities indicate this will reduce administrative costs and allow greater focus on enforcement and monitoring.

The reforms also raise turnover thresholds for registration and licensing from 1 April 2026, easing entry requirements and reducing compliance obligations for smaller businesses. More operators will fall under simpler registration regimes, while larger businesses will continue to be subject to State or Central licensing based on scale. The changes are expected to lower administrative costs, particularly for micro and small enterprises.

In parallel, a risk-based inspection system will be introduced, with controls guided by product risk, compliance history, audit results and enforcement inputs, helping to reduce repetitive inspections for compliant businesses.

Singapore

HSA updates list of notified supplements

The Health Sciences Authority (HSA) has updated its List of Notified Health Supplements and Traditional Medicines, with the latest revision published in February. The listed products are notified with HSA on the basis of voluntary declarations submitted by companies, confirming that the products comply with the

published guidelines for Complementary Health Products. This notification should not be interpreted as an endorsement or approval by HSA.

Taiwan

Taiwan proposes rules for traditional medicine ingredients in foods

Taiwan's Ministry of Health and Welfare has issued a draft framework to better define when traditional Chinese medicinal materials can be used as food ingredients, aiming to bring greater clarity to a long-standing grey area between food and medicine. The proposal introduces a two-tier system. A first category lists 75 ingredients considered suitable for food use based on traditional dietary practices. A second category identifies 73 ingredients that may still be used in foods, but only under stricter safety conditions.

For these 73 materials, the draft sets out detailed requirements, including maximum daily intake levels, mandatory warning statements for certain population groups, and, in some cases, restrictions on processing or product format (for example, limiting use to teas or requiring specific preparation steps). These controls reflect the need to manage potential risks linked to higher biological activity or traditional medicinal use.

The framework also establishes clear criteria for product classification. Products may be regulated as medicines if they contain high proportions of these controlled ingredients or if estimated daily intake exceeds defined thresholds aligned with the Taiwan Pharmacopoeia. At the same time, products can remain within the food category if they meet compositional limits and, where required, provide supporting safety data.

Indonesia

2026 Legislative drafting plan covering supplements

Indonesian Food and Drug Authority (BPOM) has released a draft decree outlining its 2026 Legislative Drafting Programme. The document sets out planned regulatory initiatives within

BPOM's remit, including measures affecting health supplements.

For health supplements, BPOM plans to revise the regulation on criteria and registration procedures to align with Law No. 17/2023 on Health and Government Regulation No. 28/2024.

The proposed direction includes updating the definition of health supplements, clarifying the status of bulk products, adjusting stability test requirements for low-risk products, and introducing refinements to import provisions, GMP (CPOB) validity periods and data submission timelines. Adjustments to maximum limits for active ingredients are also envisaged. Further draft initiatives include new guidelines on follow-up actions resulting from inspections covering traditional medicines, quasi medicines, health supplements and cosmetics. BPOM also intends to establish clearer pharmacovigilance requirements, including mandatory adverse event reporting by marketing authorisation holders. A separate draft regulation would provide a legal basis for recall and destruction procedures for non-compliant products.

South Korea

31 health functional ingredients for 2027 re-evaluation

The Ministry of Food and Drug Safety (MFDS) in South Korea has published a preliminary list of 31 health functional food ingredients scheduled for re-evaluation in 2027.

The list includes substances such as bilberry extract, garlic, plant sterols, probiotics, cranberry extract and L-arginine.

The final list and detailed re-evaluation criteria will be published in August 2026. Companies holding individual recognition for these ingredients will be required to submit safety and efficacy data by December 2026, with the re-evaluation process scheduled to take place during 2027.



EU

EFSA highlights emerging considerations on probiotics and antibiotic resistance

The latest newsletter from the European Food Safety Authority (EFSA) on Emerging Risks and Horizon Scanning (March 2026) outlines recent signals and trends identified through its monitoring activities under the One Health approach.

Among the topics covered, EFSA has issued a call for information on probiotics and antibiotic resistance. Recent studies suggest that certain probiotic strains may carry antibiotic resistance genes, which, if transferable, could contribute to the broader challenge of antimicrobial resistance.

EFSA notes that there is currently no harmonised approach for screening probiotics for such genes, alongside continued inconsistencies in product labelling. As part of its ongoing work, EFSA is seeking additional data on probiotics that may contain transferable antimicrobial resistance genes.

While no immediate regulatory changes are anticipated, this initiative may inform future considerations on the safety assessment of probiotics.

