IADSA NEWSFLASH

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Regulatory news

Japan

MHLW launches webpage on adverse events related to red yeast rice products

Kobayashi Pharmaceutical is under extreme pressure due to the health crisis involving benikoji rice dietary supplements meant to lower cholesterol. The health ministry revealed contamination with "highly toxic" puberulic acid. This acid has antibiotic properties but its effects on kidneys are unknown. The company admitted only specific lots contained the substance, initially attributing the issue to "unknown ingredients."

In response to concerns regarding the contamination, the Ministry of Health, Labor, and Welfare has unveiled a dedicated webpage providing information on adverse events associated with Beni-koji (Red Yeast Rice) related products. The relationship between puberulic acid and adverse events is currently under investigation. Link

India

India's move to tighten supplement regulations

In response to increasing complaints about non-compliant supplement products and their rising consumption, the Food Safety and Standards Authority of India (FSSAI) has highlighted the need for tighter regulatory frameworks.
Issues that are being addressed include the use of the same nutrients/ingredients and dosage forms in both pharmaceuticals and supplements and the lines between prophylactic and therapeutic uses. The review will extend to Good Manufacturing Practices (GMP) and quality control.

To this end, a National Inter-ministerial Committee has been formed, led by the Secretary of Health, and includes representatives from the FSSAI, Indian Council of Medical Research (ICMR), the Central Drugs Standard Control Organisation (CDSCO) and other experts.

Taiwan

Updated regulations on nutrition claims

Taiwan has revised its regulations regarding nutrition claims for prepackaged food products, introducing new requirements for claims like "high" and "rich in" nutrients. To indicate the presence of specific nutrients, products can feature factual nutrition claims on their packaging, such as "This product contains lutein" or "XX grams of protein per serving," with corresponding nutrient content clearly outlined in the nutrition labelling.

Additionally, new nutrients and content standards have been included for claims such as "high" and "rich in." The FDA has also issued FAQs to assist stakeholders in understanding the regulations. These FAQs clarify that if a product contains two or more nutrients eligible for nutrition claims, these claims should be made in accordance with the product's state (solid, semi-solid, or liquid).

Effervescent tablets must adhere to the provisions outlined in the regulations. For effervescent products, one of two approaches can be selected for simultaneous claims of "rich in vitamin C," "zero calories," and "low sodium":

For products in a solid state, the Vitamin C content must be 30 mg or higher per tablet, with calorie and sodium content not exceeding 4 kcal and 120 mg per 100 g of the product, respectively.

For products in a dissolved liquid state, after one tablet is dissolved in 150 ml of liquid, the Vitamin C content must be 30 mg or higher, with calorie and sodium content not exceeding 4 kcal and 120 mg per 100 ml of the dissolved liquid, respectively.

EU

Monitoring nickel in food supplements

In 2015, the European Food Safety Authority (EFSA) outlined the risks associated with nickel in food and water, highlighting reproductive and developmental toxicity as a critical concern for chronic oral exposure. In response to this, the European Commission has now asked Member States to monitor from 2024 to 2026, the presence of nickel in a number of food products: food supplements, tea, chocolate, cocoa beans, cereal-based items (especially breakfast cereals, cereal flakes, and oat milling products), and ready-to-eat soups.

Lycopene: Refined exposure assessment and data collection

EFSA was tasked by the European Commission to conduct a refined exposure assessment of lycopene, considering all intake sources. EFSA launched a public call for data to gather relevant information for this assessment. This follows the opinion of March 2023 that concluded that the safety of yellow/orange tomato extract as a novel food has not been established under proposed conditions due to its potential for exceeding the Acceptable Daily Intake (ADI) of lycopene. Previous EFSA assessments indicated that overall lycopene exposure, including from background diet, novel food, and food additives, might exceed established ADI levels.

