

# IADSA NEWSFLASH

March 2025

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## Regulatory news



### Japan

#### CAA proposes new notification requirements for foods with function claims

Japan's Consumer Affairs Agency (CAA) has issued Proposal No.235080079 outlining updated notification requirements for Foods with Function Claims (FFC). The proposal details submission procedures and documentation requirements.

Notifications must follow specific forms covering safety, manufacturing, and scientific evidence, and must be submitted in Japanese. Once approved, the CAA will assign a notification number, with most information becoming publicly available, except personal information.

New FFC products must be notified, except for minor variations in flavour, packaging, or size. Significant changes, such as ingredient modifications or updates to

recommended intake, require re-notification.

#### Japan maintains approval for Red No. 3

Japan continues to allow the use of Red No. 3, despite its recent ban in the U.S. due to cancer concerns in lab rats. The synthetic food dye, has been designated a food additive in Japan since 1948. Japan's Consumer Affairs Agency (CAA) maintains that there is no health risk data against Red No. 3.

### South Korea

#### Updates on 9 health functional food standards

South Korea's Ministry of Food and Drug Safety (MFDS) has revised the Health Functional Food Code, updating standards for nine functional ingredients. Effective from 1 January 2026, the changes include new precautionary statements, intake limits, and manufacturing standards. Key updates include warnings for Vitamin B6 and Vitamin C regarding adverse effects, with caution being advised for vitamin C taken by individuals with kidney disease. Chlorella intake guidelines have been clarified based on its benefits covering skin health. Banaba Leaf Extract, Ginkgo Leaf Extract, Octacosanol-Containing Oil, Phosphatidylserine, Guar Gum, and Theanine now include stricter precautions for children, pregnant and breastfeeding women.

Manufacturing revisions specify updated extraction methods for Phosphatidylserine, new content requirements for Guar Gum, and refined raw material specifications for Theanine. The regulations apply to products manufactured or imported after enforcement, with voluntary compliance for existing stock.



### EU

#### EFSA deems monacolins from red yeast rice unsafe at any level

The European Food Safety Authority (EFSA) has declared that the safety of monacolins from red yeast rice cannot be established at any level. This conclusion follows a review under the "Article 8 procedure", addressing food substances with questionable safety. Monacolins, substances found in fermented red yeast rice, have been under regulatory scrutiny due to emerging health concerns. Under the updated Commission Regulation (EU) 2022/860, monacolins were categorised under Part B (restricted substances) and Part C (substances under scrutiny) of Annex III to Regulation (EC) No 1925/2006.

EFSA's review focused on the variable composition of red yeast rice products and their associated health risks, particularly the severity of reactions linked to monacolin K. Despite being permitted under strict conditions that limit daily intake to less than 3 mg, recent data suggest these levels still pose significant health concerns. Severe cases of muscle damage and liver toxicity have been reported, aligning with the concerns raised in EFSA's previous assessments from 2018.

Based on these conclusions, it is likely that the European Commission will amend Annex III of Regulation (EC) No 1925/2006 to classify monacolins from red yeast rice as prohibited substances, effectively banning their use in food supplements across the EU. This change will also impact products with permitted health claims relating to monacolin K for cholesterol reduction.

### European Commission clarifies Impact Assessment Procedures in legislative processes

In a response to a written question posed by Members of the European Parliament Auke Zijlstra and Ton Diepeveen, the European Commission, represented by Mr. Valdis Dombrovskis, has reaffirmed its commitment to its 'better regulation' guidelines and the principles outlined in the Interinstitutional Agreement on Better Law-making.

This involves preparing impact assessments for initiatives that could significantly influence economic, environmental, or social factors, particularly when multiple policy options are available. The purpose of these assessments is to ensure that the benefits of any legislative proposal outweigh the applicable costs.

Mr. Dombrovskis noted that in urgent cases, traditional impact assessments may be bypassed. Instead, a detailed staff working document is prepared within three months of a proposal's adoption.

