IADSA NEWSFLASH

July 2024

Regulatory news

China

Updated regulations for health food with Ginseng, American Ginseng, and Lingzhi

China's State Administration for Market Regulation (SAMR) has updated requirements for health foods containing ginseng, American ginseng, and Lingzhi (Ganoderma), allowing them to obtain market authorisation through filing instead of registration. The regulation covers specific criteria in five areas: auxiliary materials, product dosage forms, product processing, product technical requirements, and other requirements. Furthermore, the regulation stresses compliance with existing standards for functional products and highlights the importance of traceability and provincial oversight.

Simplifying procedures

SAMR, the China State Administration for Market Regulation, has issued a notification simplifying the required documents for registering and filing applications for imported health food. In alignment with the Convention of 5 October 1961 Abolishing the Requirement of Legalisation for Foreign Public Documents, SAMR has decided to relax requirements for various documents, including qualification certifications, marketing and sales certifications, and quality management system certifications of production enterprises. For documents issued by a party to the Convention, only an Apostille of that country is now required. Consular authentication from the country and the Chinese embassy or consulate in the local area is no longer necessary, except for cases explicitly stated as not applicable in the list of contracting parties to the Convention published by the Ministry of Foreign Affairs of China.

Indonesia

New labelling regulation for health supplements

Indonesia's BPOM has issued Regulation No. 10 of 2024, requiring detailed labelling for health supplements. This applies to both local and imported products, mandating information such as product name, business details, ingredients, and usage instructions. Labels must be in Indonesian, except for the product name.

The regulation prohibits labels from featuring images or information related to health workers, religious figures, public officials, or any content offensive to ethnicities, religions, races, or groups. It also bans information about raffles, competitions, or prizes, as well as content that violates statutory provisions or contradicts norms of decency, ethics, or public order. Additionally, excessive or unrelated visualisations and any misleading information about product safety, efficacy, benefits, or quality are forbidden. Products with existing Distribution Permits have a 24-month grace period to comply with the new requirements. Non-compliance can result in administrative penalties, including warnings, product withdrawal, destruction, temporary suspension of market activities, cancellation or revocation of the Distribution Permit, and public announcements.

Amendment to supplement regulation

Indonesia has introduced a new limit for selenium for pregnant and breastfeeding women. The current daily limit for selenium is set at 0.2 mg, with a proposed increase in the maximum limit from 60 to 65 mcg/day when consumed in combination form for pregnant and breastfeeding women.

India

Use of food additives

Draft Regulation Food Safety and Standards 2022 on supplements, nutraceuticals and other categories is further extended from 1 January 2024. The Food Safety Standards Authority has decided to allow the use

of additives listed in Codex Table 3, in all categories across various formats, until final notification. It may be noted that 13.6 and Table 3 additives were earlier disallowed when health supplements and nutraceuticals are marketed in small dose forms (tablets, pills, capsules etc.).

Ministry of AYUSH challenges Danish report on Ashwagandha safety concerns

The Ministry of AYUSH has raised concerns about a May 2020 report from the Technology University of Denmark (DTU), which led to Denmark banning ashwagandha (Indian ginseng). The DTU report cited safety issues, such as potential abortifacient effects, thyroid stimulation, effects on sex hormones, and liver reactions. This report has also raised alarms in several other countries, including Sweden, Finland, France and also Australia.

The Secretary of the Ministry of AYUSH, criticized the DTU report, arguing it lacks a comprehensive evaluation of ashwagandha's properties and recent evidence supporting its safety and efficacy. A report in the Journal of Ayurveda and Integrative Medicine also questioned the DTU report's credibility, highlighting its lack of peer review, undisclosed author credentials, and potential conflicts of interest. The Ministry has formed an expert panel to review the scientific validity of the DTU report and update a detailed safety dossier on ashwagandha.

Malaysia

New variation application timelines

Malaysia has announced new timelines for variation applications of registered health supplements, aiming to improve efficiency in pre-marketing product assessment and post-approval changes. Effective from 1 June 2024, the revised timelines include specific turnaround times for different variation types. While a pilot study of 1 year will precede the finalisation of these timelines, stakeholders are encouraged to plan their submissions in accordance with the new timelines.

