

# IADSA NEWSFLASH

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## Regulatory news



### Indonesia

#### Supplements on 2025 agenda

Indonesia's food and drug agency BPOM has set out its regulatory priorities for 2025, and health supplements are a key focus. A new rule will require companies to state where their ingredients come from on product labels. The aim is to enhance the economic value and competitiveness of domestic products. BPOM also plans to introduce clear guidelines for assessing the safety of ingredients used in supplements and natural medicines. These will help prevent unsafe products from reaching the market.

Other changes will strengthen post-market controls. BPOM is updating its procedures to respond faster to safety issues, oversee online sales, and manage product recalls and destruction more effectively. Online supplement sales are growing fast, so BPOM is also revising its rules to make sure digital platforms follow the same safety standards as traditional channels.

#### New rules for stability testing

Indonesia's National Agency of Drug and Food Control (BPOM) has released new guidelines on stability testing of health supplements designed to ensure that health supplements available in the market meet established quality standards throughout their intended shelf life. The guidelines mandate that all health supplements undergo stability testing. This testing must be conducted in either accredited laboratories or in-house facilities that hold a valid good manufacturing practice (GMP) certificate. The regulation sets out requirements for designing the studies, evaluating results, and incorporating clear labelling on storage conditions and expiry.

### India

#### Digital tools to report misleading claims

FSSAI has launched a tool via the Food Safety Connect app and FoSCoS platform, allowing consumers to report misleading claims on food labels. Users can submit images, manufacturer licence numbers, and online links to help regulators act swiftly against non-compliant food businesses.

This initiative supports existing labelling and claims regulations, which require that all health and nutrition claims be truthful and scientifically substantiated. It also complements the work of FSSAI's Advertisement and

Claims Monitoring Committee, which reviews product labels and adverts for compliance.

FSSAI urges the public to participate in this effort to promote honest labelling and contribute to a healthier, well-informed India.

### Philippines

#### FDA brings new vitamin and mineral limits in line with ASEAN

The Philippines has taken a major step in updating its regulatory approach to vitamin and mineral supplements, adopting maximum levels based on the ASEAN Guidelines, and bringing the country in line with the region. Key features of the Circular:

- Nutrients must now provide at least 15% of the Recommended Nutrient Intake (RNI) to be recognised as a source.
- Products must remain below the ASEAN-set maximum levels. Aligned with WHO recommendations, limits of iron up to 30 mg/d is allowed for supplements for pre and antenatal use.
- For vitamins and minerals not listed in the ASEAN Guidelines, a default maximum level will apply: 150% of the RNI for water-soluble vitamins and 105% for fat-soluble vitamins.

The Circular also makes clear that the guidelines are strictly for adults. They do not cover products for pregnant/lactating women or children. Those categories will continue to follow nutrient levels based on the Philippine Dietary Reference Intakes (PDRI) and associated standards.

All products must follow the updated registration procedures, including submission via the FDA's electronic registration system. Locally manufactured products may submit in-house Certificates of Analysis (COA), provided the facilities have been verified by the FDA.

To help companies adapt, the FDA has introduced a transition period, with flexibility around product reformulation, registration renewals, and stock exhaustion:

- Products requiring reformulation must file for initial registration applications prior to the current Certificate of Product Registration (CPR) expiry.
- CPRs with less than one year's validity may be renewed for an additional two years.
- Label stock exhaustion may be permitted for up to 12 months upon request and approval.

Importantly, the new rules reaffirm key regulatory principles:

- No drug ingredients are permitted.
- No medical or therapeutic claims may be made

## South Korea

### MFDS extends peer-to-peer supplement sales trial to December 2025

South Korea's Ministry of Food and Drug Safety has extended its pilot allowing peer-to-peer sales of health functional foods on second-hand platforms until 31 December 2025. Initially launched in May 2024, the trial has continued without reports of safety issues. Authorities plan to adjust rules by easing limits on transaction value and expiry dates, while tightening restrictions on illegal sales and misleading advertising. Monitoring and public information efforts will be expanded, with new

platforms such as Junggo Nara under review for inclusion.

## Vietnam

### Vietnam food safety chief arrested amid widening supplement scandal

Vietnam's former food safety chief, Nguyen Thanh Phong, has been arrested alongside several officials in connection with a large-scale counterfeit health supplement scheme. Authorities allege bribes were paid to secure GMP certification and product registrations for companies producing fake dietary products, some with less than 30% of declared active ingredients. Police seized around 100 tonnes of counterfeit goods falsely marketed as imports from the US and Europe. The fallout has intensified scrutiny of Vietnam's regulatory framework. In parallel, the government is revising the core regulation governing food supplement oversight. The latest draft includes a controversial requirement for clinical, in vitro or in vivo studies on finished products.

