IADSA NEWSFLASH

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Regulatory news

China

National Centre for Food Safety Risk Assessment confirms the safety of Titanium Dioxide

A recent study by the Chinese National Centre for Food Safety Risk Assessment confirms that food-grade titanium dioxide (TiO2), also known as INS171, is safe for use as a food additive, and poses no genotoxic risks. This research directly responds to concerns raised by the European Food Safety Authority's (EFSA) 2021 opinion on the potential risks of INS171. Conducted following the Organisation for Economic Co-operation and Development (OECD) guidelines for chemical testing, the study adds to the growing body of evidence supporting the safety of the additive.

India

FSSAI sets recommendations for e-commerce

The Food Safety and Standards Authority of India (FSSAI) has issued an advisory to e-commerce food business operators (FBOs) to strengthen the food safety ecosystem and address fraudulent practices.

Key highlights of the advisory include training for last-mile delivery personnel on food safety and hygiene practices, adherence to minimum shelf life requirements (30% of shelf life remaining or 45 days before expiry at the time of delivery), and ensuring that all product claims online match the information provided on packaging to prevent the dissemination of misleading and unsupported claims. E-commerce platforms are also required to display the FSSAI licence or registration numbers and seller hygiene ratings prominently, ensuring only sellers with valid FSSAI authorisations are listed.

Japan

Japan to strengthen rules for tablets and capsules

Japan's Consumer Affairs Agency (CAA) has proposed new draft Guidelines for tablet and capsule food/supplements containing microbial-related materials, such as algae derived through cultivation or fermentation, following safety concerns linked earlier this year to red yeast rice products. The guidelines require detailed product specification documents to ensure manufacturing oversight and compliance. However, products made with traditionally food-based microbial materials may be exempt, provided they are produced in controlled environments, used in limited quantities, and have proper distribution records.

EU

EFSA draft proposes safe fluoride intake levels

The European Food Safety Authority (EFSA) has launched a public consultation on its draft risk assessment of fluoride exposure from drinking water, diet (including food supplements), fluoridated table salt, and ingested fluoridated dental care products. The assessment proposes a safe level of intake of 3.3 mg/day for pregnant women, applicable to individuals aged 9 years and above. This recommendation is based on evidence suggesting that potential effects on fetal central nervous system development may occur at or above drinking water fluoride concentrations of 1.5 mg/L, the legal limit in the European Union. Most European drinking water supplies, however, have fluoride concentrations well below this level, typically under 0.3 mg/L. For younger age groups, the draft outlines tolerable upper intake levels (ULs) to minimise the risk of dental fluorosis: 1 mg/day for infants (0–12 months) 1.6 mg/day for children (1–3 years) 2 mg/day for children (4–8 years)

This draft assessment results from a comprehensive review of the scientific

literature, analysing 152 human studies and 81 animal studies from over 20,000 papers published between 2005 and 2024.

Currently, the following sources of fluoride are authorised for use in food supplements in the European Union: calcium fluoride, potassium fluoride, sodium fluoride, and sodium monofluorophosphate. While no EU-wide maximum fluoride levels have been established for food supplements or fortified foods, past assessments by EFSA's Panel on Food Additives and Nutrient Sources Added to Food (ANS) evaluated fluoride levels ranging from 0.5–2 mg/day for children and adults.

EU reduces control frequency for Indian botanical food supplements

Since January 2022, food supplements containing botanicals from India have been subject to increased official controls on entry into the European Union due to the risk of ethylene oxide contamination, which is not authorised in the EU. Recent assessments by Member States indicate improved compliance with EU provisions.

The European Commission has therefore announced a reduction in control frequency from 20% to 10% of consignments entering the EU, as outlined in Annex II of Implementing Regulation (EU) 2019/1793. Additionally, guar gum from India, when used as a raw material for food supplements, is no longer subject to these controls following its removal from Annex I of the regulation by Implementing Regulation (EU) 2024/1662.

EU delays enforcement date for MOH regulation

The Member States Expert Group met to discuss regulations related to mineral oil hydrocarbons (MOH) in the EU. While key decisions are still pending, a significant outcome of the meeting was the postponement of the enforcement date for MOH regulations to 1 January 2027. However, Member States were unable to reach an agreement on the draft European Commission regulation, meaning further discussions will need to take place. Current proposals maintain a limit of MOAH at 10.0 mg/kg starting from 1 January *2027 (instead of 2026),* reducing to 5.0 mg/kg from 1 January 2030 for supplements.