Botanicals: Member States take the lead

EFSA has restarted its initiative to establish a Botanicals Community of Knowledge, initially postponed due to resource constraints. The project is now led by EFSA focal points, representing Member States' Food Safety Agencies, coordinated by France's ANSES and involving the Netherlands, Portugal, Italy, Ireland, and Denmark. Instead of EFSA financing the project, interested Member States are taking charge. The objective remains the creation of a community focusing on two main activities: analysing data from nutrivigilance and poison control centres regarding botanical consumption, and identifying potentially harmful substances naturally present in plants and used in food supplements. Priority will be given to substances predicted to be toxic through QSAR modelling (quantitative structure-activity relationship) and/or read-across techniques.

The saga on botanicals continues

Following recent pressure from the European Parliament on the Commission to resume the assessment of health claims for botanicals in supplements, it is now the turn of the Council of Europe's European Directorate for the Quality of Medicines & Healthcare (EDQM) to initiate a targeted consultation on draft guidance documents for healthcare professionals and draft leaflets for patients/consumers, both focusing on herbal food supplements.

According to the EDQM, the draft guidance for healthcare professionals covers legislation and scientific evidence to avoid incorrect use, and health risks associated with herbal supplements. The draft leaflet for patients also aims to provide patients/consumers with necessary knowledge on herbal supplement regulation, differences from medicines, and associated risks to ensure safe and appropriate usage.

Empowering consumers for the green transition

With the ambitious goal of being a climate-neutral continent by 2050, the European Commission has taken a significant step forward with the publication of a Directive focused on empowering consumers for the green transition. This directive aims to provide better protection against unfair practices and ensure more transparent information.

Aligned with the objectives of the European Green Deal, this directive introduces important measures. It includes defining environmental claims, which cover any non-mandatory message or representation suggesting a product, brand, or trader has a positive environmental impact or is less harmful than others. Furthermore, the Directive broadens the scope of unfair practices by expanding the blacklist, particularly focusing on the use of sustainability labels. The use of sustainability labels such as a leaf, a tree, or a green seal will face stricter regulations. Additionally, the Directive prohibits the advertisement of irrelevant benefits, such as labelling bottled water as "gluten-free" or paper sheets as "plastic-free."

Novel food status for iron-enriched yeast and CBD products

The European Commission has released new consultation results on the novel food status of five ingredients: iron-enriched yeast (Saccharomyces cerevisiae), Capsicum chinense, CBD extract via CO2 extraction to be used in sweets (gummies) with melatonin, CBD isolate, and CBD extract. Led by the Czech Republic's Food Safety Department, these reviews determined iron-enriched yeast and CBD products as novel due to limited historical consumption data pre-1997. In contrast, Capsicum chinense was not considered novel reflecting its traditional use in the EU.

EFSA clears Magnesium L-Threonate for supplements

The European Food Safety Authority (EFSA) has evaluated magnesium L-threonate on the European Commission's request, as a novel food ingredient, at a dosage of 250 mg magnesium which corresponds to the UL for supplemental magnesium from readily dissociable magnesium salts. Following a comprehensive evaluation, EFSA concluded that magnesium L-threonate, produced synthetically, is safe for use in food supplements. Studies demonstrate its bioavailability and nutritional safety, without any genotoxicity concerns. The next step involves considering its inclusion as a magnesium source in the Food Supplement Directive.

Proposed mineral oil limit in food additives

The European Commission has initiated a stakeholder consultation on mineral oil specifications for food additives, aiming to regulate mineral oil presence in all food additives with a proposed maximum limit of 2.0 mg/kg for Mineral Oil Aromatic Hydrocarbons (MOAH).

Food sectors are asked to provide input on the feasibility of implementing a proposed maximum limit in food additives. Comments should be substantiated with data

addressing reasons for non-compliance, contamination sources, existing or planned mitigation measures, proposed compliance timelines, raw occurrence data from samples following good practices, analytical concentrations, limits of quantification (LOQ), details on applied mitigation measures, and the sampling year.

EFSA proposes safe intake level for iron

EFSA has initiated a public consultation on its proposed Tolerable Upper Intake Level (UL) for Iron, running until 1 April 2024.
Despite being unable to determine a UL, EFSA set a safe intake level of 40 mg/day for adults, including pregnant and lactating women, using the appearance of black stools, which is the only indicator for which a dose-response could be established.
This approach of safe level differs from a UL as it doesn't define the intake level where the risk of adverse effects starts to increase. The EFSA assessment carried out in 2004 was not able to establish a UL.