The Commission also clarified that these assessments are designed as tools to aid policy-making, not to predetermine outcomes.

### EMA releases draft reflection paper on EU herbal monographs

The European Medicines Agency's (EMA) Committee on Herbal Medicinal Products (HMPC) has published a draft reflection paper titled "Reflection paper on the use of information in EU herbal monographs and assessment reports for borderline issues".

This reflection paper aims to provide guidance on how EU herbal monographs and their accompanying assessment reports can assist in distinguishing between herbal medicinal products and other categories such as medical devices, food supplements and cosmetics. The goal is to support national competent authorities and applicants in making informed classification decisions. In this paper, the EMA suggests that the inclusion of a botanical in a Traditional Herbal Medicinal Product (THMP) could indicate that the botanical in question could qualify as a (traditional) herbal medicinal product.

This could be interpreted as an attempt by the EMA to take greater control over botanicals included in its monographs. However, many indications in the EU herbal monographs focus on supporting physiological functions rather than treating or preventing disease. It remains to be seen how this document will shape ongoing discussions on the classification of botanicals and borderline food supplements within the EU regulatory framework.

### EFSA's latest QPS update

EFSA has released its latest review of the Qualified Presumption of Safety (QPS) list, evaluating microorganisms notified up until September 2024. The review found no new evidence requiring changes to the status of previously approved microorganisms, keeping the existing safety framework unchanged.

Out of 54 microorganisms submitted for consideration, most did not require further evaluation. Some, including *filamentous fungi*, *Enterococcus faecium*, and *Escherichia coli*, were excluded, while others had already been granted QPS status. Five microorganisms were closely examined in the latest review. *Lacticaseibacillus huelsenbergensis* secured QPS status, supported by its close relationship with other approved species within the group. In contrast, *Enterococcus*

*lactis* was not approved due to a lack of sufficient safety data, while *Serratia plymuthica* and *Bacillus thuringiensis* were deemed unsuitable because of safety concerns. *Bacillus nakamurai*, on the other hand, was not included due to insufficient scientific knowledge to support its use.

### Ombudsman closes another door on 'probiotics', confirming the Commission's position

The European Ombudsman has concluded an inquiry into the European Commission's interpretation of the term "probiotics" under EU food legislation, ruling that the Commission's position is reasonable and aligned with consumer protection goals. This decision follows a complaint by the International Probiotics Association (IPA), which argued that "probiotics" should be classified as a neutral descriptor or nutrition claim, rather than a health claim.

The complaint challenged the Commission's longstanding guidance, which treats "probiotics" as implying health benefits, thereby requiring authorisation as a health claim under the Claims Regulation (1924/2006). To date, no health claims for probiotics have been authorised by the European Commission except for yogurt due to a lack of sufficient scientific evidence. The IPA maintained that this restrictive interpretation limits consumer access to information about probiotics.

The Ombudsman supported the Commission's approach, highlighting its reliance on the World Health Organisation's (WHO) definition of probiotics as "live microorganisms which, when administered in adequate amounts, confer a *health benefit*." According to the Ombudsman, this definition justifies treating the term "probiotics" as a health claim under EU law, and the labelling foods with "probiotics" without scientific validation of health effects could mislead consumers. The inquiry also addressed concerns about regulatory inconsistencies across EU Member States. While some Member States may allow different practices, the Ombudsman emphasised that the Commission's guidance, in place since 2007, provides a clear framework for industry. Should such discrepancies arise, the Ombudsman stated that it is the Commission's responsibility as the "guardian of the EU Treaties" to

address non-compliance by Member States.

## Commission challenges Court ruling on Aloe Vera ban

The European Commission has appealed the Court ruling concerning Hydroxyanthracene derivatives (HADs).