EFSA gives its green light to quillaia extract (E 999) in supplements

The European Food Safety Authority (EFSA) has updated its evaluation of quillaia extract (E 999), focusing on extending its use in food supplements (both solid and liquid forms), excluding those for infants and young children. In 2019, EFSA set an acceptable daily intake (ADI) for quillaia extract at 3 mg of saponins per kilogram of body weight. In its 2024 review, EFSA recommended changes to the EU specifications for E999 while confirming its safety at current and proposed usage levels. Quillaia extract is currently approved for use in flavoured drinks and cider/perry. Its use in food supplements is now being considering with the following proposed maximum levels:

- Food Category 17.1 (Solid food supplements): 4000 mg/kg (dried basis), 3336 mg/kg as saponins.
- Food Category 17.2 (Liquid food supplements): 4000 mg/L (dried basis), 3336 mg/L as saponins.

EFSA concluded that, at these proposed levels and if authorised, the exposure to quillaia extract would not exceed the ADI, ensuring its safe use for all consumers.

The European Court of Auditors calls on the Commission to address botanical claims by 2027

In its report published on 25 November 2024, the European Court of Auditors (ECA) has highlighted significant gaps in the regulatory framework governing the labelling of food products. Among the issues identified is the long-standing lack of an authorised list of health claims for botanicals. It also highlights examples of weak checks on nutrition and health claims and stresses that during its 2018 audit in Belgium, the Commission pointed out that the authorities do not fully cover rules on nutrition and health claims. The European Court of Auditors has called on the European Commission to urgently address this issue by 2027. While the report is not legally binding, it adds to growing pressure on the Commission. It follows a European Parliament Resolution, which also called for a swift reassessment of pending botanical claims. The Parliament further emphasised the need to exclude claims that have already received negative opinions from EFSA (European Food Safety Authority).

The ECA report also addresses the surge in e-commerce sales of food products across the EU since the COVID-19 pandemic. This rapid growth has been accompanied by an increase in consumer complaints regarding online stores. In Lithuania, a high infringement rate of 61.6% for food products sold online in 2022 was reported —significantly exceeding non-compliance rates in traditional retail. The report therefore suggests that e-commerce may pose a higher risk of exposing consumers to misleading and potentially unsafe products. Food supplements, sold via e-commerce platforms and social media, were highlighted as a particularly problematic area. The report noted that these products are frequently sold through networks of small independent sellers.

The report also emphasises the difficulties that authorities face in controlling online retail through websites based outside the EU. In such cases, authorities may contact the operator directly or request follow-up action via the embassy of the third country where the operator is based. However, these approaches are often slow and ineffective.

The European Court of Auditor recommends that the Commission encourage Member States to strengthen their checks on voluntary labels and the online retail sector by 2027. This should involve the Commission providing clear guidance and sharing examples of good practice.

EFSA update on substances reviewed under Article 8 procedure

The European Food Safety Authority EFSA has released the minutes of its 20-21 November 2024 Working Group meeting, focusing on safety assessments under the Article 8 procedure. Discussions covered the genotoxicity of Berberine (EFSA-Q-2022-00803), including risk of bias in animal studies and updates on *Hydrastis canadensis L.* and *Chelidonium majus*. For Fennel (EFSA-Q-2022-00804), estragole exposure assessments and potential modelling scenarios were reviewed. The group also discussed monacolins from red yeast rice (EFSA-Q-2023-00424), integrating new data for a draft opinion set for further review.

EFSA launches interactive DRV finder tool

The European Food Safety Authority (EFSA) has launched the DRV Finder, an interactive tool designed to provide quick and easy access to EFSA's Dietary Reference Values (DRVs) for nutrients. The tool is primarily for risk managers, policy-makers, food manufacturers, and scientists, who rely on these values in their work.