Adding to the uncertainty, it is understood the current version of the decree provides no transition period: all existing product licences would be voided once the new regulation comes into force.



## EU

### EFSA to reassess safe intake level for DHA by June 2026

The European Food Safety Authority (EFSA) has accepted a request from the European Commission to reassess the safe level of intake for docosahexaenoic acid (DHA) and to establish a Tolerable Upper Intake Level (UL) for all population groups. The updated scientific opinion is expected by the end of June 2026. This development follows EFSA's recent scientific opinion confirming that oil derived from *Schizochytrium limacinum* (strain FCC-3204) is safe for extended use as a novel food.

As part of that opinion, EFSA also undertook a broader assessment of dietary DHA intake across the EU population – excluding food supplements. The results showed average daily intakes from authorised novel food sources ranging from 0.1 to 2.4 grams, with consumption reaching up to 4 grams per day at the 95th percentile. These figures exceed the safe intake level of 1 gram per day previously set by EFSA's NDA Panel in 2012.

In light of these findings, the European Commission decided to request a formal reassessment to ensure consumer safety as DHA is increasingly added to a wider variety of food products.

### EU eases import rules for gelatine capsule products

The European Commission has updated its import rules to reduce paperwork for certain low-risk composite products. From 19 May 2025, products that contain gelatine capsules not made from ruminant bones will no longer need an official certificate or a private attestation to enter the EU.

This change was made through Delegated Regulation (EU) 2025/637, published on 29 April 2025. Previously, EU law exempted these gelatine capsules from official certification, but still required a private attestation when used in composite products. The amendment removes this inconsistency.

### Fennel: Ban anticipated

The European Food Safety Authority (EFSA) is preparing to issue an opinion that may lead to a ban on the use of sweet and bitter fennel in food supplements. This follows a safety assessment under Article 8 of Regulation (EC) No 1925/2006, which allows the European Commission to scrutinise substances added to foods or used in food supplements that may pose a risk to consumers.

The concern in this case focuses on estragole, a compound naturally present in fennel that is a well-established genotoxic carcinogen. According to EFSA, estragole forms a harmful metabolite as soon as it is ingested, which binds to DNA and can trigger cancer. No safe threshold could be identified, meaning there is no level of exposure at which estragole is considered without risk. As a result, EFSA is expected to

conclude that fennel preparations containing estragole should not be deliberately added to food, and particularly not to food supplements, where exposure levels could be concentrated.

The assessment also included methyleugenol and safrole, structurally similar substances with the same mode of action. These compounds, all belonging to the p-allylalkoxybenzene group, are considered to have a high public health priority due to their shared capacity to form genotoxic metabolites, cross the placenta, accumulate in the body, and potentially cause cancer in offspring through breast milk exposure. Further concern arises from the fact that some individuals are genetically more susceptible to these effects, and the body's DNA repair mechanisms do not always detect or fix the damage caused.

While EFSA accepts that fennel use in culinary settings, such as in herbs, spices, vegetables, and infusions, is difficult to eliminate entirely, it advises minimising exposure, particularly during pregnancy and breastfeeding.

Importantly, EFSA's conclusions may have wider implications. Similar substances are found in many other plants, including basil, anise, thyme, rosemary, nutmeg, peppercorn, and star anise.

The draft opinion is scheduled for discussion by EFSA's Scientific Committee on 15 May, with a public consultation expected by mid-June. Once finalised, the opinion is likely to lead to an EU-wide prohibition on the use of fennel in food supplements.

### **EU targets green tea catechins and monacolins for bans, while alpha-lipoic acid remains under scrutiny**

In its latest Article 8 Working Group meeting, the European Commission proposed significant new restrictions on food supplements. Member States have been asked to respond by the end of May to proposals including a ban on green tea catechins and monacolins from Red Yeast Rice (RYR), and the placing of alpha-lipoic acid (ALA) under formal scrutiny. No final decisions were taken at the meeting.