In November 2024, the European General Court (Case T-189/21) annulled a provision in Commission Regulation (EU) 2021/468 that had classified Aloe Vera preparations containing HADs under Part A of Annex III to Regulation (EC) No 1925/2006, essentially banning them.

The dispute centred on whether the Commission had followed the correct legal and scientific process in imposing this ban under the Article 8 procedure. According to the Court, the Commission failed to consider key conditions required for such a ban, including establishing a safe intake threshold. Instead, the regulation applied a blanket prohibition, irrespective of the actual levels of HADs present in the product.

## Denmark

### Ashwagandha, Tribulus, and Maca supplements must be discarded

The Danish Food Authority (Fødevarestyrelsen) issued a strong warning about three harmful supplements sold by the TikTok profile "mpower\_dk" through the website mpowernutrition.shop. Despite being ordered to halt illegal sales, the company failed to comply. Consumers were urged to dispose of the products immediately.

The three flagged supplements, "Ashwagandha+", "Testosterone Booster", and "Tongkat Ali+", contain illegal and potentially dangerous plant ingredients, according to the Authorities:

- *Tribulus terrestris*: Can cause serious liver damage and long-term harm to the nervous system, including reduced dopamine levels, which are linked to Parkinson's disease.
- Ashwagandha (*Withania somnifera*): May negatively affect the immune system and thyroid function.

- Maca (*Lepidium meyenii* Walp.): Can disrupt hormonal balance in women and impair reproductive health in men.

Companies selling supplements are required to register with the Authorities, but this company failed to meet that obligation.

The Danish Food Authority urged consumers who have purchased these supplements to discard them immediately and recommended visiting the Authority's official website for a list of notified supplements.

### Over half of businesses found in breach of supplement claim regulations

A recent control campaign by the Danish Veterinary and Food Administration found that over half of businesses were making unlawful claims in their marketing of supplements, highlighting the need for stricter guidance and oversight. The 2024 review of 131 companies revealed widespread non-compliance. Many health claims on products and digital platforms failed to meet regulatory standards. Over 20% of businesses improperly suggested their supplements could treat diseases. Overall, 61% (80 out of 131) breached regulations on health and disease claims.

The Danish Veterinary and Food Administration noted that many companies lack understanding of the rules or have misinterpreted them. Unit manager Henrik Dammand Nielsen emphasised that while most penalties were for non-specific health claims, the most serious violations involved unlawful disease claims, reinforcing the need for stronger guidance and control.

### Denmark advises daily vitamin B12 for vegetarians

The Danish Veterinary and Food Administration now advises vegetarians to take a daily B12 supplement to support blood formation and nerve function, following a new assessment by the Technical University of Denmark (DTU). The assessment found that those who avoid meat and fish may struggle to meet their B12 needs through diet alone, increasing the risk of anaemia and nervous system issues. This recommendation aligns with existing guidance for vegans and is based on updated 2023 Nordic

Nutrition Recommendations, which highlight a greater need for B12. Additionally, Denmark suggests choosing sourdough or long-fermented bread and soaking grains before baking to enhance the absorption of iron, zinc, and calcium, nutrients that can be harder to obtain on a plant-based diet.

In addition to the new B12 recommendations, vegetarians and vegans are also advised to choose oils and foods rich in omega-3 fatty acids.

## France

### ANSES warns against Garcinia Cambogia due to health risks

The French Agency for Food, Environmental and Occupational Health Safety (ANSES) has issued a warning against the consumption of food supplements containing *Garcinia cambogia* and its preparations. This decision follows a review initiated by ANSES in 2020, examining the risks associated with the plant.

Although *Garcinia cambogia* is used in weight loss supplements, its slimming claims have not been authorised at the European level. ANSES' assessment highlighted reports of liver damage and other serious health issues, leading to the advice against its use, especially in individuals with certain health conditions like psychiatric disorders, cardiometabolic diseases, or those on liver-affecting medications.