EU to tighten control on mineral oil hydrocarbons, with a phased path for supplements

The European Union is preparing to introduce binding limits on mineral oil aromatic hydrocarbons (MOAH) in food and supplements, marking a shift from years of monitoring towards formal regulatory control.

The move follows a long period of groundwork led by the European Food Safety Authority, which first identified potential health concerns linked to MOAH in 2012 and reaffirmed these in an updated assessment in 2023. Unlike other contaminants, MOAH are treated with particular caution due to their potential genotoxic and carcinogenic properties.

Until now, the EU has taken a measured approach. A 2017 Commission Recommendation encouraged Member States to monitor mineral oil hydrocarbons across food categories. That phase is now drawing to a close.

Under a draft amendment to Regulation (EU) 2023/915, the European Commission has notified the World Trade Organization and the European Industry of its intention to introduce maximum levels for MOAH across a range of foods, including food supplements. The measure is expected to apply from 1 January 2027, with transitional provisions extending to 1 January 2030. The proposal confirms what the sector had anticipated: A phased implementation for food supplements. A maximum level of 10.0 mg/kg would apply from 2027, tightening to 5.0 mg/kg from 2030. The same approach extends to key ingredients such as fish oils and herbs. Food additives derived from these materials are also brought into scope.

Mineral oil hydrocarbons (MOH), including mineral oil saturated hydrocarbons (MOSH) and MOAH, are not intentionally added to food but can arise at multiple stages of the supply chain, from environmental contamination and processing to packaging materials. While current exposure to MOSH is not considered a health concern, certain MOAH fractions, particularly those with three or more aromatic rings, raise genotoxic and carcinogenic concerns. Alongside binding limits, the EU is also reinforcing its monitoring framework through the introduction of indicative levels. For food supplements, a reference level of 15 mg/kg for MOSH is set, complemented by values for related materials, including 50 mg/kg for fish oils and 15 mg/kg for dried herbs and herbal infusions. Additional reference points are proposed for MOAH, including 5.0 mg/kg for herbal infusions and 10 mg/kg for essential oils.

A coordinated monitoring programme running from 2026 to 2029 will support implementation. At the same time, testing requirements are being tightened. Laboratories will be expected to apply updated EU methods, with advanced techniques such as comprehensive two-dimensional gas chromatography (GC×GC) recommended to improve analytical precision. For supplements and related matrices, a limit of quantification of 5.0 mg/kg or lower will be required.

EU launches AI-powered TraceMap to strengthen food safety and fraud detection

The European Commission has launched TraceMap, a new AI-powered tool designed to help authorities detect food fraud and food safety risks more quickly across the EU. The tool aims to support quicker removal of unsafe or non-compliant products from the market, including during foodborne outbreaks, and strengthen controls on imported goods.

Until now, tracing products often relied on manual checks and exchanges between authorities, which could be slow and resource-intensive. TraceMap replaces much of this with automated analysis and visual mapping, making supply chains easier to understand and investigate. It brings together data from key EU systems, including TRACES, the Alert and Cooperation Network (ACN) and the Rapid Alert System for Food and Feed (RASFF), allowing authorities to access and use information more efficiently.

Emerging attention on polyols

A recent petition brought before the European Parliament has placed polyol sweeteners back on the radar. Submitted by a Polish citizen, Petition No 1398/2025 calls for a re-evaluation of substances such as erythritol, xylitol and sorbitol, citing recent scientific publications and personal experience suggesting possible cardiovascular, neurological and vascular risks.

The petitioner also calls for broader safety assessments covering additional health endpoints, clearer labelling on exposure, strengthened post-market monitoring, and consideration of impurities and combined effects.

In its response, the European Commission maintains that the existing EU framework remains appropriate. Polyols are authorised food additives subject to prior risk assessment by the European Food Safety Authority (EFSA), with established provisions for re-evaluation should new evidence arise.

From a regulatory perspective, the impact is limited at this stage. Petitions allow citizens to raise concerns at EU level, but they do not

in themselves lead to changes in legislation or require EU institutions to act. The regulatory status of polyols therefore remains unchanged for now, although such developments can contribute to wider attention over time.

The petition, however, illustrates how individual concerns can enter the EU institutional process and gain visibility, even in the absence of regulatory momentum. In areas such as sweeteners, where scientific assessment, public perception and policy debate often evolve in parallel, such signals can contribute to a broader context of scrutiny over time.

EFSA confirms safety of sucralose for current uses

The European Food Safety Authority (EFSA) has confirmed that the sweetener sucralose (E 955) remains safe for consumers when used under its current authorised conditions. Following a comprehensive scientific review, EFSA maintained the existing acceptable daily intake (ADI) of 15 mg/kg body weight per day, noting that current consumer exposure remains below this threshold.