The proposed ban on green tea catechins applies to extracts

containing EGCG, citing the absence of new evidence to address safety concerns raised in EFSA's 2018 opinion. Although EFSA found no consistent signs of liver toxicity below 800 mg/day, a lack of dose-response data prevents risk assessment. Traditional green tea infusions and reconstituted beverages with similar composition would be exempt.

Monacolins from RYR are also expected to be prohibited, following a second EFSA opinion confirming that safety could not be established even below 3 mg/day. While the cholesterol-lowering benefits of monacolins are acknowledged, the Commission notes that food law does not allow risk-benefit balancing, and safer, authorised alternatives such as plant sterols exist.

In a shift from its earlier position, the Commission now proposes placing ALA under scrutiny rather than banning it. This follows input from stakeholders and will allow continued use for the time being, provided that new data, particularly on the risk of Insulin Autoimmune Syndrome, are submitted during the review period.

### **New botanicals for use in supplements**

The Spanish Agency for Food Safety and Nutrition (AESAN) has confirmed the authorisation of new botanicals for use in food supplements, following their assessment under the EU's novel food consultation procedure. The plants concerned are *Silene vulgaris*, *Sonchus oleraceus* and *Scolymus hispanicus*. These species, all with a long-standing tradition of use in Spanish cuisine and in Mediterranean pharmacopoeias, have now been recognised as having a significant history of safe consumption prior to 15 May 1997, the key cut-off date for determining novel food status in the EU. As a result, they are no longer considered novel and may be legally used in food supplements across the European Union.

The European Commission has added Wax Gourd (*Benincasa hispida*) to the EU Novel Food Catalogue as a non-authorised Novel Food. It cannot be used in food or food supplements in the EU without prior authorisation.

### **Major update to EFSA's Botanicals Compendium**

EFSA has released a major update to its Compendium of Botanicals, an open-access database identifying plant species that contain naturally occurring substances of potential concern. Now covering 2,701 species and 1,538 substances, the tool is designed to support hazard identification in areas such as food supplements.

The updated database includes new data from an extensive literature review and, for the first time, predictions from three advanced QSAR platforms (VEGAHub, Danish EPA QSAR, and T.E.S.T.). These models assessed potential adverse effects such as acute toxicity, genotoxicity, carcinogenicity, and organ toxicity, based on molecular structure.

Importantly, EFSA emphasises that the presence of a substance in a botanical does not necessarily mean it poses a risk to consumer health. The database does not assess safety; rather, it is intended to help flag potential hazards for further consideration.

### **Psychological "on hold" claims invalid without pre-2008 submission**

The Court of Justice of the European Union (CJEU) has ruled that psychological and behavioural health claims for food supplements cannot be used unless they were submitted for authorisation before 19 January 2008.

The case C-386/23 centred on two specific Article 13(b) claims: one for saffron extract's effects on mood and another for melon juice extract's impact on stress and fatigue. These had been used in marketing while awaiting formal assessment by the European Commission. But the Court found that because no timely application was made, they cannot benefit from the transitional rules under Regulation (EC) No 1924/2006.

This draws a clear line between Article 13(b) claims (psychological/behavioural) and the more familiar Article 13(a) claims (physiological functions). While the latter can continue under national rules and scientific justification, the former cannot be used unless they were specifically submitted before the cut-off date.

The judgment follows the October 2024 opinion of the Advocate General and aligns with the strict interpretation seen in earlier case law. It does not affect the status of physiological “on hold” claims.

### EFSA raises safety threshold for acesulfame K

The European Food Safety Authority (EFSA) has reaffirmed the safety of acesulfame potassium (E 950), a widely used sweetener in food and supplements, increasing the acceptable daily intake from 9 to 15 mg/kg body weight. However, EFSA is calling for stricter controls on certain impurities, notably 5-chloro-acesulfame, a potential genotoxic by-product of the manufacturing process. EFSA recommends a maximum limit of 0.1 mg/kg for this impurity, or alternatively appropriate genotoxicity data for 5-chloro-acesulfame. It also suggests lowering the permitted levels of lead and mercury and including acetyacetamide and the CAS number 55589-62-3 in EU specifications to ensure better identification.

Published in April 2025, this updated opinion is part of EFSA’s systematic re-evaluation of food additives authorised prior to 2009, in line with Regulation (EU) No 257/2010.

## Belgium

### Belgium tightens labelling rules on stevia-based sweeteners

Belgium has issued updated guidance on how steviol glycosides - sweeteners derived from the Stevia plant - can be labelled and advertised. While EU law permits several forms of these additives, including those produced by fermentation and enzymatic conversion, the new rules caution against misleading claims.