EU authorises Magnesium L-Threonate as a Novel Food ingredient

The European Commission has officially authorised magnesium L-threonate as a novel food ingredient, following a positive safety assessment by the European Food Safety Authority (EFSA) in March 2024. Effective from 7 November 2024, this authorisation grants data protection until 2029, permitting its use in food supplements for adults at a maximum daily dose of 250 mg, excluding pregnant and lactating women. In line with regulatory requirements, this mineral source must be added to Annex II of Directive 2002/46/EC before it can be used in food supplements.

EFSA updates guidance on tolerable upper intake levels for vitamins and minerals

The European Food Safety Authority (EFSA) has released updated guidance on tolerable upper intake levels (ULs) for vitamins and minerals, providing a foundation for setting harmonised maximum levels in food supplements and fortified foods. This revised framework, developed by the EFSA Panel on Nutrition, Novel Foods and Food Allergens, provides an updated framework for UL assessments. Following a two-year pilot phase, the guidance incorporates practical insights and addresses key aspects of risk assessment, including uncertainty analysis.

EFSA confirms safety of saccharin

The European Food Safety Authority (EFSA) has updated its safety assessment of the sweetener saccharin increasing the acceptable daily intake (ADI) from 5 mg/kg to 9 mg/kg of body weight. The review confirmed that saccharin poses no cancer risk or DNA damage to humans, with consumer exposure remaining below the new ADI. This re-evaluation is part of the EFSA's task reviewing all food additives authorised before 2009 under EU regulations.

EU clarifies: Vitamin, mineral and probiotic supplements cannot be labelled as organic

The European Commission's Directorate-General for Agriculture and Rural Development has provided clarification on whether food supplements can be organic. The clarification confirms that only food supplements made from agricultural ingredients fall within the scope of Regulation (EU) 2018/848 and can be labelled as organic. Supplements composed of vitamins, minerals, or mainly of microorganisms (excluding certain yeasts) are not eligible for organic labelling.

Microorganisms used as probiotics are not considered agricultural ingredients under EU organic rules, meaning products primarily composed of them cannot carry the organic label. Additionally, the Commission reiterated that no health claim for "probiotics" is currently authorised under the Claims Regulation (EC) No 1924/2006.

EFSA confirms the safety of silicon dioxide as a food additive

The European Food Safety Authority (EFSA) has reaffirmed the safety of silicon dioxide (E551) as a food additive for all age groups. This long-awaited opinion provides important reassurance following months of industry concerns. In light of the recent ban on titanium dioxide in the EU, uncertainty had grown over the outcome of EFSA's delayed opinion, making this announcement very welcome. The confirmation of silicon dioxide's safety is significant, especially as the focus now shifts to the upcoming re-evaluation of the additive by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). With silicon dioxide now a priority for JECFA, a call for data is expected to support this global assessment.

Czech Republic

Czech Republic updates supplement rules to align with EU

The Ministry of Agriculture has updated Decree no. 58/2018 sb. on food supplements and food composition, aiming to harmonise it with EU regulations.
The new law tightens restrictions on what can and can't be included in food supplements. Substances with toxic, genotoxic or hallucinogenic effects, as well as narcotics, psychotropics, and anabolic agents, are now explicitly banned. The update includes recent European Commission regulations that permit the use of ferric hydroxide-adipate-tartrate, nicotinamide riboside chloride, magnesium citrate-malate, and calcium phosphoryl oligosaccharides in supplements. Several sections of the Decree have been rephrased for precision and consistency. The decree also introduces revised lists of approved substances.

The General Court overturns EU ban on products containing hydroxyanthracene derivatives

The General Court of the European Union has overturned the EU regulation which banned products containing hydroxyanthracene derivatives (HADs) under the so-called Article 8 procedure.

The Court found that the European Commission had not provided sufficient scientific evidence to justify a blanket ban on HADs.

This decision could have significant implications for EU policy under Article 8, especially as other botanical ingredients come under increasing national scrutiny.

Article 8 of Regulation No 1925/2006 allows the Commission, either at the request of Member States or on its on own initiative, to scrutinise, restrict, and, if necessary, prohibit the use of substances added to foods or used in food manufacturing when their consumption could result in the ingestion of amounts greatly exceeding those reasonably expected.

In 2016, the European Commission asked the European Food Safety Authority (EFSA) to assess the safety of HADs, compounds present in Aloe leaves and other botanicals known for their laxative properties. EFSA's 2017 opinion suggested a potential risk of genotoxicity and carcinogenicity, though insufficient data prevented EFSA from establishing a safe daily intake level.