In addition, ANSES has highlighted that the European Food Safety Authority (EFSA) is currently assessing the risks of hydroxycitric acid and related plant preparations, which include *Garcinia cambogia*. This ongoing evaluation aims to characterise the risks linked to the consumption of such plants. The agency has also criticised the regulatory ambiguity surrounding the pending health claims of *Garcinia cambogia*, noting that they are neither explicitly authorised nor prohibited.

ANSES finally warns that weight loss without medical advice can be risky, especially when it involves unbalanced and poorly diversified dietary practices. According to ANSES, any weight loss approach should be guided by a healthcare professional.

## France pauses national update for vitamin and mineral maximum levels, awaiting EU decision

The French General Directorate for Food (DGAL) has announced a temporary halt to its planned update of the national nutrient decree for food supplements. France has clarified that they will only resume work on updating national nutrient levels if EU-level harmonisation efforts fail and no agreement appears feasible in the short term.

## The Netherlands

### Dutch government moves to ban Ashwagandha

Following a critical advisory issued by the Dutch National Institute for Public Health and the Environment (RIVM) in March 2024, which highlighted the potential health risks of Ashwagandha including liver damage and its historical use in inducing abortions, the Dutch government is advancing draft regulations to ban Ashwagandha and other botanicals mentioned in the RIVM's recommendations.

## Norway

### Report on Food Additives: A Closer look at gastrointestinal safety remains inconclusive

The Norwegian Scientific Committee for Food and the Environment (VKM) published an updated scoping review on 11 March 2025, evaluating the gastrointestinal effects of specific emulsifiers, stabilisers, and thickeners such as agar (E 406), sodium alginate (E 401), carrageenan (E 407), processed Eucheuma seaweed (E 407a), sodium carboxymethyl cellulose (E 466), guar gum (E 412), and xanthan gum (E 415). Building upon a 2023 report, VKM included additional studies, bringing the total to 21. Despite the inclusion of additional studies, the findings have not changed significantly. The evidence remains scant, primarily from studies with potential systematic errors, and none sufficiently long to assess long-term impacts in humans. As a result, the report concludes that the evidence is too weak to reliably assess the risk of negative effects on the human gastrointestinal tract from these substances.

## Romania

### Romania releases consolidated list of botanicals for supplements

The Romanian Ministry of Health has released a new consolidated list of botanicals approved for food supplements, bringing data from 2022, 2023, and recent 2024 evaluations into one document.

The list includes essential details such as ingredient codes, validation status, updated botanical names, and specific usage warnings. Notably, four species – *Anchusa officinalis* L. (herba), *Bambusa bambos* (L.) Voss (herba, stipites), *Cordyceps militaris* (L.) Fr. (sporophorum), and *Paecilomyces* spp. (sporophorum) – have been removed and classified as novel foods.

## UK

### Nutrition & Health Claims Register: Update

The UK Department of Health and Social Care has released an updated version of the Great Britain nutrition and health claims (NHC) register as of 27 February 2025. This updated register, applicable to England, Scotland, and Wales, includes two separate Excel documents detailing authorised and non-authorised health and nutrition claims. Notably, it also incorporates health claims based on proprietary data that were retained post-Brexit. The register will continue to be updated, with improvements to its format anticipated.

### Greenlight for CBD isolate: Safe at 10 mg, with caution

The Food Standards Agency (FSA) and Food Standards Scotland (FSS) have assessed CBD isolate (RP349) and deemed it safe for use in food supplements and various food categories under specific conditions. CBD isolate, a highly purified form of cannabidiol ( $\geq 98\%$  purity), is classified as a novel food. Despite its availability, no CBD product had received full authorisation before this assessment. Following consultation, the maximum daily intake was set at 10 mg for a healthy adult. The assessment confirmed this level is safe but advised against use by vulnerable groups, including children, the immunosuppressed and those on medication, due to data gaps.