Japan

Reconsidering approach to food with functional labelling

In March, Chief Cabinet Secretary Yoshimasa Hayashi urged the Consumer Affairs Agency (CAA) to enhance the Food with Functional Labelling System amidst the recall of red yeast rice products. Consequently, the agency established a "Project Team to Study the Ideal Future of Food with Functional Labelling". Simultaneously, a "Study Group on Food with Functional Labelling" was formed, led by Professor Takehisa Nakagawa of Kobe University. The Committee's discussions addressed various topics, including the delay in reporting health hazards by Kobayashi Pharmaceutical, and perspectives from industry associations and consumer groups. Proposed measures include clarifying regulations on dietary supplements and advocating for specific legislation governing their use.

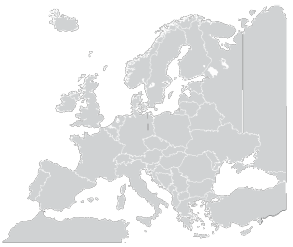
Proposing mandatory GMP for small dosage form FFC products

In response to concerns surrounding red yeast rice supplements in Japan, officials are considering the implementation of mandatory Good Manufacturing Practices (GMP) for dosage forms such as capsules and tablets etc, with a focus on Foods with Functional Claims (FFC). However, integrating GMP with the existing Hazard Analysis and Critical Control Points (HACCP) regulations, which became mandatory for all food products in 2018, may pose challenges.

Philippines

FDA to consider the creation of a task force for health supplements

In a recent quarterly FDA CFRR Kapihan meeting attended by our member HADSAP, food supplement claims emerged as a key topic of discussion. Today, FDA only authorises claims related to nutrients, leaving claims for other ingredients unaddressed. In response to industry requests, FDA has recently confirmed that establishing a Task Force dedicated to Traditional Medicines and Health Supplements (TMHS) is a priority. This initiative would aim to provide clarity on food supplement claims.



EU

EU approves iron milk caseinate as new source of iron

The European Commission has given the green light for the use of iron milk caseinate in food supplements and foods as a source of iron, starting 17 July 2024. This decision, captured in Regulation (EU) 2024/1821, follows the EFSA's validation of its safety. Adults can now benefit from up to 700 mg/day (≤ 14 mg Fe/day) of this novel iron source, while children and adolescents under 18 (excluding infants and young children) are limited to 350 mg/day (≤ 7 mg Fe/day). To ensure safety, labels must warn against its use by children under 3 and caution against consuming other iron-fortified foods simultaneously.

4-year phased reduction of MOAH levels in food supplements

The European Commission Working Group on Environmental Contaminants has discussed an amendment to Regulation (EU) 2013/915, focusing on setting stricter limits for mineral oil aromatic hydrocarbons (MOAH) in food. This proposal includes a focus on food supplements and plans to introduce stricter limits gradually. This is a change from what was initially proposed a few months ago. Proposed maximum limit for MOAH in food supplements:

- Initial Limit (from 1 January 2026): 10.0 mg/kg
- Reduction (from 1 January 2030): 5.0 mg/kg

EFSA discusses emerging issues related to supplements

The European Food Safety Authority (EFSA) has released the minutes of the recent EFSA Emerging Risks Exchange Network (EREN) meeting, highlighting

key issues related to food supplements.
The discussions focused on understanding consumer habits, the reasons behind supplement consumption, and common misconceptions. Emphasis was placed on the need for a comprehensive European approach to assess accurately supplement intake and its health effects, with a call for harmonised data collection across countries.

The meeting also addressed the rising trend of psychedelic truffles sold as microdosing food supplements online, identifying potential emerging risks and the need for further information. Additionally, Eurocigua II, an European project on Ciguatera (a food poisoning due to marine biotoxins present in certain fish) revealed significant knowledge gaps about ciguatera poisoning among EU stakeholders.

EFSA establishes safe iron intake levels across age groups

Instead of establishing a UL, which indicates a threshold beyond which adverse effects may occur, EFSA has determined safe levels of iron intake. These safe levels are designed to guide risk managers in setting intake recommendations that are considered safe across different age groups. Notably, EFSA has concluded that no specific UL can be established due to insufficient data correlating iron intake with adverse health outcomes across various populations. The primary indicator for which a dose-response could be established was black stools which indicates unabsorbed iron in the gut, though it was not considered adverse. Based on studies where black stools did not occur at supplemental iron intakes of 20-25 mg/day (with a background intake of 15 mg/day), a safe intake level of 40 mg/day for adults (including pregnant and lactating women) was determined. For children and adolescents, this value was scaled based on body weight.