The General Court has now ruled against the blanket ban on

preparations from the leaf of Aloe species containing hydroxyanthracene derivatives, aloe-emodin and all preparations, emodin and all preparations, due to several key considerations:

- Lack of safe intake threshold: EFSA did not establish a safe intake level for HADs. Without a defined threshold, the ban lacked the scientific basis required by Article 8.

- Need for consumption data and burden of proof: Article 8 specifies that bans should be supported by data on the quantity of the substance that can be consumed through a balanced and varied diet, or on the levels reasonably expected to be ingested under normal dietary conditions. Without such data, food business operators—responsible for ensuring product safety—cannot effectively compare the amounts typically consumed with the quantities that may result from the use of the substance in concentrated form.

- Differentiation between preparations and substances: The Court clarified that only individual 'substances' or 'ingredients' can be listed in Part A or Part C of Annex III of Regulation No 1925/2006 —not broad plant preparations or whole foods, which have a wider scope than individual substances.

Denmark

Denmark expands permitted substances

Denmark has recently published an amendment to its national regulation on the addition of substances other than vitamins and minerals to foods, including food supplements (BEK nr 1319 af 28/11/2024). The update expands the list of permitted substances under Annex I, allowing their use in food supplements with defined maximum daily intake levels: Chlorophyllins (200 mg/day), L-Arginine Hydrochloride (1125 mg/day), and Lecithins (1200 mg/day).

Danish Authority warns of harmful supplements & urges notification database check before purchase

The Danish Veterinary and Food Administration has issued a warning about the food supplement Ginseng Kianpi Pil, which has been linked to liver damage. The supplement contains Polygomum multiflorum Thunb, a root identified as harmful by the DTU Food Institute in 2018. Consumers who have taken this supplement have reported serious liver effects.

The sale of Ginseng Kianpi Pil was stopped after discovering it was marketed online on a second hand market place (Den Blå Avis). The supplement also contains undeclared medicinal substances: dexamethasone and cyproheptadine. Dexamethasone, a steroid, can cause weakened immunity, high blood sugar, muscle issues, and mental health problems, while cyproheptadine, an antihistamine, can be sedative. Both pose severe risks, especially when combined with other medications. The Danish authorities urge consumers to avoid purchasing supplements from unofficial sources and to use the Food Supplement National Register to verify if the food supplement has been notified for marketing in Denmark.

France

ANSES proposes measures to prevent neural tube defects through folate supplementation

The French National Agency for Food, Environmental and Occupational Health Safety (ANSES) has released updated recommendations to combat neural tube defects (NTDs). It proposes fortifying flours with 200 µg of folic acid per 100 g to address insufficient maternal folate levels—a critical risk factor for NTDs. However, the agency highlights that this value excludes potential losses from cooking or food storage. Further research is needed to refine fortification levels by accounting for such losses during processing.

ANSES also emphasises the importance of collaboration at the European level. It urges that the proposed enrichment levels be presented to the European Working Group on Food Supplements and Vitamin and Mineral Addition to align national measures with broader EU strategies.

Additionally, ANSES calls for increased awareness among health professionals and women of childbearing age about the role of folate in NTD prevention. It highlights the importance of a folate-rich diet, including legumes and leafy vegetables, alongside periconceptional folic acid supplementation where necessary.

France aims to redefine vitamin limits

In response to a request from the Directorate General for Food (DGAL), ANSES (French Agency for Food, Environment, and Occupational Health and Safety) has published a new expert opinion on the update of the Decree of 9 May 2006, which regulates nutrients permitted in the manufacture of food supplements.

The updated opinion considers two key perspectives. From a nutritional standpoint, food supplements meant to complement the diet are only beneficial when there is an identified nutritional or physiological need that cannot be met by the regular diet. In this context, the Maximum Daily Intake is set to enable individuals with deficiencies to meet their nutritional requirements without exceeding the population's recommended reference intake, where available. The second perspective is toxicological, emphasising that the consumption of food supplements is acceptable as long as it does not lead consumers to exceed the upper safety limits (ULs), when these are defined.