The FSA and FSS concluded that CBD isolate poses no nutritional risk under

the proposed conditions. However, clear labelling is recommended to prevent exceeding the 10 mg daily limit and to warn vulnerable groups.



## Argentina

### Argentina eases import rules

Argentina will allow food products, packaging, and food-contact materials certified by countries with high sanitary standards – or covered by trade agreements – to enter the market even if they don't comply with local regulations. Imports will require an Import Affidavit with a marketing authorisation or free sale certificate from the country of origin. Recognised countries include Australia, Canada, the EU, Israel, Japan, Switzerland, the UK, and the USA.

### Argentina proposes Euglena gracilis Algae as a new ingredient for supplements

The National Commission of Foods (CONAL) has launched a public consultation regarding the inclusion of *Euglena gracilis* algae as a permitted ingredient in dietary supplements. This proposal aims to amend Article 1417 of the Argentine Food Code, allowing the use of *Euglena gracilis* algae powder only in dietary supplements. The draft regulation outlines specific requirements for its use, including maximum permissible levels for metals such as cadmium, inorganic arsenic, mercury, and lead.

## Peru

### Ministry of Health advises against erythrosine consumption

The Ministry of Health has issued a press release advising the public to avoid erythrosine and to carefully read food and beverage labels, following the recent ban on the colour by the US Food and Drug Administration (FDA). The Ministry recommends that parents steer clear of red food colouring number 3 (erythrosine) due to its health risks. This recommendation comes in

response to the FDA's decision to prohibit the use of the colour because of its potential link to cancer. The Ministry further highlights that this colourant is predominantly used in medicines and various food products.



## USA

### HHS Secretary directs FDA to review GRAS pathway

HHS Secretary Robert F. Kennedy Jr. has directed the acting FDA Commissioner to explore revising the GRAS Final Rule to eliminate the self-affirmed GRAS pathway, which currently allows companies to introduce new food ingredients without notifying the FDA. This move according to Secretary Kennedy aims to close a loophole that permits the use of “new ingredients and chemicals often with unknown safety data” into the U.S. food supply “without notification to the FDA or the public”. The proposed changes would require companies to publicly submit safety data to the FDA before using new ingredients.

### FDA revokes use of FD&C Red No. 3

The FDA is revoking the authorisation of the colour additive FD&C Red No. 3 in food and ingested drugs under the Delaney Clause of the Federal Food, Drug, and Cosmetic Act. This decision follows a 2022 petition citing studies showing cancer in male rats exposed to high levels of the dye. While the cancer-causing mechanism does not occur in humans and human exposure levels are much lower, the clause mandates prohibition for additives linked to cancer in animals or humans. FD&C Red No. 3, used in supplements, candies, baked goods, and certain medications, will be phased out by 2027 for food and 2028 for drugs. U.S. imports must comply with domestic regulations.



## Australia

### ew TGA guidelines for probiotics

The Therapeutic Goods Administration (TGA) has introduced the Guidelines for the Quality of Listed Probiotic Medicines to support sponsors and manufacturers in adhering to the technical, scientific, and regulatory requirements under the Therapeutic Goods Act 1989. These guidelines aim to ensure that probiotic medicines listed on the Australian Register of Therapeutic Goods (ARTG) meet acceptable quality standards, thereby protecting public health.

The guidelines apply specifically to listed probiotic medicines (AUST L or L(A)) containing live microorganisms designed to provide health benefits. They explicitly exclude products featuring inactivated microorganisms, known as postbiotics, or probiotic foods. The document places significant emphasis on controlling key quality parameters essential for maintaining the safety and efficacy of probiotic medicines.

Critical areas of focus include the composition of products, the strength and potency of probiotic strains, and stability. Additionally, the guidelines address purity and bioburden, requiring stringent measures to prevent the presence of contaminant microorganisms.

### TGA removes requirement for excipients and stabilisers on probiotics labels

TGA has updated Table 6 of the probiotics quality guidelines, removing the expectation to list excipients and stabilisers on labels of probiotics conforming to Ph. Eur./BP 3053. However, TGO 92 requirements, including allergen declarations, still apply.



