IADSA NEWSFLASH

August 2025

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Regulatory news

ASEAN

No breakthrough on Indonesian declaration

The 37th meeting of the Traditional Medicines and Health Supplements (TMHS) Product Working Group took place recently in Singapore. A key development was the transition of leadership, with Dr. Suchart Chongprasert of Thailand assuming the Chair from Marie Tham of Singapore. On the core agenda, no agreement was reached on the Indonesian Declaration concerning the protection of genetic resources in the draft Agreement on Traditional Medicines. ASEAN Member States considered three options to resolve the impasse:

- Indonesia withdraws the Declaration
- Acceptance of the Declaration by all Member States
- Proceeding with the Health Supplements Agreement independently

In the absence of consensus, Indonesia was encouraged to revise the Declaration by the end of August.

The next PWG meeting will take place in November 2025.

China

China eases seafood ban on Japan

China has partially lifted its two-year ban on seafood imports from Japan. As of 29 June 2025, imports from selected regions may resume, following GACC Announcement No. 140/2025.

The original blanket ban, imposed in August 2023, followed Japan's discharge of treated Fukushima wastewater. Imports remain prohibited from ten prefectures, including Fukushima, Tokyo, and Chiba.

To export, Japanese producers must re-register with Chinese authorities and meet new documentation requirements, including radiation tests and origin certification. China has warned it will reimpose controls if safety standards are not met.

New testing standard for melatonin in health foods

The State Administration for Market Regulation (SAMR) has released a new national standard, GB/T 45443-2025: "Determination of Melatonin in Health Food", which will take effect on 1 October 2025. The standard improves the testing method by updating its scope, technical details, and procedures.

Korea

Amendments to Health Functional Food Code

South Korea's Ministry of Food and Drug Safety has proposed amendments to the Health Functional Food Code introducing revised standards for two nutrients (iron and zinc) and nine functional raw materials, including soy isoflavones, lecithin, and guava leaf extract. Key updates include adjusted daily intake limits, updated manufacturing standards, and labelling requirements. Notably, Reishi mushroom fruiting body extract is set to be removed from the list of approved functional ingredients.

Indonesia

BPOM issues stricter guidelines for probiotic supplements

Indonesia's Food and Drug Authority (BPOM) has issued new guidelines, replacing the 2021 rules with stricter requirements for assessing and registering probiotic health supplements.

Under the new framework, products must first be classified as supplements, drugs, or processed

foods based on their composition, use, form, and claims. A decision flowchart guides this categorisation.

Probiotic strains already registered may proceed through standard registration. New strains, novel combinations, or products making claims beyond digestive health must undergo scientific evaluation, including validated strain identification, safety studies (in vitro, in vivo, and clinical), and efficacy evidence. Strains must be deposited in recognised culture collections, and additional risks, such as antibiotic resistance or immune overstimulation, must be assessed.

Claims relating to digestive health may be supported by foreign studies. However, for any claim beyond this, clinical trials must be conducted in Indonesia or, under specific conditions, in countries with similar public health and dietary profiles, namely Malaysia, Thailand, or Vietnam, following Good Clinical Practice and BPOM approval.

The regulation also outlines strict quality standards, including proof of strain viability over shelf life, compatibility in multi-strain products, and stability data. Labels must indicate strain names, CFU counts at the end of shelf life, usage instructions, and storage conditions.

All probiotic supplements must be registered with BPOM, which will decide on applications within 85 working days. Previously authorised products remain valid until expiry, but new or renewal applications must follow the updated rules.

To support global alignment, the regulation requires safety and efficacy data to meet internationally recognised standards, specifically citing WHO and FAO guidelines as valid scientific references.

Japan

Plans to extend oversight to all forms of supplements

In response to the recent red yeast rice incident, the Japanese government has issued a series of administrative notifications and regulatory changes, significantly intensifying daily operational requirements for businesses. Authorities are now preparing to launch formal discussions on new measures aimed at safeguarding the safety and quality of all foods in supplement form.

Taiwan

Knee joint care added to approved health food claims list

Taiwan's Food and Drug Administration (TFDA) has added knee joint care as an officially recognised health care effect under the Health Food Control Act.
Alongside this update, TFDA published the Efficacy Assessment Method for Health Foods with Knee Joint Care. Companies seeking to register products under this new category must submit an efficacy assessment report in line with the specified method. Approved products may carry claims such as "helps alleviate mild knee joint discomfort" or other scientifically substantiated statements.
This brings the total number of approved health care effects in Taiwan to 14, including bone care, blood lipid regulation, gastrointestinal function improvement, liver health protection, and anti-aging benefits.

Thailand

New controls on ethylene glycol in additives

Thailand's Food and Drug Administration (FDA) has announced new regulations to limit contamination of ethylene glycol (EG) and diethylene glycol (DEG) in selected food additives. The measure comes in response to concerns raised by the World Health Organization (WHO) following international incidents involving contaminated medicinal syrups.