The assessment forms part of the EU's ongoing re-evaluation of food additives approved before 2009. Alongside the safety review, EFSA also examined a request to extend the use of sucralose to additional fine bakery products beyond those already authorised.

While no safety concerns were identified for existing uses, EFSA concluded that it could not confirm the safety of the proposed new applications. The Panel highlighted uncertainties linked to processes involving prolonged exposure to high temperatures, where studies suggest that chlorine may migrate from sucralose and potentially lead to the formation of chlorinated compounds with unknown health effects.

EFSA also noted that similar conditions may occur during certain domestic cooking practices, such as baking or frying, and recommended that the European Commission further consider this issue.

For the food supplement sector, existing provisions applicable to supplements are therefore expected to be reconfirmed.

France

France renews suspension of food supplements containing *Garcinia cambogia*

France has renewed its suspension of food supplements containing *Garcinia cambogia* Desr. A new order, published on 17 April and effective from 18 April 2026, extends the prohibition for a further one year. The measure bans the importation, introduction and placing on the market of all food supplements containing the plant and its derivatives.

The decision is based on assessments by ANSES, which identified acute health risks associated with *Garcinia cambogia* extracts. France has taken this action as a precaution while an EU-level evaluation of hydroxycitric acid (HCA), the plant's main active component, is still ongoing.

Food business operators are required to ensure full compliance, including reviewing product formulations and supply chains.

Germany

BfR: folic acid recommended before and during early pregnancy, other supplements only where needed

Expectant mothers may not always meet all their nutritional needs through diet alone, according to a recent communication from the German Federal Institute for Risk Assessment (BfR).

The institute explains that while most vitamin and mineral requirements can usually be covered by a balanced and varied diet, some nutrients require particular attention during pregnancy because needs increase.

In particular, BfR recommends that women who are planning a pregnancy or who could become pregnant take 400 micrograms (µg) of folic acid per day, starting at least four weeks before conception and continuing through the first trimester. This reduces the risk of neural tube defects affecting the baby's brain and spine.

BfR also notes that iodine intake is often too low in Germany and that supplementation of around 100-150 µg

per day may be appropriate, depending on individual circumstances and medical advice. Iron supplements are not generally recommended for all pregnant women but should be taken if a deficiency is diagnosed. The institute also stresses the importance of avoiding excessive intake of certain vitamins, particularly vitamin A.

BfR refers readers to its mikroco.info platform for detailed information on recommended intakes and safe levels. It also urges caution that pregnant women should not take food supplements, over-the-counter medicines or herbal products without consulting a healthcare professional, as both deficiencies and excessive intakes may pose risks to mother and child.

Draft update of algae list

German authorities have opened a public consultation on a revised edition of the “Algae Substance List”, a scientific reference increasingly used to guide how algae ingredients, many of them found in food supplements, are classified on the market.

Unlike vitamins and minerals, algae and other so-called “other substances” are not harmonised at EU level, leaving national authorities to interpret how such ingredients should be regulated.

The substance list was developed to help close this gap. Prepared by a scientific working group bringing together regulators, risk assessors and academic experts from Germany, Austria and Switzerland, it provides coordinated recommendations to help authorities determine whether a substance should be treated as a food, a novel food or, in some cases, a medicinal product. Although not legally binding, the list is widely used in enforcement practice and can influence market access decisions.

The updated draft reflects the growing presence of algae in food supplements. It expands the number of species covered, updates scientific naming, including clarification around spirulina-type organisms, and provides more precise identification of algae used commercially.

No immediate regulatory changes result from the update. However, the revision highlights increasing attention from authorities towards algae ingredients.

The Netherlands

The Netherlands draws a line on GLP-1 references for supplements

The Dutch Inspection Board (Keuringsraad) has issued new guidance clarifying that references to GLP-1 in the marketing of food supplements fall outside the boundaries permitted under food law. The publication comes as GLP-1 medicines continue to reshape global discussions around weight management, with the terminology increasingly appearing beyond pharmaceutical settings.

According to the Inspection Board, statements suggesting that supplements “support GLP-1”, “stimulate GLP-1 production” or work through similar mechanisms are not permitted, as they imply medicinal effects linked to pharmaceutical products. The guidance stresses that there are currently no authorised EU health claims relating to GLP-1 and that even indirect references may be interpreted as implicit medical claims.