Terms like “with stevia” or “with stevia extract” remain acceptable, but only if they accurately reflect the type of additive used. The aim is to prevent consumers from confusing sweeteners with those extracted directly from leaves.

The guidance also reinforces EU labelling requirements, which mandate clear identification of additives (e.g. “sweetener: steviol glycosides (E960c)”). The update comes as the EU expands approvals for new production methods, including

the use of *Yarrowia lipolytica* in fermentation.

## Czech Republic

### EU Novel Food Catalogue made legally binding

The Czech Republic has made the European Commission’s non-binding Novel Food Catalogue enforceable under national law. As of 1 April 2025, it is now illegal to place on the market any product listed as a “novel food” in the catalogue, except those noted as “not novel” in food supplements. The measure was included into Act No. 70/2025 Coll. via an amendment to the veterinary law and made public just days before taking effect.

The change, reportedly promoted by the Ministry of Agriculture and the Czech Food Inspection Authority, follows a series of lawsuits from companies selling products in unclear legal territory. To protect the state from being held liable, authorities acted to tighten the rules. This development prompts questions about how a non-binding EU reference list has effectively become enforceable law. The Commission clearly states that the catalogue is only a guidance tool, regularly updated, not legally binding.

## France

### ANSES flags CBD as a potential reproductive risk

ANSES, the French Agency for Food, Environmental and Occupational Health & Safety has proposed that cannabidiol (CBD) be classified as a “presumed human reproductive toxicant” based on animal studies indicating impaired fertility and developmental issues. This recommendation aims to classify CBD under the European CLP Regulation (Classification, Labelling and Packaging of substances and mixtures) as Reproductive Toxicity; Category 1B, which includes warnings about potential damage to fertility and unborn children, as well as risks for breastfed infants.

Despite the increasing sales of CBD products in France since 2021, with 16.4% of adults having consumed CBD at least once, it has been highlighted that CBD has not been registered with the European Chemicals Agency

(ECHA) under the REACH Regulation, leaving its health risks un-assessed. The analysis of the hazards conducted by ANSES was based on available scientific literature and data from pre-clinical trials for the medication Epidyolex®, which contains CBD alone.

Following the consultation, the feedback will be reviewed by ECHA’s Committee for Risk Assessment to form an opinion on the classification of CBD. This regulatory process focuses on hazard assessment, not on risk management measures for CBD-containing products, which are governed by separate regulations by sector.

### Rules on ‘Made in France’ label

Claiming a product is “Fabriqué en France” now demands more than tricolour branding. Under EU customs rules, the label may only be used if the product is either entirely made in France or has undergone its final substantial transformation there. The French customs authority offers free guidance under its “Information sur le Made in France” scheme, but the support is advisory. Misuse of the label is treated as a deceptive commercial practice, punishable by fines of up to €300,000 or 10% of annual turnover.

To help firms promote compliant products, France Industrie has released a communication toolkit, including an official logo. Additional labels, such as Origine France Garantie or Entreprise du Patrimoine Vivant, offer further ways to certify national provenance

## Hungary

### New rules for GABA and Chaste tree in supplements

The Hungarian National Public Health and Pharmaceutical Centre (NNGYK) has updated its opinions on GABA (gamma-aminobutyric acid) and Vitex agnus-castus (chaste tree), leading to changes in their regulatory status for use in food supplements.

GABA has been identified as a substance with notable physiological effects, including blood pressure reduction and insulin modulation. Due to these effects, supplements containing GABA must now be limited to a maximum of 120 mg per day and carry warnings against use by pregnant or breastfeeding women,

those under 18, and individuals with low blood pressure or undergoing antihypertensive treatment. Unless used within these conditions, GABA is considered unsuitable for inclusion in food supplements.

Meanwhile, *Vitex agnus-castus* has moved from prohibition to restricted use. The fruit may now be used in food supplements and herbal teas at doses up to 240 mg of dried fruit per day, provided that labels warn against use by pregnant or breastfeeding women and individuals under 18 years of age. However, higher doses and ethanolic extracts remain banned due to potential hormonal effects. These changes update Hungary's list of plants not recommended for use in Foods (including food supplements) and serve as a guide for supplement notifications and market surveillance.