The FDA's new notification will come into effect on 21 September 2025, ninety days after publication. It sets maximum levels of EG and DEG in twelve high-risk food additives, including substances such as glycerine, sorbitol solution, and propylene glycol. These ingredients are widely used in food and may be susceptible to contamination during production processes.

The regulation applies to both imported and domestically manufactured food additives. It requires manufacturers and importers to ensure compliance through proper testing, documentation, and quality control procedures. The FDA encourages all relevant businesses to begin preparations for implementation.

Vietnam

Vietnam proposes new food safety framework with major impact on supplements

Vietnam has released a new draft decree proposing extensive amendments to Decree 15/2018 on food safety. The draft decree notified to the World Trade Organization introduces far-reaching changes to product declaration, inspection procedures, and post-market surveillance, marking the most significant regulatory shift since the Decree's adoption.

One of the most notable changes is the redefinition of who is responsible for product declarations. Under the draft, the obligation no longer remains solely with manufacturers but extends to any party placing the product on the market, including authorised representatives. Micronutrients are newly added to the list of products requiring self-declaration, alongside pre-packaged foods, food additives, and packaging materials.

a certificate of Analysis must now be issued by an ISO/IEC 17025-accredited laboratory or a GMP-compliant facility, and a power of attorney is required where an authorised party is filing the declaration. The procedure also introduces a 21-day review period for authorities, though products approved by Stringent Regulatory Authority (SRA) abroad may enter the market immediately upon submission.

Health supplements now fall under mandatory registration. Novel food additives, by contrast, are removed from scope. The draft outlines detailed new dossier requirements, including scientific evidence of efficacy, GMP certification, and product stability studies. Health supplements will require registration with the Ministry of Health; other categories will be overseen by provincial authorities.

A key change is the removal of inspection exemptions for registered products. New criteria and timelines are introduced for reduced, normal, and tightened inspections, with reduced inspection now limited to a

12-month period under specific conditions.

The draft establishes formal post-marketing inspection for the first time. Supplemented foods, medical nutrition products, and foods for special diets will be inspected annually; health supplements at least once every three years. Products sold online will also be subject to consistency checks between digital listings and physical labels.

Firms will have 18 months to align existing product registrations with the new rules, and six months to update self-declared dossiers. After these windows, non-compliant products may no longer be placed on the market, though existing stock can be sold through its shelf life.

EU

Parliament targets online supplement marketing

There are calls in the European Parliament for new rules to restrict the online promotion of food supplements and related health products to minors.

Amendments to a draft report on the Protection of Minors Online propose banning influencer-led marketing of products that lack scientific backing or are considered inappropriate for young people. Under the proposed amendments, Members of the European Parliament (MEPs) have asked the European Commission to introduce measures, potentially through the upcoming Digital Fairness Act, to prohibit the marketing of unhealthy food supplements, unhealthy food and beverages, diets and beauty routines to minors, particularly when promoted by influencers on social media.

A number of amendments call for a ban on the online promotion of food supplements that lack scientific evidence or are unsuitable for young people. Others highlight the need to restrict influencer content promoting food supplements and diets without a clear scientific basis. Several proposals reiterate this approach, calling for a ban on influencer marketing of unhealthy food, food supplements, and related content aimed at minors. The report and its amendments are awaiting the decision of the Committee.

Separately, the European Commission has launched a public consultation on the Digital Fairness Act. The 12-week consultation invites stakeholders to comment on whether new EU rules should restrict influencer claims directed at minors, not only about dietary supplements, but also a wider range of product categories, including unhealthy foods and beverages, plastic surgery, cosmetic procedures, tobacco and vaping products, and the promotion of unrealistic beauty standards.

Digital practices may exploit consumers' vulnerabilities, particularly those of minors, due to their developmental stage and psychological susceptibility. The European Commission and Parliament have emphasised the need to strengthen protections to prevent young people from being influenced into making purchases that may be unsuitable or potentially harmful.

While neither the amendments nor the consultation define what constitutes "unhealthy" or "inappropriate," both documents indicate growing political momentum for stronger regulation of online supplement marketing and stronger expectations around age-appropriate communication.

Magnesium Orotate Dihydrate fails safety assessment for use in supplements

The European Food Safety Authority (EFSA) has issued a scientific opinion concluding that the safety of magnesium orotate dihydrate, proposed as a novel food ingredient for use in food supplements, cannot be established under the conditions of use presented.

The ingredient was intended for use at levels delivering up to 400 mg of magnesium and approximately 5000 mg of orotic acid per day. However, EFSA noted this would significantly exceed the tolerable upper intake level of 250 mg/day for supplemental magnesium.

Of particular concern were tumour-promoting effects observed in animal studies with orotic acid. The proposed exposure level resulted in a margin of safety below what EFSA previously deemed acceptable. No new toxicological data were provided to address these risks. Additionally, uncertainties remain about the presence of small particles or nanoparticles in the product. EFSA therefore concluded that the novel food does not meet safety requirements for approval and did not assess magnesium bioavailability due to these issues.