The publication also signals that authorities are likely to scrutinise not only explicit claims, but also broader positioning strategies, product names, testimonials and target group references linked to GLP-1 medicines.

While the guidance is specific to the Netherlands, it is likely to be closely watched across Europe as regulators increasingly face questions around how existing food law frameworks apply in the context of rapidly evolving consumer awareness surrounding obesity medicines and appetite-related mechanisms.

Norway

Norway clarifies CBD rules amid growing market confusion

The Norwegian Food Safety Authority and the Norwegian Directorate of Medical Products have issued a joint overview of cannabidiol (CBD) regulations, aiming to address widespread confusion over the legality of CBD products in Norway. Authorities warn that misinformation is common and emphasise the need for clearer understanding among both businesses and consumers.

Under Norwegian rules, CBD derived from the cannabis plant (*Cannabis*

sativa), including products without THC, is classified as a narcotic and therefore prohibited. Synthetic CBD is not treated as a narcotic, but remains subject to strict regulation depending on its use.

The overview sets out a strict position across product categories. CBD is banned in foods, beverages and food supplements regardless of its source. In cosmetics, CBD extracted from the plant (except from seeds) is also considered illegal. E-cigarettes containing CBD fall under drug legislation and are not permitted. Only certain CBD-based medicines may be authorised, subject to pharmaceutical regulation.

Spain

Spain clarifies rules on “medicinal” naming of food supplements

The Spanish Agency for Food Safety and Nutrition has published a new interpretative note on the use of commercial or “fantasy” names for food supplements.

The guidance clarifies that product names must comply with the principles set out in Regulation (EC) No 1924/2006 and broader EU food information law. In particular, names that attribute properties of preventing, treating or curing disease, or that otherwise suggest medicinal or therapeutic effects, are considered non-compliant. AESAN emphasises that such naming may mislead consumers by blurring the distinction between food supplements and medicinal products.

To support this interpretation, AESAN provides concrete examples of wording considered problematic on the Spanish market. These include prefixes linked to diseases or medical contexts, such as “cist-”, “dolo-” or “onco-”, which are understood to refer to cystitis, pain or oncology. The note also flags terms implying medical intervention, including “treatment”, “therapy” or “relief”. In addition, references to traditional or quasi-medical systems, such as “ayurvedic” or “mycotherapy”, are considered problematic where they contribute to an overall medicinal positioning of the product.

AESAN also acknowledges that some of these naming practices have historically been present on the Spanish market. However, it makes

clear that this tolerance will no longer apply and that enforcement will now align more strictly with EU legal principles.

To allow for adaptation, a transition period has been introduced. From 1 January 2028, new products placed on the Spanish market must fully comply with this interpretation. Products already on the market before this date may continue to be sold until the end of their shelf life.

Turkey

Supplements cannot claim antiviral effects

The Turkish “Güvenilir Gıda” (Reliable Food) platform has published a consumer Q&A addressing whether any food supplements are effective against viruses.

The response explains that food supplements are products designed to supplement normal nutrition and may contain vitamins, minerals, proteins, carbohydrates, fibre, fatty acids, amino acids, botanicals or other substances with nutritional or physiological effects, presented in dose form.

It also reiterates the mandatory labelling requirement that food supplements must carry the statement: “Not a medicine. Not for the prevention or treatment of diseases.”

Turkey aligns food additive specifications with EU rules

Turkey has adopted amendments to its Turkish Food Codex Regulation on Specifications for Food Additives.

The revisions are designed to further align national legislation with EU Regulation (EU) No 231/2012, which sets detailed specifications for food additives listed in Annexes II and III of Regulation (EC) No 1333/2008.

The updated regulation revises technical specifications, definitions and purity criteria for a range of authorised additives. It also introduces new specifications for certain additives.

Draft omnibus bill revives debate over authority for food supplements

A draft omnibus law under review at the Ministry of Health has raised new questions about the future regulatory oversight of food supplements in Turkey.

The draft legislation foresees the creation of a new commission operating under the Ministry of Health. One of the most consequential elements would require food supplement products that have already received regulatory approval to undergo a new review process. The commission would assess each product individually to determine whether it should fall under the authority of the Ministry of Health or the Ministry of Agriculture.

Early interpretations suggest that products presented in small dosage forms could be handled by the Ministry of Health, while powder-based products may remain under the Ministry of Agriculture’s remit, although how this distinction would be applied in practice remains unclear.

The proposal remains at an early stage and has been transmitted to the Ministry of Agriculture for consultation. Before any measures could enter into force, the omnibus bill would need to complete several legislative steps, including submission to Parliament, committee review and approval in plenary.