EFSA reviews ULs for preformed vitamin A and ß-carotene

EFSA conducted a review on the tolerable upper intake levels (ULs) for preformed vitamin A and ß-carotene, focusing on potential health effects from excessive intake. For preformed vitamin A, teratogenicity was identified as the critical effect, leading to retain the recommended UL of 3000 µg RE/day for adults, with scaled-down values for other age groups. Consumption of liver and similar products should be limited to avoid exceeding this UL, particularly for women planning pregnancy or who are pregnant.

ß-carotene was evaluated separately, focusing on potential adverse effects particularly in relation to lung cancer risk when consumed in supplemental form. The review highlighted insufficient data to establish a definitive dose-response relationship or to identify a specific UL for ß-carotene supplementation. However, no adverse health effects were associated with ß-carotene intake from the background diet.

Given these findings, the general population is advised to limit supplemental ß-carotene intake to meeting vitamin A requirements only. Notably, smokers are cautioned against using food supplements containing ß-carotene due to potential health risks.

EFSA confirms ULs for vitamin E, concluding its review of ULs for vitamins and minerals

The European Food Safety Authority (EFSA) has adopted its draft scientific opinion on the Tolerable Upper Intake Level (UL) for vitamin E, maintaining the UL at 300 mg for adults, pregnant and lactating women. The Panel believes it is unlikely that the UL for vitamin E (α-tocopherol) is exceeded in European populations, except for those who regularly use food supplements containing high doses of α-tocopherol.

This opinion on vitamin E is the last in a series requested by the European Commission, covering various vitamins and minerals. Previous opinions on nutrients like vitamin A, folic acid, and vitamin D have already been published. With the completion of this work, the European Commission now has the necessary information to establish maximum amounts of vitamins and minerals in fortified foods and food supplements.

Heads of European Food Safety Agencies identify 13 food supplement substances with potential health risks

In its first report, the Heads of European Food Safety Agencies have prioritised 13 substances as posing potential health risks, particularly concerning their enhanced intake via food supplements compared to a balanced diet. Among these substances, they state that some exhibit possible carcinogenic, mutagenic, or reprotoxic properties.

In response to growing concerns regarding botanicals and other substances in supplements, the Heads of European Food Safety Agencies (HoA) established the "Food Supplements" working group (HoA WG FS) in 2020. Their mission: to develop a common list of substances that should not be used or should only be used with restrictions in food supplements due to their potential risk to human health.

While general food laws like the Fortified Food Regulation and Novel Food Regulation exist, there are no specific regulations for 'other substances' with nutritional or physiological effects. According to the HoA, this gap poses significant challenges for authorities tasked with surveillance and risk assessment.

Furthermore, the use of 'other substances' in food supplements is only partially harmonised across the EU. Although some member states have developed lists of permitted substances, these lists are not always legally binding and may be subject to conditions. Despite attempts to establish harmonised rules for these substances in the past, no consensus was reached. Recognising the need for a unified approach to risk management, the HoA agreed in 2019 to prioritise the establishment of a harmonised list of 'other substances' to be prohibited or restricted in food supplements.

The HoA WG FS began its review with a collection of 117 substances, including those from the DACH-list (Germany, Austria, and Switzerland) and suggestions from members. Thirteen substances were identified as posing potential health risks, particularly concerning their enhanced intake via food supplements compared to a balanced diet. These substances are: Actaea racemosa, Coumarin in plant preparations, Curcumin in Curcuma spp.-preparations, Hypericum perforatum, Lepidium meyenii, Melaleuca spp.-essential oils, melatonin33, Ocimum tenuiflorum, piperine, p-Synephrine in Citrus spp.-preparations, Tribulus terrestri, tryptophan and Withania somnifera.

Among these substances, Curcumin in Curcuma spp.-preparations, Lepidium meyenii, Melaleuca spp.-essential oils, Ocimum tenuiflorum, piperine, Tribulus terrestris, and Withania somnifera exhibit possible carcinogenic, mutagenic, or reprotoxic properties.