To add or not to add? EFSA examines the role and limits of supplements

Do we need food supplements? Are they always beneficial or can they carry risks? In the latest Science on the Menu podcast, EFSA experts explore these questions and more.

The episode addresses the wide range of supplement formats available, clarifying their definition and intended role.

The discussion distinguishes between supplements, fortified foods and medicinal products, while underlining that supplements are not a substitute for a balanced diet, nor intended to prevent or treat disease.

The discussion highlights that while certain population groups, such as pregnant women, older adults, or those with limited sun exposure, may have increased nutritional needs, for the general healthy population in the EU, supplements are often unnecessary. The episode also cautions that inappropriate or excessive use can lead to intakes above safe levels.

EFSA draft opinion points to ban on estragole-containing products

EFSA's Nutrition and Food Innovation (NIF) Unit has released its draft scientific opinion on the safety of preparations from the fruit of sweet and bitter fennel (Foeniculum vulgare and Foeniculum piperitum) for public consultation (PC-1533). The opinion, accompanied by exposure assessments and a BMD report, is open for comment until 17 September 2025.

At the heart of EFSA's assessment is the presence of estragole, a compound identified as both genotoxic and carcinogenic. According

to the draft opinion, estragole forms reactive metabolites that bind to DNA, leading to the potential development of liver tumours. Importantly, EFSA finds no scientific basis for establishing a safe daily intake level, citing the lack of evidence for a threshold below which these genotoxic effects would not occur. The opinion also notes wide inter-individual differences in susceptibility, linked to genetic variations, and highlights that DNA damage appears to accumulate over time.

Particular concern is raised about exposure in young children through fennel fruit infusions and across all population groups via food supplements. EFSA further points to potential risks to unborn and newborn children, as estragole can cross the placenta and be transferred via breast milk, with evidence of carcinogenic effects in offspring in animal studies.

Should the conclusions remain unchanged, the European Commission and Member States may move to prohibit the use of fennel fruit preparations in food supplements and consider warnings or restrictions on infusions, especially those targeting vulnerable population groups. Similar action could also be considered for other estragole-containing plants such as anise seed, basil leaves, pepper fruits, star anise, tarragon and thyme.

EU set to approve Magnesium L-threonate for use in supplements

The European Commission has proposed the inclusion of Magnesium L-threonate as a permitted source of magnesium in food supplements under Annex II of Directive 2002/46/EC. Magnesium L-threonate was authorised as a novel food in October 2024, following a positive safety assessment by EFSA. The proposed conditions of use limit magnesium intake from this source to a maximum of 250 mg per day, for adults only. Use is explicitly excluded for pregnant and lactating women.

Bacillus coagulans not novel for supplement use

The European Commission has now made it official: *Bacillus coagulans* (also known as *Heyndrickxia coagulans*) is not considered a novel food when used in food supplements. This means companies can continue using it in supplements without needing authorisation.

However, the rules are different for general foods. When B. coagulans is added to foods other than supplements, it is considered novel, and would require EU approval before being sold.

This clarification follows recent concerns raised by Sweden, where the national food agency classified B. coagulans as novel in food, citing insufficient evidence of its use before 1997. Notably, the Swedish opinion focused on food use and did not directly address its use in food supplements.

EU to tighten controls on PAHs in supplements containing oils

At its latest Standing Committee meeting, the European Commission introduced important clarifications to strengthen the implementation of Regulation (EU) 2023/915 on contaminants, specifically targeting polycyclic aromatic hydrocarbons (PAHs).

A key amendment aims to introduce a general principle: when a product can fall under multiple categories with differing maximum levels (MLs) of PAHs, such as a herb used in cooking versus in an infusion, the most stringent ML will apply.

Of particular note is a clarification concerning food supplements that contain vegetable oils. Until now, these products were not directly addressed under the PAH ML for food supplements; instead, the oil component was assessed using the standard for oils and fats. Under the revised approach, the contaminant level in the final supplement will be calculated according to the proportion of oil(s) it contains, in line with Article 3(1)(c).

Furthermore, businesses will be required to provide clear justification of both the PAH concentration and the composition of the product's ingredients during official controls, as set out in Article 3(2).

EFSA delays key safety opinions that could shape future EU restrictions

EFSA has pushed back the timelines for delivering its much-anticipated safety assessments of several substances under Article 8 of Regulation (EC) No 1925/2006. New publication dates have been set: sweet and bitter fennel by 31 January 2026, hydroxycitric acid (HCA) by 31 March 2026, and berberine by 30 April 2026. These scientific opinions will be critical in shaping future EU decisions on whether these substances can continue to be used in foods and supplements or face restrictions or bans.