The opinion highlights that certain nutrients, particularly vitamins A, D, and E, and folic acid, as well as minerals like calcium, copper, iodine, and molybdenum, are unlikely to cause excess intake in most population groups. However, concerns were raised about exceeding ULs for other nutrients, especially in children.

Regarding vitamin C, while the new proposal aims to raise the allowable level from 180 mg to 1,000 mg, the expert committee raised concerns, stressing that the safety of such high intakes cannot be adequately assessed. Instead, they recommend setting a more cautious limit at 208 mg, based on the 95th percentile of observed consumption. For vitamin B6, although the proposal seeks to increase the level from 2 mg to 12 mg, the expert committee advises a lower threshold, recommending that the limit should not exceed 9.4 mg, as

detailed in the table on page 15 of the opinion.

ANSES also advises against the use of food supplements for children under 3 without medical supervision, due to the risk of overconsumption.

New warning statements on labels are recommended for smokers (ß-carotene) and those on anticoagulant treatment (vitamins K and E), along with specific advice for pregnant women regarding folic acid.

France's national proposal adds complexity to EU harmonisation of vitamin and mineral limits

The European Commission has been seeking to advance its long-debated discussions with Member States on harmonising maximum levels for vitamins and minerals in food supplements. However, insufficient representation of Member States during the November meeting didn't allow the Commission to gain sufficient support and move forward. With a follow-up meeting now delayed until February and the call for evidence pushed to a date certainly beyond March, questions arise about the future direction the Commisson may take.

Recent developments in France have added to the complexity of the discussion. The French Ministry responsible for food supplements (DGAL) has released a draft amendment to its national food supplements legislation, which aligns with the maximum levels proposed by the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) in its recent opinion (saisine n° 2023-SA-0165).

These proposed maximum levels for vitamins and minerals are significantly lower than current levels in France, creating potential conflicts with the broader EU harmonisation project. These proposed limits are set to take effect seven months after the amendment's publication, with a transition period extending until 30 June 2026 for non-compliant products under the new provisions. This approach and timeline appears to stand in direct contradiction to the broader goals of EU harmonisation.

The Netherlands

Risks of NAC in food supplements

The Dutch National Institute for Public Health and the Environment (RIVM) has put food supplements containing N-acetylcysteine (NAC), L-cysteine, and L-cystine under review. Widely marketed for their detoxification benefits, these substances are now facing scrutiny after the Dutch Ministry of Health, Welfare and Sport requested an evaluation of their safety.

The review set a safe intake limit of 13 mg per kilogram of body weight per day for L-cysteine, equivalent to 900 mg/day for adults (or 1200 mg/day NAC) and lower doses for children. The review concluded that while supplements within these limits are generally considered safe, exceeding them could lead to gastrointestinal distress or other side effects. For children under two, NAC is deemed unsafe, aligning with its contraindication in medicinal use. A key warning in the report advises against combining NAC-containing medicines with supplements, as this can result in high exposure levels.

RIVM report highlights need for updated regulations on micronutrients

The National Institute for Public Health and the Environment (RIVM) has published a report "Addition of Micronutrients to Foods and Food Supplements: Review of the Legislation in the Netherlands." Commissioned by the Ministry of Health, Welfare, and Sport, the report examines current nutrient regulations in the light of new scientific findings.

The findings primarily address fortified foods, but also include recommendations for food supplements. One key conclusion is that a ban on the addition of selenium to food is not necessary. The report suggests that there is room for safe additional intake of selenium before reaching the established Upper Limit (UL), and this gap could be allocated between fortified foods and supplements. The report also notes that while maximum limits have been set for certain micronutrients in fortified foods, no such limits exist for food supplements. It suggests the establishment of maximum levels for both fortified foods and supplements. However, for certain micronutrients—including boron, biotin, silicon, pantothenic acid, manganese, chromium, chloride, and molybdenum—it is not currently possible to set these limits based on available data regarding typical intake in the Netherlands.

Furthermore, the report stresses the importance of considering the different chemical forms of micronutrients, as these forms can vary in bioavailability. To accurately calculate total intake and make sound evaluations, it is essential to know the specific chemical forms and quantities of micronutrients added to foods and supplements.