The HoA recommends initiating the 'Article 8 procedure' for these substances The majority of the HoA WG FS supported submitting the relevant information to the European Commission, who could then consider including these substances on a list for prohibition, restriction, or community scrutiny to be reviewed within four years. This recommendation was supported by the majority of the HoA WG FS, with 15 of 19 members participating in the vote and two members abstaining.

HoA clarified that the recommendations are not intended to duplicate or precede the work of corresponding working groups of the Commission or to prejudge their decisions. The HoA WG FS has not yet completed the list of substances which shall either not be added to food supplements or only be added with restrictions. To proceed with the work, the HoA WG FS proposes to assign the new task to the group.

Limits for tartaric acid and its derivatives

The European Commission has recently set limits for Tartaric acid (E 334) and its derivatives (E 335, E 336, E 337, and E 354) following EFSA's establishment of a group acceptable daily intake (ADI) of 240 mg/kg bw per day, expressed as tartaric acid. These additives, previously allowed at Quantum Satis, now have specific provisions particularly in food supplements. Solid supplements are restricted to 100,000 mg/kg (except chewables) or 130,000 mg/kg for chewables, while liquids are limited to 6,000 mg/L. These limits apply to additives, whether used alone or in combination, with the maximum levels expressed in terms of the free acid. They are applicable to supplements in their ready-to-use form as per manufacturer instructions. Products lawfully on the market before 16 December 2024 can continue to be sold until their minimum durability or 'use-by' date.

Edging towards ban on Rheum palmatum L. amid EFSA safety concerns

The European Food Safety Authority (EFSA) has concluded that the safety of preparations derived from Rheum palmatum L., Rheum officinale Baill., and their hybrids, as well as Rhamnus purshiana DC., cannot be established.

EFSA's stance is primarily based on the presence of substances with well-known genotoxic properties in these plant preparations. Despite the submission of various genotoxicity studies suggesting negative results, EFSA continues to be concerned about the safety of botanicals and highlights the lack of adequate characterisation of these preparations, particularly concerning HAD content and other constituents.

In response to EFSA's opinion, the European Commission is expected to consider prohibiting the use of these plant preparations in food and food supplements.

NF Catalogue updated

The Novel Food Catalogue has been revised regarding 5-hydroxytryptophan (5-HTP) and Griffonia simplicifolia. 5-HTP remains classified as novel, regardless of whether it's chemically synthesised or selectively extracted from Griffonia simplicifolia seeds. However, the seeds themselves are not considered novel in food supplements. Aqueous extracts are now classified as non-novel in food supplements if they contain concentrations of 5-HTP up to 30%.

Insights from the Scientific Committee Botanicals Working Group

EFSA recently released cumulative meeting minutes from the Scientific Committee Botanicals Working Group's sessions on Toxicity Characterisation, spanning January 2023 to February 2024. These sessions focused solely on toxicity characterisation, aiming to validate data sourced from literature regarding substances of concern in the Compendium of Botanicals.
Over this period, data on toxicity for 1,518 naturally occurring plant substances were compiled, drawing from an extensive screening of approximately 60,000 articles.
While the minutes do not outline specific next steps, EFSA aims to potentially release an initial update of the Compendium of Botanicals (COMBO) database within 2024.

Belgium

Notification of food supplements

Belgian authorities have recently notified the European Commission and Member States via the TRIS Notification System about a new Royal Decree regarding the use of nutrients, plants, and other substances in food supplements.The proposed amendments aim to modify, harmonise, and clarify the current procedure for notifying food supplements and fortified foodstuffs, as outlined in three existing royal decrees. They cover various aspects, including the scope of application, the definition of food supplements and foodstuffs, the obligation of notification, and the process for assigning a notification number. Additionally, the decree outlines the procedures for placing food supplements containing specific plants on the market, emphasising compliance with established conditions and restrictions.

France

Caution about Ashwagandha

ANSES has issued a caution regarding the use of Withania somnifera in food supplements. Despite its authorisation in Belgium and Italy without specific restrictions, its safety is under scrutiny in France. Reports dating back to 2009 have flagged adverse effects to Withania somnifera-containing supplements, echoing concerns raised in Denmark and Germany. ANSES emphasises the absence of sufficient data to assess its safety fully. Of particular concern are its main metabolites— withanolides, tropane, and piperidine alkaloids. ANSES advises against the use of Withania somnifera supplements for individuals with thyroid, liver, or heart conditions, hyperandrogenism, pregnant and breastfeeding women, those on sedatives, and children under 18. Due to potential interactions with medications, medical consultation is recommended before use.
ANSES stresses the importance of mandatory reporting of adverse effects related to these supplements. They advocate for enhanced coordination among EU risk assessment bodies to avoid duplication of expertise and call for European

harmonisation of the use of plants in food supplements.