EFSA confirms safety of yellow tomato extract in supplements

EFSA has confirmed the safety of yellow tomato extract for use in food supplements for adults at a maximum daily dose of 100 mg. The extract is rich in carotenoids, mainly phytoene and phytofluene, with smaller amounts of zeta-carotene, beta-carotene, and lycopene. The lycopene intake from such supplements would be just 0.4 mg per day, around 1.1% of the acceptable daily intake (ADI) established by EFSA (0.5 mg/kg body weight), which does not raise safety concerns.

EFSA also noted that background dietary intake of these carotenoids is higher in infants and toddlers than the total intake anticipated in adults from the supplement. As these substances are already commonly consumed through the normal diet without causing health concerns, the extract is not considered nutritionally disadvantageous at the proposed intake level of up to 100 mg/day in food supplements for adults.

EFSA therefore concludes that the novel food, yellow tomato extract, is safe under the proposed conditions of use.

New direction on MOAH limits in food additives

EU is currently reviewing how to manage the presence of mineral oil aromatic hydrocarbons (MOAH) in food additives. A discussion paper has highlighted that several authorised additives may contain MOAH, leading to discussions on how best to set appropriate safety limits.

An earlier proposal to apply a single maximum levels (ML) across all additives has been reconsidered. However, the need for flexibility was raised, particularly for additives derived from edible oils or spices. In such cases, a temporary ML above the limit of quantification (LOQ) may be required.

The prevailing approach is now to align the ML for additives made from foods with the ML already set for the source food itself. This reference would be included as a footnote in the MOAH ML table. ("For food additives that are produced from food sources, the foods that are used as a source shall comply with the MLs set out in "this" Regulation")

For other additives, such as waxes where the source of the additive is not a food, a separate approach is being discussed within the Working Group on Food Additives. A specific ML of 2.0 mg/kg is being proposed for waxes, provided suitable mitigation measures are applied.

Some Member States have raised concerns about the challenge of controlling raw materials sourced from outside the EU and have indicated a preference for setting specific MLs directly for food additives. The Committee acknowledged that establishing such limits is the long-term objective as monitoring data first needs to be collected.

Belgium

Major revisions to mushroom and botanicals lists

Belgium has formally notified the European Commission and Member States (TRIS 2025/0342/BE) of a draft Royal Decree revising its rules on the production and sale of foodstuffs containing plants or plant preparations.

Key changes include a complete restructuring of the mushroom list. The previous separation between cultivated and wild species is replaced by a unified “List 2: Edible Mushrooms,” now indicating cultivation status for each entry. The revision aims to improve safety and traceability of mushroom-containing products.

The draft also updates the lists of authorised and prohibited plants in food supplements. Several new entries have been added following review by Belgium’s advisory committee.

Mesembryanthemum tortuosum and *Mitragyna speciosa* are proposed for prohibition under List 1, while Angelica keiskei and Vaccinium angustifolium are added to List 3, meaning they may be used under specific conditions.
Additional updates cover botanical names, plant parts, conditions of use, and required warnings, reflecting evolving scientific opinion
A two-year transition period is foreseen for products compliant with the previous decree. Draft texts are available in French and Dutch.

Czech Republic

Vangueria agrestis *extract is novel*

The Czech Ministry of Agriculture has determined that a 10:1 extract of Vangueria agrestis (syn. Fadogia agrestis) is a novel food, citing a lack of evidence of significant consumption in the EU before 15 May 1997.

The extract, derived from the root, stem and aerial parts, is produced using water, alcohol or CO_2 extraction and standardised for flavonoids (15–25%), alkaloids (5–10%) and saponins (5–12%). It is intended for use in food supplements in capsule forms at 200–1000 mg/day. *Vangueria agrestis* is not listed in the EU Novel Food Catalogue.

Denmark

Danish authorities add oat betaglucan to supplement list

The Danish authorities published an amendment to their national regulation on the use of substances other than vitamins and minerals in food and food supplements. Under Administrative Order BEK 616, a new ingredient has been added for use in supplements: 1,3-1,4 beta-D-glucan from oat, Avena sativa, with a maximum level of 1100 mg.
Alongside this, Denmark has also updated the specifications and purity standards, known as Annex 2, to reflect this new entry, referenced as DK 224.

Germany

Calls for stricter rules to protect consumers from misleading supplement claims

A German leading consumer association, vzbv, has raised concerns over widespread misinformation in the marketing of food supplements, calling for stricter regulation following a national survey.

The survey revealed that a significant proportion of consumers misunderstand the legal status and safety oversight of supplements, with many wrongly assuming they are medically tested or essential to a healthy diet. Misleading claims, particularly on social media, were found to be pervasive, often promoting unapproved health benefits.

In response, vzbv is urging policymakers to introduce EU-wide pre-market authorisation, set maximum levels for nutrients, and tighten controls on advertising, especially by influencers.

Ireland

Guidance on determining Novel Food status under EU law

The Food Safety Authority of Ireland (FSAI) has published comprehensive guidance for food business operators (FBOs) seeking to determine whether a food or ingredient qualifies as “novel” under Regulation (EU) 2015/2283. The new document outlines how to prepare an Article 4 request, a formal consultation with national authorities when the novel food status of a product is uncertain.