Clarification on the approval pathway for supplements

Turkish authorities have published updated guidance clarifying how food supplement applications should be prepared and assessed, providing greater transparency on the country’s pre-market approval system.

Under the Turkish framework, food supplements must obtain individual product approval before being placed on the market. While no new legal requirements have been introduced, the guidance explains more clearly what authorities expect in practice when reviewing applications.

Applications must include comprehensive documentation covering product composition, ingredient specifications,

recommended daily intake, manufacturing information, labelling materials and evidence supporting product safety and quality. Authorities place strong emphasis on traceability, requiring clear identification of raw materials, production methods and supplier information.

Particular attention is given to categories subject to increased scrutiny, including botanicals, bee-derived ingredients, probiotics and combination products. Authorities also reiterate rules on product naming and presentation, stressing that products must not be positioned in a way that suggests medicinal effects.

The guidance also highlights common deficiencies observed in applications. Documents must be properly signed and authenticated, where original handwritten (“wet”) signatures cannot be provided, certified true copies are required. Raw-material specifications must be issued and signed by the ingredient manufacturer and include detailed information on source, production method, content and purity. For fermentation-derived ingredients, applicants must additionally declare the microorganism used, including genus, species and strain identification.

Genetically modified production processes remain a highly sensitive regulatory topic in Turkey. Since the Biosafety Board was dissolved in 2018 and has not been re-established, there is currently no operational authority able to grant approvals for products manufactured using GMO microorganisms. In practice, this creates significant uncertainty for ingredients produced using GMO-derived organisms, as no clear authorisation pathway is available.

UK

UK clears turmeric-derived novel ingredient for supplements

The Food Standards Agency and Food Standards Scotland have concluded that tetrahydrocurcuminoids, a derivative of turmeric (*Curcuma longa*), are safe for use in food supplements under specified conditions.

The assessment, published under application RP2124, finds that the ingredient is sufficiently characterised

and does not raise safety concerns in the proposed uses.

Tetrahydrocurcuminoids are produced by hydrogenating curcuminoids extracted from turmeric. While turmeric itself is not considered novel, this modified form requires authorisation before being placed on the GB market.

The review identified no new scientific issues and no divergence from the EU assessment. However, regulators noted that rare cases of idiosyncratic liver reactions cannot be entirely ruled out in susceptible individuals, suggesting that risk management measures such as labelling may be appropriate.

UK-EU SPS negotiations: Implications for food supplements

The UK Government is negotiating a Sanitary and Phytosanitary (SPS) Agreement with the EU, expected to allow alignment with EU rules across food and feed safety and consumer information.

Guidance on the legislation in scope has been published alongside a six-week consultation, seeking evidence on business impacts.

While alignment may support trade with the EU, it raises more immediate questions for products placed solely on the Great Britain (GB) market. Food supplements are potentially exposed. Products containing substances restricted or prohibited in the EU, such as titanium dioxide, green tea catechins or monacolins from red yeast rice, may require reformulation or relabelling. The same applies where authorised novel foods are subject to different conditions of use between the GB and the EU, including ingredients such as partially hydrolysed protein from barley and rice.

With further EU restrictions expected in the coming years, alignment could impact product availability in the GB supplements market.

Ukraine

Proposed scientific assessment system for supplement ingredients

Ukraine has notified the WTO of a draft measure introducing a scientific methodology for assessing vitamins,

minerals and other substances used in food supplements.

The proposal would establish the principles and criteria authorities will use to evaluate the impact of these substances on human health as part of Ukraine's food supplement framework.

Under the proposed system, scientific dossiers may be required for the evaluation of certain vitamins, minerals, amino acids and other substances used in food supplements. The assessment would consider factors such as toxicological data, intake levels, manufacturing processes, stability and overall safety.

The draft also refers to international and European scientific risk assessment approaches, including methodologies used by EFSA.

The measure forms part of Ukraine's broader efforts to modernise its food supplement framework and align aspects of its regulatory system more closely with European scientific and regulatory practices.



Brazil

New limits and warnings on curcumin supplements

Brazil has updated its food supplement rules for curcumin. On 22 April, the National Health Surveillance Agency published Administrative Order IN 438/2026, amending Administrative Order IN 28/2018, which sets the conditions for ingredients, use, claims and labelling. The measure was adopted as urgent, without public consultation.