The Netherlands

Health risks identified in supplements containing Mucuna Pruriens seed extract

The National Institute for Public Health and the Environment (RIVM) has warned about the health risks associated with food supplements containing Mucuna pruriens seed extracts. Their risk assessment found limited scientific data on the extract but identified potential adverse effects on the liver, kidneys, reproductive function, and foetal development. Additionally, the levodopa content in these supplements could lead to side effects similar to those in Parkinson's disease treatments. RIVM advises against using these supplements during pregnancy, breastfeeding, or if one has liver or kidney issues, and recommends consulting a healthcare provider before use.

UK

Positive opinions for CBD extracts in supplements

The UK Food Standards Agency (FSA) has granted its first positive safety assessment to cannabidiol (CBD) products intended for use as a novel food supplement.
Synthetic Cannabidiol: The synthetic form of CBD, with a purity exceeding 98%, is intended for use as a food supplement in capsule and oil drop form, specifically for adults. .The FSA published a provisional Acceptable Daily Intake (ADI) of 10 mg/day for CBD, considering factors like pregnancy, breastfeeding, medication, and immune system status.
Cannabidiol Isolate: This isolate, also exceeding 98% purity, is derived from industrial hemp using a controlled, multi-step extraction process. It is intended for use as a food ingredient in supplements, beverages, and confectionery for adults, with an Acceptable Daily Intake (ADI) of 10 mg of CBD. Similar to the synthetic form, the Committee found that the applicant provided sufficient information to ensure safety under proposed conditions of use, with no nutritional disadvantage anticipated.

Both applicants have adhered to the joint recommendations of the ACNFP and the Committee on Toxicity by recommending a daily dose of 10 mg of CBD. Notably, these ingredients were already allowed for marketing in England and Wales, as they were included on the list of CBD-based products permitted for transitional marketing.

Call for Evidence on Ashwagandha

The UK Food Standards Agency (FSA) is gathering information on ashwagandha food supplements to guide future risk management decisions. This call for evidence, open from 8 July to 2 September, seeks input from food business operators, experts, trade organizations, local authorities, consumers, and researchers.

Key areas of interest include: Safety assessments and toxicological data, reports of adverse effects, product ingredients and contaminants, manufacturing processes, market data and consumer demographics.

This information will aid in establishing safe levels of ashwagandha in food supplements. Currently, the UK has not established safe levels or set limits for its use in food supplements.

Turkey

Proposed additions to Plant List

The Turkish Ministry of Agriculture has recently released four draft scientific opinions concerning the use of various plants in foods. These evaluations focus on Buckwheat Sprouts, Whole Fruit Part of Lychee, Leaf Part of Holy Basil, Fruit and Seed Parts of Zanthoxylum piperitum.
Buckwheat (Fagopyrum esculentum) Sprouts: Despite containing potentially phototoxic compounds, such as fagopyrin, Fagopyrum esculentum sprouts are proposed for addition to the Plant List with the condition of excluding extracts.
Whole Fruit Part of Lychee (Litchi chinensis): While the fruit can lower blood sugar levels, caution is advised due to potential interactions with medications and allergic reactions. The proposal suggests inclusion on the Plant List, excluding extracts.
Leaf Part of Holy Basil (Ocimum tenuiflorum L.): No adverse effects were found in studies of the leaf part, commonly used for herbal tea. The proposal recommends its addition to the Plant List, excluding extracts.
Fruit and Seed Parts of Zanthoxylum piperitum (Japanese Pepper): Used as spices, the fruit and seed parts are proposed for inclusion with restrictions, limiting the alcohol distillate derived from them to the production of alcoholic beverages.
Changes to the national Plant List will be made once the opinions are finalised.

Brazil

Changes to permitted additives in supplements

Brazil has recently introduced changes to the additives permitted in food supplements. The changes were initiated through Administrative Order IN 295/2024, which amends Administrative Order IN 211/2023, outlining approved additives across all food categories. These amendments include:
An updated definition for anti-caking/anti-humectant has been provided in Annex I of IN 211/2023.