Under the Regulation, FBOs are legally required to verify whether a food has a history of significant consumption in the EU before 15 May 1997. If unclear, they must consult the competent authority of the Member State where they first intend to place the product on the market, in this case, the FSAI.

The guidance explains the steps FBOs should take before making a request, including checking the Union list of authorised novel foods, the Novel Food Catalogue, and the results of previous Article 4 consultations. Importantly, the product must not fall under another regulatory framework, such as food additives legislation.

FSAI will assess Article 4 requests in line with Commission Implementing Regulation (EU) 2018/456. FSAI may consult with other Member States or the European Commission, and its final conclusions are published on the Commission website. Confidentiality requests must be substantiated.

The document also sets out what constitutes acceptable proof of a history of consumption. Verifiable sales data or official records from EU Member States are considered primary evidence. Evidence from the UK must be validated by UK authorities and will be evaluated by the FSAI on a case-by-case basis. Herbal medicines, cosmetics, or anecdotal evidence are not accepted as primary proof.

Crucially, the guidance outlines that history of consumption (HOC) does not automatically extend to all forms of a food, including extracts or forms derived from fermentation.

Changes to the production process, chemical composition, or nutritional profile may also trigger a novel status, even for previously accepted foods.

Poland

Resolution on tablet splitting for supplements

Poland's Food Supplements Team has adopted Resolution No. 1/2025, outlining its opinion on labelling requirements when tablet splitting is indicated as the method of use for food supplements. To indicate tablet splitting on a product label, the following four conditions must be met:

- The full tablet must not exceed the maximum daily amounts of individual ingredients.
- Each split portion must contain the declared amount of vitamins, minerals, or other substances with nutritional or physiological effects.
- The tablet must include a suitable score line to allow effective and easy splitting by consumers.
- Labelling must clearly instruct consumers on how to split the tablet and on the recommended dose.

Spain

Labelling for all: Braille and QR code

Spain has notified the European Commission of a draft Royal Decree introducing mandatory accessible labelling for key consumer goods, a first in national legislation. The new regulation will require products such as food, cosmetics and household chemicals to carry Braille and digital access tools (e.g. QR codes with tactile markers), ensuring that persons with visual impairments can access essential product information independently.

This measure responds to Spain's commitments under the UN Convention on the Rights of Persons with Disabilities and recent legal reforms recognising persons with disabilities as vulnerable consumers. According to national data, over 4.3 million people in Spain live with some form of disability, including more than 218,000 with visual impairments.

Under the proposal, packaging with a surface area of at least 10x1 centimetre must include Braille indications of the product name and allergen information. QR codes or similar tools must provide access to the range of mandatory labelling information in clear and accessible language, without requiring the user to disclose personal data, register, or incur any cost. A two-year transition period is foreseen to enable industry compliance, with additional measures in place for products (e.g. adhesive overlays) already on the market.

The draft Decree supports UN SDGs 10 and 12, aligns with new EU packaging rules, and forms part of Spain's Recovery and Resilience Plan. It was developed through wide consultation with disability and consumer organisations.

Spain revises supplement labelling guidance

The Spanish Agency for Food Safety and Nutrition (AESAN) has published Version 3 of its Interpretative Notes to the Guide for the Control of Labelling and Composition of Food Supplements. The update aims to harmonise enforcement across Spain by clarifying how national and EU rules are interpreted and applied in practice.

Prepared by the Spanish Food Supplements Working Group, the document includes practical guidance, including clarification on the use of QR codes, the inclusion of leaflets in packaging, and the prohibition of unauthorised stimulants.
This latest version replaces the 2023 edition. The document is available in Spanish only.

Sweden

New e-learning course on food

supplements The Swedish National Food Agency has launched a free online course to help people better understand the rules around food supplements. The training is aimed at businesses that sell or market supplements, as well as inspectors who check these products.

The short course (around 30 minutes) explains what a food supplement is, which rules apply to them, and how to check whether an ingredient is permitted. It also looks at labelling requirements and how inspections are conducted by authorities.

One part of the course involves reviewing different product examples to decide whether they should be classified as supplements.

All e-learning courses are free to access through the training portal and only require users to register an account.

UK

FSA eases path for CBD reformulations

The Food Standards Agency (FSA) has revised its guidance to permit CBD businesses in England and Wales to reformulate products already on its Public List, aiming to improve consumer safety without requiring new applications.

Reformulation is encouraged to align with the FSA's provisional acceptable daily intake (ADI) of 10 mg of CBD per day, and a newly established safe upper limit for THC of 0.07 mg per day, based on advice from independent scientific committees.