## Spain

### Clarifying mutual recognition rules

The Spanish authorities have issued updated guidance clarifying the procedure for notifying food supplements under the principle of mutual recognition. The guidance outlines the documentation required to demonstrate that a product is legally marketed in another EU Member State. This may be done by submitting one of the following:

- A Mutual Recognition Declaration (self-declaration), confirming that the product complies with, or is not subject to, the regulations in the country of origin and is available to end users there. The declaration must follow the format set out in Regulation (EU) 2019/515 and be supported by evidence such as references to legislation, invoices, website links, or online sales records.
- Alternative documentation: Where a declaration is not provided, the competent authority may request relevant documentation within 15 working days to

verify that the product is lawfully marketed.

The Spanish authorities will assess each submission to ensure that the product's composition, labelling, and conditions of use align with those of the version marketed in the Member State of origin, and that the responsible operator is clearly identified.

This procedure is particularly relevant for food supplements containing substances listed in the Spanish regulation under different conditions (e.g. differing maximum levels or labelling requirements), as well as for "other substances with a nutritional or physiological effect" that are not regulated under Spanish law.

Mutual recognition is a core principle of the EU internal market. It allows products that are lawfully marketed in one Member State to be placed on the market in another, even if they do not fully comply with the technical rules of the destination country. This mechanism plays a crucial role in supporting the free movement of goods across the EU.

## Sweden

### Sweden serves up new dietary rules

Sweden's National Food Agency has released updated dietary guidelines that emphasise health, environmental sustainability, and support for national food production. The message: eat more vegetables, legumes, whole grains, and fish; consume less sugar, salt, and red meat. Meat remains on the menu, but only in moderation at under 350 grams per week. The advice also recommends fermented dairy, iodised salt, rapeseed oil, and a daily dose of nuts and seeds.

### Sweden defers to EU reevaluation of Ashwagandha

The Swedish National Food Agency (NFA) has updated its website regarding the use of *Withania*

*somnifera*, commonly known as ashwagandha, in food supplements, reflecting developments at EU level. Previously, the NFA had highlighted safety concerns based on an assessment by the Technical University of Denmark (DTU), which concluded that no safe lower dose could be established for ashwagandha in food supplements. That national reference has now been withdrawn.

This change follows the launch of an EU-level review prompted by the publication of the Heads of Food Safety Agencies Working Group on Food Supplements (HoA WG FS) report. The report identifies twelve substances and plants, including ashwagandha, as priorities for assessment due to potential health risks, and proposes that they should either not be used or only be used under restrictions in food and food supplements. Based on the findings of this review, the European Commission may request a formal opinion from EFSA.

The NFA has made clear that it has not conducted its own risk assessment on ashwagandha and is currently awaiting the outcome of the EU process before taking further steps. In the meantime, it reiterates that all companies placing food supplements on the market must be able to demonstrate the safety of their products for consumers. The updated text on the NFA website now clearly states that ashwagandha is under EU review, and any future national position will be guided by the conclusions of that process.

## The Netherlands

### Mare's and donkey's milk sellers penalised for false health claims

The Dutch food authority NVWA has taken enforcement action against 24 websites selling mare's and donkey's milk products for making illegal health and medical claims. Sellers claimed the products could treat or prevent

conditions like eczema, psoriasis, allergies, and even COVID-19, claims that are strictly prohibited for foods and supplements under EU law. The companies received official warnings or fines and were ordered to correct their websites immediately. Only health claims approved by the EU and backed by science are permitted.

## UK

### CBD permitted with caution

The UK has inched ahead of the European Union in the regulatory review of cannabidiol (CBD) as a novel food ingredient. The Food Standards Agency (FSA) and Food Standards Scotland (FSS) have published three separate safety assessments for applications seeking authorisation of  $\geq 98\%$  pure CBD isolate for use in food supplements. The applicants each sought proprietary data protection and authorisation for use in supplements for the general adult population, excluding vulnerable groups.

Despite minor variations between the applications, the three assessments converge on a single regulatory principle: CBD isolate, when used in food supplements, is considered safe for healthy adults at a maximum daily intake of 10 mg. This figure, established in 2023 by the Advisory Committee on Novel Foods and Processes (ACNFP) and the Committee on Toxicity (COT), has been applied to all assessments. Originally proposed use levels ranged from 35 mg to 70 mg per day, but were revised downward by applicants in consultation with UK authorities. Each applicant proposed use in typical supplement formats: capsules, tablets, liquids, or drops. While the assessments affirm the safety of single daily doses up to 10 mg, they also highlight the need for risk management measures, including clear labelling and consumer information to prevent inadvertent overconsumption.