## EAEU

### Introduction of ID tagging for e-commerce

The Eurasian Economic Commission is stepping up its e-commerce regulations with a new requirement for ID tagging on all goods sold online that are eligible for returns. Announced on 30 September 2024 under resolution No. 75, this move aims to boost traceability and consumer protection across the region.

From now on, e-commerce operators must assign an ID code – a 20-character identifier made up of numbers, Latin letters, or barcodes – to every product or its packaging. QR codes from the 2018 EAEU ID Tagging Agreement or batch numbers can also be used. Importantly, all codes must be registered in the operator’s information system, ensuring full traceability.

The requirement will take effect once the Protocol Amending the Treaty on the EAEU Customs Code (2017), signed on 25 December 2023, is enacted. Russia ratified the Protocol in August 2024, but implementation depends on other Member States completing ratification.

### Unified reference list of plant genera and species

The Eurasian Economic Commission (EEC) has introduced a unified reference list of plant genera and species (attached). The list is available in both Russian and Latin. Effective from 26 January 2025, it serves as a tool for ensuring consistency and compliance across the Eurasian market.

## Mongolia

### Mongolia introduces functional foods with modulating action

Mongolia's Parliament is reviewing amendments to its 2012 Food Law, introducing a new category called "foods with modulating action," which aligns with the concept of functional foods. These products are designed to support specific organ and system functions, contain beneficial nutrients or live microorganisms, and promote health without medicinal effects or side effects. The proposed regulations require clear labelling, including a modulating function symbol and safety information, as well as a formal process for declaring biological activity and nutrient content. To prevent misleading claims, product labels and advertisements will be prohibited from mentioning disease diagnosis, treatment, or cure. If passed, the amendments are expected to take effect in 2025.

## Russia

### Russia rolls out next phase of supplement ID Tagging

As of 1 November 2024, Russia has implemented the next stage of dietary supplement ID tagging under government decree No. 1944 (21 November 2023). Retailers are now required to verify each purchase at the point of sale by scanning the Authentic Mark QR code. This process confirms ID accuracy, market status, bans or suspensions, expiration dates, and ensures the product hasn't been previously withdrawn.

Non-compliance by retailers can result in fines of RUB 50,000-100,000 (approximately 500-1000 USD), as per article 15.12.1 of the Code of Administrative Offences.

In parallel, the Ministry of Industry and Trade is analysing the dietary supplement market across the Russian region. This initiative supports the Strategy for Combating Illegal Trade in Industrial Goods until 2025 to enhance regulatory enforcement and market transparency.

## Rules for prescribed supplements

Russia is drafting new rules to allow doctors to prescribe dietary supplements for disease prevention, with implementation targeted for 1 September 2025. This supports amendments (No. 638771-8) to federal laws, now moving through parliament, with a second reading scheduled for early 2025.

Key provisions in the draft rules include:

- Empowering the government to establish quality criteria for dietary supplements.
- Allowing doctors to prescribe supplements for specific population groups to prevent diseases.

A related draft by-law tasks the Ministry of Health with developing:

- A list of dietary supplements (active substances) eligible for prescription.
- A list of diseases, conditions, and risk factors for which supplements may be prescribed.

The draft does not specify how frequently these lists should be updated or a timeline for considering new additions.

Despite parliamentary debate, the proposal aims to position supplements as a formal tool in health promotion and disease prevention.

### Certain PET packaging banned for supplements

Effective 1 September 2025, Russia will prohibit specific PET packaging types under resolution No. 2827-r. The ban covers PET bottles in colours other than blue, white, green, brown, and clear; multilayer PET bottles; and PET packaging with polyvinyl chloride labels (shrink sleeve labels exempted). The Ministry of Industry and Trade will update the list annually by 1 September.

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