According to the FSA, companies do not need to notify the agency if changes do not affect the product's listing details. However, if

adjustments alter listed specifications, businesses must submit updated information confirming the changes are related solely to safety. The FSA is also advising companies to update product labelling to reflect the CBD intake limit and include safety warnings for vulnerable groups, including under-18s, pregnant or breastfeeding women and people on medication.

New FSA guidance responds to high rate of non-compliance in caffeine supplements

The Food Standards Agency (FSA) has released findings from its fifth annual food safety survey, revealing that 83% of caffeine supplements tested had labelling or content issues. In some cases, caffeine levels were significantly higher or lower than declared.

In response, and in partnership with Food Standards Scotland (FSS) and the Department of Health and Social Care (DHSC), the FSA has issued updated guidance for industry to address the risks of caffeine overconsumption, including from pure caffeine powders.

COT confirms ginger safe during pregnancy

The UK Committee on Toxicity (COT) has reviewed the safety of ginger and ginger supplements during pregnancy, as part of a broader assessment on maternal nutrition and health.

Ginger, widely consumed in food and as a supplement, is commonly used to relieve nausea, including in pregnancy, and is recommended by NHS and NICE for mild morning sickness. However, supplements vary widely in strength and composition, including increasingly popular concentrated “ginger shots”.

COT found no strong evidence of harm from dietary ginger use in pregnancy, though some animal studies suggest possible adverse effects at very high doses. While no definitive risks were established, potential contamination with heavy metals and mycotoxins remains a concern.

The Committee concluded that there is no need to change current NHS guidance, which supports ginger use for nausea in pregnancy, but recommends checking with a pharmacist before taking supplements.

Turkey

Back in the firing line

Just before its summer recess, Turkey’s Parliament passed a wide-ranging health law that tightens controls on cannabis-derived products. However, much of the debate centred on food supplements, with growing political pressure to reform how these products are regulated and sold.

MPs from across the political spectrum raised concerns about the continued sale of unregulated supplements in supermarkets, petrol stations, and online platforms. Several cited serious health incidents, including hospitalisations for liver failure, as evidence of the risks posed by weak oversight.

A cross-party agreement in the Health Committee had called for supplements, multivitamins, and herbal and sports products to fall under the exclusive authority of the Ministry of Health, with sales limited to pharmacies.

With pressure continuing to build, further debate is expected when Parliament returns in October.

Updated procedure for probiotic and postbiotic supplements

The Turkish Ministry of Agriculture and Forestry has published a revised version of the Application Procedure for Food Supplements Containing Probiotic Microorganisms, which now also covers products containing postbiotics.

Probiotics are defined as live microorganisms which, when administered in adequate amounts, confer a health benefit on the host. Postbiotics are inanimate microorganisms and/or their components that also provide a health benefit to the host. With this update, both categories fall within the scope of the national regulatory framework for food supplements.

Among the key changes, the requirement for accelerated stability data has been replaced with the submission of real-time stability results presented in six-month intervals. Additionally, the maximum permitted water activity level in the final product has been lowered to 0.2. The updated procedure outlines detailed application requirements. Probiotic strains must be identified by their strain code and the internationally recognised culture collection in which they are registered. For imported probiotic strains, the collection must be listed under Annex 3 of the procedure, which refers to culture collections recognised under the Budapest Treaty.

Applications must include specific documentation demonstrating the taxonomic identity of the microorganism, the origin and production site, and evidence of registration in a recognised collection. In cases where the strain is not already included in the restricted substances list or the Ministry’s internal list of approved probiotic strains (TEG List), further documentation is required. This includes data on biosafety, probiotic characteristics such as acid and bile resistance, and scientific literature or study results from in vitro, in vivo, or human trials. Documentation must also confirm the genetic purity and preservation of the strain, supported by valid certificates from accredited institutions.

For imports of probiotic raw materials, approval must first be obtained through the procedures outlined in the regulation. Imports are only permitted if the strain and producer are listed in the Ministry’s internal TEG Probiotic Microorganisms List.

A short transition period applies to postbiotic products. As of 29 August 2025, all new approvals for food supplements containing postbiotics will be subject to the updated procedure.

Argentina

Definition for hydroelectrolytic supplements

Argentina has introduced a formal definition for hydroelectrolytic

supplements. Published in the Official Gazette under Resolution 38/2025, the new rule amends the Argentine Food Code to define these products as non-alcoholic beverages designed to support fluid and electrolyte replacement.

To meet the definition, products must contain specific levels of sodium and potassium in their ready-to-drink form, with sodium ranging between 450 and 1150 mg/l and potassium between 78 and 700 mg/l. The regulation allows for the inclusion of other minerals, vitamins, and carbohydrates, provided that vitamin and mineral levels do not exceed the recommended daily intake per serving. Products may be formulated with fruit or vegetable juice, juice pulp, or concentrates, and can be presented as ready-to-drink, in powder form, or as liquid concentrates for reconstitution.

Labelling must clearly indicate the sodium and potassium content, any added nutrients and flavouring, and whether the product is carbonated. All labelling must also comply with general requirements for packaged foods, including mandatory nutritional declarations.