In all three cases, the FSA and FSS emphasise that their conclusions apply only to the specific uses proposed, namely, food supplements within the scope of UK food law, and do not extend to broader food categories or higher dose formats. Any future applications seeking expanded use would need to undergo a separate review under the “change in conditions of use” process. Crucially, the safety assessments relied on proprietary scientific data submitted by the applicants. Without this data, the FSA and FSS confirm that the assessments would not have been possible, and as such, proprietary data protection will be granted in each case.

While the UK moves toward clarity, the EU remains hesitant. The European Food Safety Authority (EFSA) has not yet issued any favourable opinion on CBD isolates but has now launched a formal re-evaluation, with updated guidance expected by December 2025.

### FSA grants new powers to tackle food fraud in England and Wales

The Food Standards Agency has confirmed that its National Food Crime Unit (NFCU) now holds formal investigatory powers under the Police and Criminal Evidence Act (PACE), nearly a decade after the unit was established in response to the 2013 horse meat scandal.

The new powers allow NFCU officers in England and Wales to apply for and execute search warrants, enhancing their ability to investigate and disrupt serious food fraud. The move is intended to strengthen consumer protection and bolster the UK’s enforcement capacity across the food supply chain. The FSA said the change reflects its continued commitment to tackling food crime in partnership with police and local authorities.

## Ukraine

### Ukraine brings food supplement regulation in line with EU framework

The Ukrainian government has adopted the new law aligning its regulation on food supplements with European Union standards. Published by the parliament on 26 March 2025, Law No. 4122-IX introduces a revised regulatory framework designed to close longstanding legislative gaps in market oversight, in line with commitments under the EU-Ukraine Association Agreement.

The law adopts the EU definition of food supplements set out in Directive 2002/46/EC and replaces the previous state registration model with a notification-based system. Under the new regime, companies will be required to notify products before placing them on the market, with the Ministry of Health empowered to establish the list of authorised nutrients and bioactive substances, including their maximum permitted levels.

The legislation also strengthens enforcement by increasing liability for the manufacture and sale of non-compliant products. The law will come into force on 27 September 2025.



## Turkey

### The future of supplements

The food supplement industry in Turkey is facing a significant challenge that could destabilise the sector. A sudden proposal to transfer regulatory authority from the Ministry of Agriculture to the Ministry of Health has raised urgent concerns, as it would invalidate all existing product approvals and require complete re-notification under new rules. The supplement industry has mobilised to oppose the shift and there are encouraging indications that food supplements will not be moved out of the current food law framework.



## Brazil

### Updates on food additives

Brazil has recently revised its food additive regulations, introducing new authorisations and usage conditions for specific additives in food supplements.

#### Partially Hydrolysed Lecithin (INS 322(ii))

Approved as an antioxidant and emulsifier at Quantum Satis in liquid supplements and solid supplements. Also authorised as an emulsifier at max 5,000 mg/kg in supplements for infants and young children (Category 14.3).

#### For solid supplements only:

- Polydimethylsiloxane (INS 900a): Anti-foaming agent, max 10 mg/kg
- PVP-Vinyl Acetate Copolymer (INS 1208): Glazing agent, max 100,000 mg/kg (not permitted in chewable forms)

### ANVISA investigates creatine supplements

Brazil's health authority ANVISA has published the results of a 2024 investigation into 41 best-selling creatine food supplements, mostly sold in 300g containers and sourced directly from manufacturers. The study assessed creatine content, labelling compliance, and contamination, with samples collected in triplicate and analysed by INCQS, part of the Fiocruz Foundation.

The findings showed that most products met the required creatine levels, with only one falling below the 3,000 mg minimum and deviating by more than 20% from the labelled amount. No contamination or foreign matter was detected, indicating good overall product safety. However, labelling compliance was a significant issue. ANVISA found that 40 of the 41 products contained some form of labelling inaccuracy, including unauthorised or misleading claims, often in foreign languages, along with incorrect or incomplete nutritional information such as missing values for

total or added sugars and unclear serving details.

While the products do not present a health risk warranting further inspection, ANVISA warned that inaccurate labelling can mislead consumers and announced it will notify manufacturers to enforce corrective actions.

### Updates to food supplement rules and new regulation on ingredient specifications

ANVISA is holding a public consultation on two regulatory proposals. The first amends the existing food supplement regulation (RDC 243/2018) and its associated positive list (IN 28/2018). The second introduces a new regulation to define identity and purity specifications for all food ingredients, including those used in supplements.