The update brings a number of changes. The existing minimum and maximum limits for curcumin now apply to the total curcuminoid content, rather than to curcumin alone. The combination of curcumin extract (*Curcuma longa* L.) with tetrahydrocurcuminoids from the same plant is no longer permitted. Products must also include a mandatory warning, advising against use by pregnant or breastfeeding women, children, and people with liver, biliary or gastric conditions, and

recommending medical advice for those under treatment.

Companies have six months (from 22 April 2026) to comply. During this period, products may still be produced or imported if the warning is made available via company websites and consumer service channels. Existing products can remain on the market until the end of their shelf life.

Update on food additives for supplements

Brazil published Administrative Order IN 432/2026 in the Official Gazette, updating the existing framework set out in Administrative Order IN 211/2023, which defines the additives permitted across different food categories.

The latest update focuses on liquid food supplements. It revises the conditions of use for several substances, including tartaric acid (INS 334), different forms of tocopherols (INS 307a, 307b and 307c), and L(+)-sodium tartrate (INS 335ii). These changes adjust how these additives can be used in practice, reflecting ongoing regulatory fine-tuning of the category. The measure also introduces a new element, with glycolipids (INS 246) now permitted as a preservative in this category. This addition provides manufacturers with an additional option for product stability.

The updated rules apply immediately from the date of publication.

Ingredients, claims and labelling requirements

Brazil has taken a further step in refining its food supplement framework, introducing new ingredients, intake thresholds and more detailed rules on claims and labelling.

On 2 April 2026, the Agência Nacional de Vigilância Sanitária (ANVISA) published Normative Instruction No. 431/2026, updating the country's core regulation for food supplements (IN No. 28/2018). The measure entered into force immediately.

The update expands the list of authorised constituents. Newly permitted substances include lipid sources such as baru almond oil and DHA-rich microalgae oil, alongside açai-derived bioactives and additional probiotic strains and combinations.

At the same time, ANVISA has introduced more precise conditions of use. Minimum and maximum daily intake levels are now defined for several newly authorised substances, including açai polyphenols and anthocyanins. For probiotics, minimum levels expressed in CFU/day are established, while maximum limits remain flexible in certain cases, consistent with the Brazilian regulatory model.

The framework for claims has also been further developed. New authorised claims include function claims for vitamins B1, B6 and B12 linked to the normal function of the nervous system, as well as claims for specific probiotic strains related to gastrointestinal health and, in certain cases, reduction of the risk of upper respiratory tract infections. As in other jurisdictions, these claims are conditional on meeting defined compositional thresholds.

In parallel, the update strengthens labelling provisions. New mandatory warnings have been introduced for certain ingredients, particularly targeting vulnerable population groups.

Chile

Chile warns of rise in melatonin-related cases in children

Chile's Instituto de Salud Pública de Chile has raised concerns over a growing number of melatonin-related intoxications in children and adolescents, based on national toxicology data.

The authority reports hundreds of cases in recent years, linked to both accidental ingestion and unsupervised use, with increasing notifications also recorded through pharmacovigilance systems.

In Chile, melatonin is classified as a prescription medicine, and no products are authorised for use in people under 18.

The regulator also points to the role of products marketed as food supplements in other markets, including formats such as gummies, which are entering the country through online purchases and personal imports.

Chile seeks clarity on borderline products, including supplements

The Institute of Public Health (ISP) of Chile has launched a public consultation on draft guidance aimed at clarifying how products subject to health control should be classified, including food supplements.

The document does not introduce new regulatory rules but explains how the authority interprets and applies existing requirements when dealing with borderline products. The guidance outlines how the ISP determines the correct category of a product covering aspects such as permitted ingredients, import procedures and advertising rules.

According to the ISP, incorrect classification can create regulatory uncertainty and potential public health risks, particularly where products are marketed under an inappropriate category; for example, food supplements that may fall within the definition of medicines or products promoted with claims not permitted for their category. The draft also explains how companies can proactively request a classification decision or seek an opinion on ingredient permissibility.

Ecuador

Outsourced testing rules

Ecuador's National Agency for Regulation, Control and Sanitary Surveillance (ARCSA) has launched a public consultation on a draft update to its guidance governing the outsourcing of laboratory analyses for food supplements, foods for special dietary uses, and processed foods.

The proposal aims to clarify the requirements and procedures for the registration of conformity assessment bodies (accredited laboratories) with ARCSA. These bodies would be authorised to carry out post-notification quality control analyses for products subject to sanitary surveillance.

The draft introduces updates across several areas, including general provisions and definitions, registration requirements, and operational procedures. In particular, it revises processes for the registration of laboratories, handling of samples, and submission of analytical reports and results, with the objective of improving consistency and traceability.