Updated guidance for micronutrient source assessment

EFSA has initiated a public consultation for an updated guidance on scientific principles and data requirements concerning the safety and relative bioavailability assessment of substances proposed as new micronutrient sources. This revised guideline aims to refine the assessment process for all new forms of micronutrients and establish criteria for deriving conversion factors for their addition to foods, including supplements. The update incorporates insights from the 'Expert Survey on the Derivation of Conversion Factors for New Sources of Nutrients' and an online workshop held in 2023. The draft guidance outlines scientific principles, data requirements, and minimum information standards for human studies. EFSA anticipates finalising the guideline by 8 June 2024.

Titanium dioxide alerts in food supplements: Analytical issue or fraudulent Use?

Several rapid alerts regarding titanium dioxide in food supplements, mainly from Latvia and Slovenia, primarily linked to one company, have been notified in the EU. During a recent Additives Experts Group meeting of the European Commission and Member States, the issue concerning the unintentional presence of titanium dioxide in chewing gum was also raised. The Commission recommended the use of sensitive methods with low limits of detection and quantification (LOD and LOQ) indication to assess the presence of TiO2 in food, while also noting that the specified background value of 250-280 ppm (mg/kg) by the FBO was considered high.

In a recent industry call, this issue was discussed further. It was pointed out that during a typical analysis of the total composition using X-ray fluorescence (XRF), titanium is usually measured and reported as oxide. Consequently, in a certificate of analysis, it may be listed as titanium dioxide. However, it was stressed that this does not necessarily imply the presence of titanium dioxide in the material. In some cases, titanium may substitute other atoms in the crystalline structure, leading to its measurement. Therefore, the titanium present may not solely exist in the form of titanium dioxide, which is the regulated aspect, but rather in various forms.

Further clarification indicated that utilising X-Ray Diffraction would be more appropriate for distinguishing the main crystalline forms of titanium dioxide. One form corresponds to standard titanium dioxide, while the other is more indicative of titanium present in the samples, often involving substitution forms.

EFSA consults on Tolerable Upper Intake Levels for preformed vitamin A and ß-carotene

EFSA has opened a public consultation regarding the Tolerable Upper Intake Levels for preformed vitamin A and ß-carotene.

The draft opinion suggests maintaining the established UL for preformed vitamin A at 3,000 µg retinol equivalents (RE)/day for adults, with varying levels for different age groups. However, no UL could be determined for ß-carotene due to insufficient data, particularly concerning its interaction with preformed vitamin A and its potential association with lung cancer risk, particularly among heavy smokers.

While European populations are unlikely to exceed the UL for preformed vitamin A, EFSA advises limiting liver and liver product consumption to once a month or less. Pregnant or planning-to-be pregnant women should avoid these products. Smokers are cautioned against ß-carotene supplements. Further research is recommended.

European Commission faces obstacles with nano definition revision

The European Commission's attempt to revise the definition of engineered nanomaterials has hit a roadblock. While their proposal aimed to bring clarity and objectivity to the definition by establishing a default threshold for nanoparticle presence of 50%, it faced opposition in the European Parliament. On 24 April, the Parliament voted to object to the Commission's delegated regulation, citing concerns regarding the threshold, which they argue should be lowered from 50% to 10%.

As a result, the Commission will have to rework their proposal. However, with the EU elections, it's unlikely that a revised draft will be ready by November.

Belgium

The ongoing debate: Omega-3 fatty acids cardiovascular risks and benefits

The debate in Europe surrounding omega-3 fatty acid and their cardiovascular benefits versus risks is ongoing. Recent meta-analyses indicate an increased risk of atrial fibrillation with omega-3 fatty acid preparations, leading some national regulatory agencies to label atrial fibrillation as a common adverse effect for medicines.

In reference to omega-3 fatty acid supplements, CBIP (The Belgian Center for Pharmacotherapeutic Information) has reaffirmed its position: Based on existing evidence, omega-3 fatty acid supplements available in Belgium are not advisable for primary or secondary prevention of cardiovascular diseases.