In the first draft resolution, ANVISA proposes to remove allicin (garlic oil) and lactulose from the positive list of ingredients permitted in food supplements. Allicin would be excluded due to its instability and lack of reference specifications, while lactulose would be reclassified from a dietary fibre to a carbohydrate, aligning with RDC 429/2020, as it does not meet the dietary fibre definition. Lactulose would continue to be allowed, but listed under carbohydrates.

The proposal also includes a revision to Article 8 of RDC 243/2018 to require that all ingredient sources of nutrients, bioactive substances, enzymes and probiotics comply with the new specifications outlined in a separate draft Administrative Order (IN).

The second proposal, sets out identity, purity and composition requirements for all food ingredients, including those listed under IN 28/2018. It introduces four annexes covering ingredients with specifications approved either generally, under novel foods regulation (RDC 839/2023), for specific companies, or under other specific regulations. It also details how equivalence between specifications may be established, including reference sources.

Both proposals are open for comment until 16 June 2025, with a two-year adaptation period foreseen.

### New ingredients in food supplements

Brazil has updated its food supplement regulations with the publication of Administrative Order IN 361/2025 on 15 May, amending IN 28/2018. The new measure introduces several additions to the list of permitted ingredients, claims, and labelling requirements.

The regulation authorises calcidiol derived from *Saccharomyces cerevisiae* as a new source of vitamin D. Its use is limited to food supplements intended for individuals aged 11 and over, including pregnant and lactating women. Also approved are phenolic compounds and extracts from *Opuntia ficus-indica*, with a maximum permitted level of 54.6 mg, and xylo-oligosaccharides, capped at 2 mg. No minimum use levels have been established for either substance. The Order also introduces new authorised health claims for astaxanthin, along with specific labelling warnings required for products containing calcidiol, phenolic compounds from *Opuntia ficus-indica*, and xylo-oligosaccharides.

The changes took effect immediately on 15 May 2025.

## Costa Rica

### Costa Rica signals review of synthetic food dyes after US phase-out move

Costa Rica's Ministry of Health has announced a formal review of synthetic food colourings authorised for use in the country, signalling a possible regulatory shift in response to recent developments in the United States. The move follows the US Food and Drug Administration's decision to phase out certain petroleum-derived artificial colourings.

In response, Costa Rican authorities have urged the food industry to review product formulations and consider switching to natural alternatives. A technical reassessment of authorised colourings will begin shortly, guided by the latest recommendations from Codex Alimentarius, the FDA, and the European Food Safety Authority (EFSA).

While no immediate bans have been issued, the Ministry has not ruled out regulatory changes, including possible

amendments to the Central American Technical Regulation on Food Additives. It stressed that any measures will be science-based, aligned with international standards, and developed in consultation with the food, supplement, pharmaceutical and cosmetics sectors.

The Ministry has reaffirmed its commitment to protecting public health and will continue to inform the public as the evaluation progresses.

## Dominican Republic

### Proposed rules for supplements

The Ministry of Public Health of the Dominican Republic has opened for public consultation a draft Sanitary Regulation of Foods, aimed at establishing a unified framework for all food products, including food supplements. Currently, there is no specific regulation in place for food supplements in the country, making this the first proposed framework for the category.

Key elements of the proposal related to food supplements include:

- **Definition:** Products comprising nutrients, combinations of nutrients, and other components naturally present in foods, such as vitamins, minerals, amino acids, lipids, and dietary fibre or its fractions.
- **Presentation forms:** Solid, semi-solid and liquid formats.
- **Additives:** Limited to those permitted under the Dominican Standard NORDOM - General Standard for Food Additives (Codex Stan 192-1995).
- **Levels of nutrients:** Minimum and maximum limits for vitamins, minerals and other components to be set by DIGEMAPS, based on international references.
- **Claims and labelling:** Nutrition and health claims, as well as labelling requirements, to follow the relevant NORDOM standards.
- **Legal name:** Products must clearly display the term "Food Supplement".
- **Ingredient:** Composition per dose form must be detailed.
- **For botanicals,** the common name, scientific name, and part of the plant used must be indicated.

- For probiotics, the scientific name and the quantity included in the product must be specified.