Germany

New BfR podcast explores the risks of melatonin supplements

The Federal Institute for Risk Assessment (BfR) has released a new episode of its science podcast, "Risiko," which examines the effects and potential risks of melatonin in food supplements. Titled "Gentle Sleep Aid?" the episode from Dr. Britta Nagl discusses the scientific background and health implications of melatonin products, which are widely marketed for sleep problems. Melatonin is a hormone that regulates the body's sleep-wake cycle, and while it is used in prescription medications for specific sleep disorders, its presence in over-the-counter supplements raises concerns according to BfR. Dr. Nagl emphasises that melatonin should not be viewed as a "gentle sleep aid."

"In drug studies, undesirable side effects are often observed such as fatigue, headaches, and reduced attention or ability to react especially on the following day " explains Dr. Nagl. "This is something to be aware of when operating machinery or driving a car, for example."
The podcast highlights that many melatonin-containing food supplements, including capsules, drops, sprays and gummy bears, often contain doses significantly higher than those found in prescription medications. In addition, it highlights the potential risks of these higher doses, especially their capacity to disrupt the body's hormonal balance and sleep-wake rhythm.

It also warns that melatonin can also interact with various medications, such as antibiotics, antidepressants, and oestrogen. Vulnerable groups—including children, adolescents, pregnant or breastfeeding women, and individuals with pre-existing

conditions—are particularly advised to avoid uncontrolled use of melatonin supplements.

Norway

Norway consults on new limits for other substances

Norway has opened a public consultation on proposed changes to its regulation on adding vitamins, minerals, and other substances to foods. New limits for "other substances" in supplements include hesperidin (60 mg/day for adults), quercetin dihydrate (500 mg/day for adults), and rutin (25 mg/day for adults; 5 mg/day for children aged 3-11).

Poland

Revision of provisions for supplements

The Polish Chief Sanitary Inspector (GIS) has introduced a series of resolutions aimed at refining the regulatory framework for food supplements.

1. Ban on Chelidonium majus L. in food supplements
Resolution No. 1/2024 adds Chelidonium majus L. (greater celandine)

2. New limits for vitamin B6:
Resolution No. 2/2024 reduces the maximum daily dose of vitamin B6 for adults in food supplements from 18 mg to 6 mg. The decision takes into consideration the dietary intake assessments and EFSA's tolerable upper intake levels.

3. Conditions for Bacopa monnieri:
Resolution No. 4/2024 defines conditions for using Bacopa monnieri herb preparations in food supplements.

- Up to 5 g of dried herb (≤2.5% bacosides) per daily portion.
- Up to 200 mg of extract (≤100 mg bacosides) per daily portion.

Labels must warn against use by children, pregnant or breastfeeding women, and recommend a usage period of no more than four weeks.

4. Rules for Passiflora incarnata:
Preparations Resolution No. 5/2024 sets conditions for Passiflora incarnata preparations, limiting powdered herb use to 0.5 g daily. Labels must warn against use by children, pregnant or lactating women, prolonged use beyond 12 weeks, and combining with central nervous system-affecting substances. Warnings about drowsiness and impaired ability to drive or operate machinery are also required.

UK

COT highlights potential risks of curcumin supplements

The UK Committee on Toxicity (COT) has identified potential health risks associated with turmeric and curcumin supplements, particularly when consumed in high doses. While dietary consumption of turmeric and curcumin as food additives or spices is generally within safe limits, supplements may occasionally lead to levels exceeding the acceptable daily intake (ADI), particularly formulations designed to enhance bioavailability.

The Committee reviewed reports of hepatotoxicity linked to turmeric consumption and concluded there is reasonable evidence of a connection, with cases typically resolving after stopping consumption. These incidents are consistent with rare idiosyncratic reactions, which may affect genetically susceptible individuals, even at doses below the ADI. Contaminants, such as heavy metals, were ruled out as the likely cause of these effects.

COT also highlighted concerns over novel supplement formulations, including micellar and nano-curcumin, which may alter curcumin's bioavailability and toxicity profile. Further research is needed to better understand the risks associated with these products.

COT emphasised potential risks for individuals with altered hepato-biliary functions or those on medications.

UK Committee on Toxicity evaluates safety of raspberry leaf

The UK Committee on Toxicity (COT) has issued a statement addressing the potential health effects of raspberry leaf, a supplement or tea traditionally consumed during pregnancy to stimulate labour and potentially shorten its duration.