The annexes are also updated, notably to include standardised forms for

confidentiality commitments and registration applications.

If adopted, the revised guidance would replace the current (4th) version and further formalise the role of third-party laboratories in Ecuador's post-market control system.



Canada

A new reference point for prebiotics

The Health Canada Natural and Non-prescription Health Products Directorate (NNHPD) has published a Prebiotics Monograph, establishing a framework to support Product Licence Applications (PLAs) and labelling for natural health products.

The monograph defines prebiotics based on function, namely their ability to selectively stimulate beneficial gut microbiota and confer a health benefit, while distinguishing them from dietary fibre. It emphasises that prebiotic and fibre claims are assessed independently and must not be conflated.

A defined list of eligible ingredients is provided, including inulin, fructooligosaccharides (FOS), galactooligosaccharides (GOS), xylooligosaccharides (XOS) and acacia.

For each, the monograph specifies acceptable sources, compositional criteria and validated analytical approaches for quantification. Conditions of use are set out through daily intake ranges linked to specific claims, including support for beneficial gut bacteria, digestive health and, in certain cases, relief of constipation.

The monograph also provides detailed labelling information, including warning statements.

Canada tightens oversight of vitamin B6 supplements, with new warning requirements

Health Canada has identified a possible link between vitamin B6 in natural health products (NHPs) and the risk of peripheral neuropathy at daily doses of 10 mg or higher. The conclusion follows a safety review of scientific literature, international

data and pharmacovigilance reports. While only a limited number of cases were identified and assessed, Health Canada noted that the available evidence supports a potential association with sensory nerve symptoms, such as numbness, tingling and pain in the extremities.

In response, Health Canada will update its monograph for vitamin B6-containing NHPs and expects licence holders to revise product labels. Updated labelling will be required to include information on early symptoms of peripheral neuropathy and to advise consumers to stop use and consult a healthcare professional if such symptoms occur.

For prescription medicines, Health Canada did not find sufficient evidence to establish a link with peripheral neuropathy. No changes to product information are planned, as these products are used under medical supervision, including in pregnancy. Health Canada will communicate these updates through its Health Product InfoWatch and other outreach to healthcare professionals and consumers, and will continue to monitor safety data.

Safety warnings for turmeric Supplements

Health Canada has warned of a possible link between oral turmeric and curcuminoid supplements and rare cases of liver injury, following a review of international safety data and reported cases.

The regulator said the products remain authorised for use, but concluded that, in rare cases, their oral use may be associated with hepatotoxicity, which can lead to serious health outcomes. In response, Health Canada will update official guidance and require manufacturers to strengthen warning information on product labels, including advice on symptoms such as yellowing of the skin or eyes, dark urine and stomach pain.

Health Canada stressed that the findings do not apply to turmeric used as a culinary spice or to topical applications. The agency will now inform healthcare professionals and consumers of the updated safety information and continue monitoring adverse event reports.

USA

FDA public meeting explores future approach to dietary supplements

The U.S. Food and Drug Administration (FDA) public meeting held in March 2026 brought together regulators, industry leaders, and consumer representatives, with more than 500 virtual participants and approximately 150 attendees in person.

A notably supportive opening address from Deputy Commissioner Kyle Diamantas emphasised both innovation and responsible enforcement. Discussions highlighted opportunities to modernize FDA's approach to dietary ingredients, including reconsideration of longstanding interpretations related to chemical alteration, botanicals, and the scope of substances eligible under DSHEA.

Key themes included the need to refine the New Dietary Ingredient (NDI) process, encourage innovation while ensuring safety, and expand FDA's interpretation of eligible dietary ingredients under Section 201.

The FDA opened a 30-day public comment period, which closed on 27 April.



Australia

Australia proposes ban on Andrographis

Australia's Therapeutic Goods Administration (TGA) has launched a consultation on plans to remove *Andrographis paniculata*, a plant commonly used in herbal medicines, from its list of permitted ingredients.

The move follows a safety review triggered by ongoing reports of severe allergic reactions, including anaphylaxis, linked to products containing *Andrographis*. The consultation is open until 30 April. The TGA says its review, based on adverse event data, expert advice and input from industry, found that the risks associated with *Andrographis* cannot be adequately managed within

the current low-risk framework for listed medicines. It also noted that reactions may be underreported and that milder symptoms could go unrecognised.

According to the regulator, the risk of anaphylaxis appears unpredictable, with no clear evidence that specific extracts or formulations are safer than others. It also suggests that stronger warning labels would not be enough to address the issue.