The proposal also outlines mandatory warning statements, including:

- "This product does not replace a balanced diet and is not recommended for children under 4 years of age, or for pregnant or lactating women unless advised by a competent professional."
- "Food supplements must not be used as a substitute for a balanced diet."
- "This product is not intended to diagnose, treat, cure, or prevent any disease."
- "Keep out of reach of children."
- "This product is not adequate to be consumed as the only source of food."
- "If you are taking any medication, consult your physician before using this product."

Specific warnings depending on content:

- **Tartrazine:** "Contains tartrazine (Yellow No. 5), which may cause allergic reactions in sensitive individuals."
- **Aspartame:** "Phenylketonurics: contains phenylalanine."
- **Caffeine:** "Not recommended for individuals sensitive to caffeine."

## Paraguay

### Paraguay proposes new procedures for post-registration changes to dietary supplements

Paraguay's National Directorate of Health Surveillance (DINAVISA) has launched a public consultation on a Draft Resolution that sets out the criteria and procedures for making post-registration modifications to dietary supplements. The proposed measures would apply to both locally produced and imported products. The modifications are categorised into two types:

**Type I - Major modifications:** These can be implemented automatically without prior authorisation, but DINAVISA must be notified before the

change takes effect. Examples include changes to excipients that do not affect the nutritional composition, reductions in product presentation or primary packaging, updates to label design, changes in the commercial name, and revisions to the way the dosage form is expressed.

**Type II - Critical modifications:** These require prior evaluation and approval by DINAVISA before they can be implemented. They include changes such as alterations to shelf life or the manufacturer.



## USA

### Ban of petroleum-based synthetic dyes

The US Government has announced it will ban petroleum-based synthetic dyes currently permitted in the country.

The move, unveiled by Martin Makary, newly appointed head of the U.S. Food and Drug Administration (FDA), signifies a reform of food additive regulations. Speaking at a press conference alongside U.S. Health Secretary Robert Kennedy Jr., Dr. Makary confirmed the FDA's intention to phase out eight synthetic dyes derived from petroleum. The colourings targeted for removal are FD&C Green No. 3, FD&C Red No. 40, FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Blue No. 1, and FD&C Blue No. 2, Citrus Red No. 2 and Orange B.

This new regulation builds on a January 2025 decision to prohibit Red 3 (E127). In total, two (Red No 2 and Orange B) of the eight targeted colourings will have their authorisations revoked within the next few months, with the remainder to follow in cooperation with the food industry.

At the same time, the FDA plans to approve four new natural colourants and accelerate the evaluation of additional alternatives to ensure a smooth transition.



## Australia

### Australia reaffirms NMN ban in supplements

The Therapeutic Goods Administration (TGA) of Australia has reissued a clear warning that nicotinamide mononucleotide (NMN) and related compounds such as NAD+ are not permitted in listed medicines, including health supplements, sold domestically.

Only NMN products approved as 'export only' can be manufactured in Australia, with local sales prohibited. Consumers may import NMN for personal use under strict limits, but resale remains illegal.

The TGA cautioned sponsors that any reference to NMN or NAD in product names or advertising could breach Australian law, and enforcement action may be taken.



## Kazakhstan

### Pilot project to ID-tag food supplements

Kazakhstan's Ministry of Health has initiated a voluntary pilot programme to introduce ID tagging for food supplements, as part of broader efforts to enhance product traceability and regulatory oversight. The measure was enacted through Order No. 198, issued on 28 March 2025 and effective from 1 April. Under the scheme, participating companies must apply a two-dimensional Data Matrix code to the labelling or packaging of each food supplement placed on the market. Each code must display the product's Global Trade Item Number (GTIN) and a unique serial number in human-readable form.

The pilot applies to a wide range of food supplement categories, including those classified under harmonised codes such as extracts, concentrates, protein powders, amino acids and vitamins. Key tariff codes include 1211 90 860 8, 1212 99 950 9, 1302 20, 1603 00 100 0, 1806 90 900 0, 1901 90 980 0, 2102 20 110 0, 2106 10 800 0, 2202 10 000 0, 2202 99 910 0, 2922 49 850 0, 2925 29 000 0, 3502 90 700 0, 3503 00, 3802 10 000 0, and 3913 10 000 0.

Imported supplements from Eurasian Economic Union (EAEU) member states must be tagged prior to crossing Kazakhstan's border, while those from non-EAEU countries require tagging before entering the Union's customs territory.

The pilot is being supervised by the Committee of Sanitary and Epidemiological Control. Participation in the pilot is voluntary.

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