Several changes have been made to Annex III of IN 211/2023 specifically targeting liquid food supplements:
Silicon Dioxide (INS 551): Silicon dioxide, previously permitted in solid and semi-solid forms, including liquid forms, has now been authorised as an anti-caking agent for products in suspension form, effervescents and powders at quantum satis.

Ethyl Para-Hydroxybenzoate (INS 214): This preservative now has a maximum limit of 1500 mg/kg with the limit applying to the product ready for consumption according to the manufacturer's instructions. It is not allowed in effervescents and powders for preparing food supplements. Description of the combination with other additives has been removed.

Sodium Saccharine (INS 954iv): With a maximum limit of 800 mg/kg, sodium saccharine is permitted as a sweetener. However, it is prohibited in the liquid content of capsules, with the limit applying to additives INS 954(i), 954(ii), 954(iii), and 954(iv), either alone or combined, and

referring to the ready-to-consume product as per the manufacturer's preparation instructions.

A new additive, Methacrylic Acid Polymer (INS 1207), has been introduced in Annex III of IN 211/2023 for solid and semisolid food supplements. It serves as a glazing agent with a limit of 100,000 mg/kg, not permitted in chewable forms, and applicable to the product ready for consumption following the manufacturer's instructions.

Updated guide for the determination of shelf life

The National Agency for Sanitary Surveillance (ANVISA) has issued the second version of Guide 16/2018 for determining the shelf life of foods, including food supplements. This updated guide, which is effective immediately, aims to enhance food safety regulations by incorporating recognised international standards. The new version establishes guidelines based on best regulatory practices, with contributions from authorities in Australia, New Zealand, and IADSA. It also integrates recommendations from the Pan American Health Organization (PAHO) and the European Food Safety Authority (EFSA).
The second version of the guide updates terminologies, refines methodologies, and incorporates feedback from the public and experts received during the initial consultation period. The document is divided into two parts: theoretical concepts about changes affecting foods and practical methods and protocols for determining expiration dates. The updated guide will be open for further contributions until 30 December 2024.

New substances for use in supplements

The National Agency for Sanitary Surveillance (ANVISA) in Brazil has updated regulations regarding substances permitted in food supplements through Administrative Order IN 304/2024, modifying the previous IN 28/2018. Key updates include:

Revision:
Inositol's use has specific conditions for liquid carbohydrate and electrolyte supplements, limiting potassium to 700 mg/L and sodium to 460-1,150 mg/L.

Infant and young children supplements: Introduction of a new vitamin D source and a probiotic.

New substances and limits: Addition of dihydrocapciate, lactoferrin, probiotics (Lactobacillus helveticus - 52, Bifidobacterium longum ssp. infantis - 33, Bifidobacterium bifidum - 71), d-limonene, glucosamine, bioactive whey peptides, and furostanol glucoside saponins with specific minimum and maximum limits.

The previously petitioner-specific probiotics are now available for any company.

Updated limits and claims: Revised maximum limit for hydroxytyrosol and derivatives for adults over 19.

New health claim regarding gastrointestinal benefits for the combination of Bifidobacterium longum ssp. infantis - 33 and Bifidobacterium bifidum - 71.

Warnings: New warnings for the added substances.

The enforcement date for these changes is July 1, 2024. Further details can be found in the official publication here.

Changes to food supplement additives

Brazil has recently approved amendments to the list of additives permitted for food supplements. The revisions specifically impacting food supplements include:

Amendments to Annex I of IN 211/2023 for solid and semi-solid forms

Updated note for the use of phosphoric acid (INS 338), disodium hydrogen phosphate (INS 339ii), trisodium phosphate (INS 339iii), potassium dihydrogen phosphate (INS 340i), and hydrogen phosphate dipotassium (INS 340ii) as acidity regulators.

Updated note for the use of sodium polyphosphate (INS 452i) as a sequestrant.

Changes to Annex XX of IN 211/2023 for processing aids relevant to food supplements: enzymes and enzymatic preparations. All enzymes and enzymatic preparations will be permitted if authorised by Resolution RDC 728/2022 and its updates.

These provisions do not apply to supplements intended for infants and young children.