Recognising the widespread use of raspberry leaf, the Scientific Advisory Committee on Nutrition (SACN) commissioned COT to review herbal supplements commonly used by pregnant individuals. The review focused exclusively on products regulated under food law, excluding those overseen by the Medicines and Healthcare products Regulatory Agency (MHRA). Raspberry leaf was identified as a priority for further investigation.

COT's assessment revealed a nuanced picture. While the overall risk associated with raspberry leaf consumption appears low, critical uncertainties remain. These include insufficient data on its active components, varying effects depending on preparation methods, and limited understanding of its pharmacokinetics and toxicity.
The Committee highlighted that combined daily intake of raspberry leaf—whether from tea alone (up to 10 g) or from a combination of tea, tinctures, and capsules (up to 12.4 g)—can exceed the doses tested in randomised controlled trials by up to four times, raising concerns about the safety of higher consumption levels during pregnancy.

Given these uncertainties, COT was unable to establish a health-based guidance value for raspberry leaf use.

EFSA and UK COT align on green tea safety

The UK Committee on Toxicity (COT) has confirmed the European Food Safety Authority's (EFSA) 2018 conclusion that doses of up to 800 mg/day of EGCG, a primary green tea catechin, are "probably safe" for most individuals.

Following reports of rare liver damage linked to concentrated green tea extracts, COT conducted a thorough review. While traditional green tea infusions remain safe, it concluded that concentrated extracts, particularly at higher doses, may pose risks for susceptible individuals. Although rare, unpredictable idiosyncratic reactions at lower doses are possible, and no new evidence was found to challenge EFSA's assessment.

Romania

Five new botanicals for supplements

The Romanian Ministry of Health has added five new botanicals to its permitted list of food supplements, as outlined in its recent Technical Consultative opinion. The additions

include *Aegle marmelos* (seed), *Geranium macrorrhizum* (herb, root, rhizome), *Handroanthus impetiginosus* (bark), *Platostoma palustre* (herb), and *Rosa roxburghii* (fruit).
This update builds on the 2022 and 2023 consolidated permitted lists.

These lists are maintained under law no. 56 of 2021 which regulates food supplements and law 491/2003 which addresses medicinal, aromatic plants, and beehive products.

Turkey

Botanicals: Updates foreseen

The Turkish Ministry of Agriculture has released draft opinions on six plants to revise the national Plant List, that categorises botanicals as "positive (P)" or "negative (N)" based on their safety. The proposals include adding *Amaranthus caudatus* seed oil and *Artocarpus heterophyllus* fruit (excluding extracts) as positive. While *Berberis aquifolium* and *Berberis vulgaris* fruits remain positive, their roots and bark are recommended for reclassification as negative. Additionally, *Hebanthe erianthos* root and *Peganum harmala* seed are considered as unsafe and proposed for negative classification.

List of permitted substances updated

The Food Supplements Commission has updated its list of substances that can be used in supplements at its 136th meeting.

Argentina

Argentina proposes new ingredients and sweetener for food supplements

The National Commission of Foods (CONAL) has launched a public consultation on two proposals to amend the Argentinean Food Code (CAA) by including two new ingredients for use in food supplements under Article 1417:
Gelatinised maca flour: Allowed exclusively in food supplements, with specifications limiting daily intake to a maximum of 1.5 grams.
Chia gum/chia mucilage: Approved for use in all food products, including food supplements, with specified conditions.

In addition, CONAL proposed approving the use of monk fruit extract as a sweetener for all food products, including food supplements, aligned with the FCC and Schedule 15 of the Australia New Zealand Food Standard Code.

Brazil

AI tool tackling e-commerce advertising irregularities

Brazil's National Agency for Sanitary Surveillance (ANVISA) has unveiled the initial results of its AI tool, EPINET, designed to monitor e-commerce for products under sanitary surveillance. The tool has, according to ANVISA, proven effective in detecting and addressing advertising irregularities.

EPINET automatically searches for potentially non-compliant advertisements, flags them, and sends notifications to websites, requesting the removal of the content. Website administrators must then contact ANVISA to resolve the issues.
Early findings show that 31% of flagged irregularities involve food supplements.