The regulation enters into force immediately, with a two-year transition period for companies to adapt products already on the market.

Health claims on supplements, with conditions

Argentina has recently issued Resolution 33/2025, amending Article 1381 of the Argentine Food Code to allow the use of health claims on food supplements. The revised text specifies that "only those health claims authorised by the national sanitary authorities will be permitted." The measure takes effect from 27 June 2025.
As Argentina has no positive list of authorised claims, approvals will be granted on a case-by-case basis.

ANMAT issues new rules on advertising

Argentina's National Administration of Drugs, Food and Medical Devices (ANMAT) has issued an updated regulation governing the advertising of food supplements and related health products, aiming to bring oversight in response to the growing influence of digital platforms and social media.

Food supplements are explicitly covered under the updated rules. Advertising targeting the public must include the mandatory statement: "SUPLEMENTA DIETAS INSUFICIENTES. CONSULTE A SU MÉDICO Y/O FARMACÉUTICO" (Supplements insufficient diets. Consult your doctor and/or pharmacist). This message must be clear, legible, and appropriately presented across all media formats, including digital. Only products that have obtained marketing authorisation from ANMAT may be advertised. All claims must be truthful, verifiable, and consistent with the product's approved use. Misleading messages or those suggesting unauthorised therapeutic benefits are strictly prohibited.

The resolution introduces stricter controls on indirect and non-traditional advertising, including influencer content, product placement in audiovisual media, and the use of brand elements without direct product references. It also bans the use of health authority endorsements, unauthorised expert recommendations, and promotional messages that incite fear or imply adverse health consequences if the product is not used.

ANMAT emphasises that advertising must avoid blurring the line between product categories. Medicinal products cannot be presented as foods or cosmetics, and vice versa.
The use of healthcare professionals in adverts is permitted only under strict conditions, including the display of their professional registration.

Advertising aimed at children or featuring children is prohibited unless accompanied by adult guidance. Companies remain responsible for the accuracy and appropriateness of advertising content and must ensure they align with the approved label and product dossier. ANMAT retains the right to request supporting documentation in Spanish for any scientific or technical claims used in advertising.

Violations of the new rules may result in sanctions under Argentina's Medicines and Food Laws. The new regulation enters into force the day after its publication in the Boletín Oficial and effectively repeals Disposition 4980/2005 and related articles of Disposition 7730/2011.

Brazil

New approved ingredients and claims

Brazil has issued a new administrative order updating the list of authorised ingredients for use in food supplements.

Published on 9 June, Administrative Order IN 373/2025 amends IN 28/2018, the key regulation that defines permitted constituents, their conditions of use, authorised claims, and labelling requirements for supplements marketed in the country.

The update introduces several new substances. Among these are citrus fibres, and 2'-fucosyl-lactose produced via microbial fermentation using Escherichia coli K12 strains, approved as sources of dietary fibre. *Chlorella pyrenoidosa*, also known as C. *sorokiniana*, has been added as a permitted source of vitamin A. The bioactive compound GABA, or gamma aminobutyric acid, is now included as well.

The order also expands the list of authorised probiotics, adding strains such as Lactobacillus acidophilus DDS-1®, *Bacillus coagulans* SNZ 1969, and a combination of *Lactobacillus plantarum* and *Pediococcus acidilactici*.

In addition to these ingredients, the regulation sets out the specific health claims permitted for the new probiotic strains, along with the mandatory warning statements to accompany their use.

Chile

Chile moves to regulate Novel Foods

Chile's Ministry of Health has opened a public consultation on a proposed framework to regulate novel foods and novel ingredients, which would also cover substances intended for use in food supplements.

The proposal is based on Article 106 of the Sanitary Regulation of Foods and reinforces the requirement that novel foods and ingredients must meet national safety standards and contribute to the population's nutrition. Evaluations could be initiated by the interested party through a formal letter to the Sub-

Secretariat of Public Health, or alternatively by a public institution or the Ministry of Health itself. The draft sets out in detail the information required for submission.

Should a petition be accepted, it would move to a public consultation phase, with measures in place to protect industrial property rights. The proposed process excludes the evaluation of food additives, genetically modified foods or raw materials, and health claims. The timeframe for assessment is estimated at approximately 180 days.

Peru

Risk of liver damage from Ashwagandha use: Health Authorities urge caution

The National Centre for Documentation and Information on Medicines (CENADIM), under the Ministry of Health, has issued a public communication following updated reports from the Netherlands Pharmacovigilance Centre Lareb on liver toxicity associated with products containing *Withania somnifera* (L.), commonly known as ashwagandha or Indian ginseng. Lareb first reported cases of liver injury related to ashwagandha-containing products in September 2023 and has since updated this information in June 2025 to include new reports received to date.