On that basis, the TGA is proposing to remove *Andrographis* from the permitted ingredients list for low-risk listed medicines (AUST L medicines).

New Zealand

Proposed phase-out of PVC and polystyrene packaging

The Minister for the Environment intends to seek a Cabinet decision later this year to progress the phase-out of remaining PVC and polystyrene food and beverage packaging. If approved, the next step would be to draft regulations. These are not expected to come into force before 2030, aligning with the anticipated position in the EU under the Packaging and Packaging Waste Regulation. The proposed scope of the policy would exclude:

- PVdC
- Items smaller than 50mm at their widest point (in line with the kerbside standard materials policy)
- Expanded polystyrene used in cold-chain supply
- PVC blister packs (for example, for dietary supplements)
- Packaging for products intended for export



Uzbekistan

Proposed new rules for food supplements

In Uzbekistan, supplements are currently regulated mainly under the general food safety framework rather than through a dedicated regulatory regime. Authorities are now seeking to clarify and consolidate oversight through new draft sanitary rules.

Prepared by the Committee for Sanitary and Epidemiological Welfare and Public Health under the Ministry of Health, the proposal would introduce a structured regulatory framework for the category, covering safety requirements, ingredient control, claims and post-market monitoring.

The draft also signals an intention to align national provisions with internationally recognised approaches, including those of the Codex Alimentarius Commission and European regulatory practice. The proposed rules apply to supplements marketed in finished dosage forms, including capsules, tablets, powders, liquids, oils and chewable forms.

The framework includes provisions requiring companies to monitor and document adverse events associated with supplement use, including serious reactions that may require medical intervention. It also establishes detailed requirements for traceability, product withdrawal and recalls, strengthening post-market safety oversight.

The draft establishes rules governing the composition and safety of supplements, including microbiological criteria, contaminant limits and controls for pesticide residues. It recognises a broad range of ingredients used in supplements, including nutrients, plant extracts, probiotics, prebiotics and other food-derived bioactive substances described as nutraceuticals.

The proposal also introduces a structured approach to claims used in labelling and marketing, limiting them to nutrition claims, health claims and

claims relating to reduction of disease risk. Such claims must be scientifically substantiated and must not imply that supplements treat or cure diseases. Health claims may rely on evidence such as clinical or observational studies, systematic reviews, or assessments by recognised authorities including the European Food Safety Authority and the U.S. Food and Drug Administration.

Another notable aspect concerns tolerable upper intake levels (ULs). The draft clarifies that UL values are not regulatory maximum levels for nutrients, but scientific reference points used to assess the safety of total nutrient intake. Nutrient levels exceeding the UL may be permitted where supported by scientific evidence.

The draft also includes annexes listing prohibited substances, permitted vitamin and mineral forms and nutrient reference values (NRVs) used for labelling.

The proposal is not yet final and will undergo further review before proceeding to interdepartmental approval.

Russia

Russia adopts simplified criteria for assessing supplement quality and efficacy

Russia has adopted new rules establishing simplified criteria for assessing the quality and efficacy of food supplements, following significant revisions to earlier draft proposals circulated during the policy development process.

Government Decree No. 398 of 13 April 2026, which entered into force on 1 May 2026, sets out the framework for evaluating food supplements based on their impact on human health. Compared with previous draft versions, the final decree has been substantially reworked.

Under the new framework, product quality will be assessed based on state registration, product ID tagging, compliance with safety and declared active substance levels confirmed by accredited Russian laboratories, and conformity with EAEU technical regulations.

The decree also introduces simplified efficacy requirements, allowing evidence to be supported through scientific publications, references in

clinical guidelines, or manufacturer's own study data on effectiveness.

Rospotrebnadzor blocks websites selling banned supplements

The Consumer Protection Agency, Rospotrebnadzor, blocked nearly 1,000 online resources within one week for promoting or selling dietary supplements prohibited in Russia. In total, around 3,000 websites have been restricted following enforcement actions.

The agency reported that the affected sites included advertisements and online listings for unregistered products marketed as supplements but containing prohibited ingredients or pharmaceutical substances. These included weight-loss products, thyroid-related preparations, sleep and stress capsules containing GABA, animal-derived melatonin, and high-dose vitamin D3 exceeding permitted levels.

The measures are based on a November 2025 order enabling the inclusion of such websites in the national register of prohibited information. Authorities stated that the actions aim to protect public health and ensure compliance with legislation. Consumers are advised to purchase supplements only from authorised sellers and verify registration documents.

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