Brazil updates permitted additives for supplements

ANVISA has issued Administrative Order IN 334/2024, updating the list of permitted additives for food supplements. Key changes include the approval of new additives for liquid supplements: ethyl cellulose (INS 462) as a glazing agent (*Quantum satis*, for effervescent products) and carbomer (INS 1210) as a thickener and stabilizer (up to 30,000 mg/kg or mg/L). For solid supplements, fatty acids (INS 570) as a carrier agent (up to 30,000 mg/kg or mg/L), calcium chloride (INS 509) as a firming agent (quantum satis), and carbomer (INS 1210) as a stabiliser and raising agent (up to 200,000 mg/kg or mg/L) were approved. Additionally, for supplements for infants and young children, calcium chloride (INS 509) is permitted as a firming agent (quantum satis). The regulation is effective immediately.

Honduras

Nutritional supplements rules foreseen

Honduras has introduced Agreement 0632-ARSA-2023, setting requirements for sanitary registration, labelling, packaging, and transport for food and nutritional supplements. Nutritional supplements, considered "high-risk", will continue to require pre-market registration, with existing rules integrated into the new regulation. Notably, the registration process for supplements remains unchanged.

Mexico

National Institute of Public Health challenges benefits of supplements in X post

The National Institute of Public Health (INSP) in Mexico has published a statement citing that, in most cases, nutritional supplements do not provide additional benefits beyond those achieved through a healthy diet. This announcement was shared through the X account of the Nutrition and Health Research Center of the INSP, which stated: "I*n most cases, the use of nutritional supplements does not generate a special or greater benefit than what we can get from a healthy diet. Their recommendation usually comes from commercial interests or misinformation. It is better to consume natural foods."*

USA

FDA Updates “healthy” rules

The U.S. Food and Drug Administration (FDA) has finalised a new definition for the nutrient content claim “healthy” in food labelling, addressing diet-related chronic diseases and aligning with current dietary guidelines. This change, according to FDA, aims to help consumers identify foods that support balanced eating patterns and encourage manufacturers to develop healthier options.
To qualify for the “healthy” claim, foods must:

- Contain specific amounts of recommended food groups (e.g. fruits, vegetables, grains, low-fat dairy, or protein foods)
- Meet limits for added sugars, saturated fat, and sodium.

Criteria vary by product type (e.g. single items, mixed products, meals) and are tied to serving sizes based on Reference Amounts Customarily Consumed (RACCs).

Key updates

- Dietary supplements: Must meet the same nutrient and food group requirements as conventional foods.
- Coffees and teas: They qualify if they contain fewer than 5 calories per serving and no added caffeine.
- Dried and powdered fruits/vegetables: Recognised as food group equivalents if they are essentially dried forms of the whole food.
- Existing Labels: Products labelled "healthy" under the prior definition remain compliant if produced before the new compliance date.
- Structure-Function Claims: The term "healthy" can still be used in valid structure function claims.

The FDA is also exploring a front-of-pack symbol to indicate foods that meet the updated "healthy" definition, aiming to simplify consumer choices.

Congress urged FDA to ban Red3

23 members of Congress urged the FDA to ban Red 3 in foods by 3 January 2025. The letter highlights concerns about Red 3 causing cancer in rats and potential neurobehavioral issues in children. California has already banned Red 3 in foods, effective 1 January 2027, and the FDA is reviewing a petition to revoke its use in foods, dietary supplements, and ingested drugs.

New Zealand

Repeal Bill implements a 'lift-and-shift' of the dietary supplements regulations 1985

The New Zealand Parliament passed the Repeal Bill in December, repealing the Therapeutic Products Act 2023. The Bill implements a 'lift-and-shift' of the Dietary Supplements Regulations 1985, transferring them under the Food Act 2014. Key changes include:

- Inserting a clause that provides that the adopted joint food standards do not apply to dietary supplements. Despite this, changes can be made in the future to the Regulations to adopt joint food standards where necessary.
- Offences and penalties under the Food Act 2014 apply to dietary supplements in the same way as for other "food" regulated under the Act.

The 'lift-and-shift' means that all the administrative powers under the Food Act 2014 apply to dietary supplements, including the exemption powers for exported products. Exporters will be able to apply for exemptions from New Zealand labelling and composition requirements to enable them to better compete in international markets

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