Australia

New labelling requirements for large dosage forms following choking incidents

The Therapeutic Goods Administration (TGA) has opened a public consultation, aimed at introducing new labelling requirements. These proposed regulations are specifically targeted at large solid oral dosage forms intended to be swallowed and exceeding a certain size. Following a two-year transition period, if the proposals are adopted, all Listed Medicines meeting these criteria would be mandated to include on their container, intermediate packaging (if applicable), and primary pack:
A warning statement alerting consumers to the size of the dosage form, such as "Warning: Large tablet"
A true-to-size image of the dosage unit with the words "actual size," unless the dosage unit is visible through the container and primary pack (without opening the packaging)
Clear instructions that the dosage form should be swallowed with water.
The proposal was triggered by reports of serious choking incidents, particularly related to glucosamine/chondroitin, fish/krill oils/omega 3, Calcium with vitamin D3, and Multi-vitamin/minerals.
The TGA's proposal does not include separate or additional requirements for children's medicines. Furthermore, the TGA suggests that if these new labelling requirements are insufficient to adequately address the identified risks, further regulatory changes may be considered in the future, potentially including limits on the size of dosage forms.

New Zealand

New Zealand's MPI considers new export exemption pathways

The Ministry for Primary Industries (MPI) in New Zealand is exploring new options for export exemptions from the Food Act 2014's composition and labelling requirements. They propose four pathways: maintaining the current system or introducing varying levels of exemptions through new regulations. Currently, exemptions are necessary when these differ from importing countries' requirements, requiring businesses to apply individually to MPI.

Therapeutic Products Act to be repealed

The Therapeutic Products Act (TPA), a legislative framework designed to regulate medicines, medical devices, and health products in New Zealand, is set to be repealed.

The repeal aims to address criticism of the TPA regarding its potential to over-regulate products and impose unnecessary costs. According to the government this decision will help to develop a modern, risk proportionate regulatory regime for medicines and medical devices, and a separate modernised regime for natural health products.

Most provisions in the Act were intended to come into force 1 September 2026. The government plans to introduce new legislative proposals later this year after consulting with industry groups, consumers, and practitioners to craft laws that better meet stakeholder needs.

EAEU

Delay in implementing the 5-year registration limit

The Eurasian Commission has drafted a resolution which potentially delays adoption of amendments to the technical regulation of the Eurasian Economic Union CU TR 021/2011 on food safety until 2027.
The amendments which provoked broad criticism from the industry and experts limit validity period of state registration of dietary supplements to five years (currently the registrations are issued indefinitely).
Originally, the amendments were scheduled for adoption in 2024 implying that all current registrations would have to be renewed within the next five years. With the new resolution, the industry would be given three extra years to prepare for the switch.

Repeal of the Therapeutic Products Act: Update

Originally scheduled to take effect in 2026, the repeal of the Therapeutic Products Act (TPA) this year will mean that none of the provisions in the TPA will come into force. Instead, the current regulations under the Medicines Act 1981 will continue to govern medicines and medical devices, while the Dietary Supplements Regulations 1985 will maintain their role in overseeing the composition and labelling of certain natural health products. The bill to repeal the TPA will be introduced into Parliament and come into force before the end of 2024.

The Government has asked the Ministry to develop options for modern, risk-proportionate, fit for purpose regulation of these products that could replace the current outdated system. The Government will then decide on the elements of future legislation for medicines, medical devices and natural health products.

Russia

Mandatory ID tagging of dietary supplements: Government closes loopholes in custom classification

The Russian government has introduced amendments to the list of dietary supplements subject to mandatory ID tagging (the list was approved by governmental resolution No. 792-r of 28 April 2018).
The following harmonisation codes, often used to disguise supplements from the ID tagging, have now been added to mandatory tagging list (clause 22 of resolution No. 792-r):
- codes 1211 90 860 8, 1212 99 950 9, 1302 20 100 0, 1302 20 900 0, 1504 20 100 0, 1516 10 100 0, 1603 00 100 0, 1806 90 310 0, 1901 90 980 0, 2102 20 110 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, 3913 10 000 0.
Dietary supplements classified under these codes will be subject to mandatory ID tagging starting 1 September 2024.

International Alliance of
Dietary/Food Supplement Associations
International Non-Profit Organisation
Gridiron Building, One Pancras Square,
London, N1C 4AG, United Kingdom
Website: www.iadsa.org

IADSA
International Alliance of Dietary/
Food Supplement Associations