Lareb highlights that only limited studies have been conducted on the safety of ashwagandha, and its adverse effects are not well documented. Clinical trials have reported drowsiness, diarrhoea, and abdominal pain more frequently with ashwagandha than with placebo. No increases in serum liver enzymes, serious adverse events, or hepatotoxicity were observed during clinical trials. However, it reports that several cases of clinically evident liver injury have been reported during commercial use of herbal products containing ashwagandha.

Lareb concludes that while liver injury associated with ashwagandha appears to be rare, it is important to raise awareness of this potential risk. The Peruvian alert highlights that herbal products may include several plant ingredients and may include herbs not listed on the label. Therefore, it cannot be excluded that factors other than ashwagandha contributed to the liver damage.

Healthcare professionals are encouraged to report any suspected adverse reactions related to ashwagandha-containing products to the Peruvian Pharmacovigilance and Technovigilance System via NotiMED.

USA

Disclosure tools fail to build trust in influencer marketing

Influencer marketing continues to grow rapidly in the US, reaching a market value of over USD 24 billion. But a new report released by BBB National Programs and The Benchmarking Company shows that consumer trust isn't keeping pace.

The 2025 Influencer Trust Index surveyed over 3,700 U.S. adults and found that 74% of consumers express any level of trust in influencer advertising, with just 5% saying they fully trust it and 69% indicating partial trust. By contrast, 87% of consumers report some or complete trust in general advertising across traditional and digital platforms, highlighting a trust gap between influencer content and more conventional forms of advertising.

Although disclosure tools such as "#ad" or "#sponsored" are now common, they do not significantly increase perceptions of trustworthiness among consumers. The report found that transparency and honesty about brand relationships were the primary drivers of trust, while a lack of these qualities was the leading cause of distrust.

FDA calls to accelerate phase-out of FD&C Red No. 3

The U.S. Food and Drug Administration is urging manufacturers to remove FD&C Red No. 3 from foods and dietary supplements ahead of the formal deadline of 15 January 2027. The appeal follows the FDA's January 2025 decision to revoke authorisation for the colour additive under the Delaney Clause, which prohibits substances shown to cause cancer in humans or animals.

While the regulation allows a two-year transition period, the FDA, has called on companies to act more swiftly. The agency is encouraging reformulation "as soon as practicably possible" to support the broader effort to eliminate petroleum-based synthetic dyes from the food supply.

The FDA recognises that replacing FD&C Red No. 3 may involve scaling up the use of authorised alternatives or developing new colour additives, including those derived from natural sources. However, all substitutes must meet the legal safety requirement of a "reasonable certainty of no harm" under intended conditions of use.

FDA launches educational materials on dietary supplement ingredient review process

The U.S. Food and Drug Administration (FDA) has published new resources aimed at improving industry compliance with its New Dietary Ingredient Notification (NDIN) requirements.
The materials include two short videos and a fact sheet designed to guide manufacturers and distributors through the NDIN process. The resources highlight common mistakes that can lead to rejection or delays. FDA hopes that these new resources will reduce procedural errors and improve the quality of submissions.

FDA to step up surprise inspections at foreign manufacturing sites

The U.S. FDA will expand its use of unannounced inspections at overseas facilities producing food and medical products for the American market. The move aims to bring foreign oversight in line with domestic standards and close enforcement gaps.

Building on pilots in India and China, the agency will also tighten internal rules to protect inspector independence. The shift is part of a broader strategy to improve product safety and hold all manufacturers, foreign and domestic, to the same level of scrutiny.

Australia

TGA plans to limit vitamin B6 doses over 50 mg

The Therapeutic Goods Administration (TGA) has released its interim decision on the scheduling of vitamin B6, suggesting that only products delivering more than 50 mg per day should be classified as Schedule 3 (Pharmacist Only). This marks a significant shift from an earlier proposal, which would have affected more than 1,500 products by setting the threshold at just 5 mg. Under the new plan, fewer than 30 products are expected to be impacted.
The decision follows public submissions and expert advice. The proposed change would see:

- Products below 50 mg remain eligible for general sale as listed medicine
- A new Schedule 3 entry created for medicines containing 50–200 mg of vitamin B6 per daily dose (Pharmacist only medicine)
- Products delivering 200 mg or more remain classified as Prescription Only (Schedule 4)

Russia

New law allows doctors to prescribe approved supplements

Russia has enacted a major change to its regulatory framework for dietary supplements. For the first time, doctors will be able to prescribe dietary supplements officially approved by the Ministry of Health. At the same time, the law prohibits clinical trials of such products by medical institutions.

Key measures include:
Healthcare professionals may prescribe dietary supplements included on an approved list maintained by the Ministry of Health and the consumer watchdog Rospotrebnadzor. Prescriptions must follow established usage indications and directions.

Only products that meet state-defined standards of quality and efficacy will be eligible for inclusion on the list.
The law prohibits healthcare professionals from accepting payments or other incentives from supplement manufacturers or distributors.

The law takes full effect on 1 September 2025. Regulatory guidance to support implementation is currently being developed.

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