One chip challenge: Hot for Capsicum

The Commission on Plant Preparations has issued an opinion on the safety of the "Hot Chip" in the "One Chip Challenge," commissioned by the Directorate-General for Animals,

Plants, and Foodstuffs of the Federal Public Service for Public Health, Food Chain Safety, and Environment. This challenge involves consuming a single tortilla chip containing Carolina Reaper and Trinidad Moruga Scorpion peppers, with a Scoville Heat Units (SHU) rating of approximately 2 million. Concerns were raised following adverse reactions, including the death of a teenager shortly after participating. Despite the withdrawal of the original product, similar items remain available with reported adverse effects. The Advisory Commission for Plant Preparations is of the opinion that the consumption of this product involves a risk for the consumer since respiratory, skin, and eye problems cannot be excluded. The Advisory Commission for Plant Preparations also concludes that Capsicum annuum L and Capsicum frutescens L. are not synonyms and must be mentioned separately in list 3 of the Royal Decree of 31 August 2021. Necessary amendments should be expected to the Royal Decree of 31 August 2021.

It is important to note that List 3 botanicals are permitted for use, but marketing supplements containing any plants listed in List 2 and List 3 of the Decree is prohibited without prior notification to Authority.

Similar concerns about products with high capsaicin levels were reported by Luxembourg authorities and others through the EU's Rapid Alert System for Food and Feed (RASFF) Portal, highlighting an ongoing issue across multiple countries.

Denmark

Revised Danish guidance levels for vitamins and minerals in supplements

The Danish authorities have updated their guidance levels for the use of vitamins and minerals in food supplements. While the Danish law on food supplements doesn't specify daily maximum levels for vitamins and minerals, guidance levels have been established in a separate document called the Guidance on Food Supplements. The updated guidance, effective from 2024, covers various population groups and aims to ensure safe nutrient intake.

Companies exceeding these levels should provide documentation demonstrating the safety of their products. Requirements vary based on the declared content of nutrients, ranging from no documentation for content up to the guidance value to a full safety assessment for content above certain upper limits with a clear explanation of which scientific studies are included and why they apply. Producers and importers are encouraged to monitor content fluctuations to prevent exceeding these limits.

Germany & Austria

AG Stoffliste 3rd edition includes algae

A list of algae has now been added to the so-called AG Stoffliste which currently covers botanicals and mushrooms. This new list is intended to help companies and authorities with the classification of algae and algae products.

France

Vitamin D at 75 mcg/d

The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) recently conducted an evaluation at the request of the Directorate General for Food regarding a food supplement containing 75 µg of vitamin D per tablet, exceeding the maximum level in France set at 25 mcg/d. ANSES assessed its safety using nutrivigilance data and compared nutrient intakes at the 95th percentile of consumption with upper safety limits.

Nutrivigilance data revealed isolated, low-severity adverse effects, which did not raise significant safety concerns. Analysis of dietary intakes indicated that vitamin D levels from the supplement, when combined with the diet, did not exceed upper safety limits for adults. Thus, ANSES concluded that for the adult population, consuming the supplement as recommended does not pose a risk of exceeding the upper limit. However, this conclusion is specific to adults and doesn't apply to all populations. ANSES emphasised the importance of clear labelling regarding the target population.

Germany

Aligning with EFSA ULs

The German Federal Institute for Risk Assessment (BfR) has updated its recommendations following the decision of the European Food Safety Authority (EFSA) to lower the tolerable upper intake levels for adults from 25 mg to 12 mg per day for B6 and from 300 to 255 mcg per day for Selenium.

Finland

Finland's revised nutrition and health claims guidance

The Finnish authorities have released a new Nutrition and Health Claims Guidance, replacing the previous version of 2017. This guide addresses terms like "superfood," "immunity," and specific diets such as Ayurveda and Keto. It emphasises consumer protection, prohibiting misleading claims, especially those suggesting that food can prevent or treat diseases. The guide targets companies, supervisors in the food industry, and social media influencers. Practical examples are provided to clarify permitted and prohibited claims, covering topics like vitamin content and caffeine-related health claims. Furthermore, it discusses terms like "probiotics" and "antioxidant," which according to Finland are considered general claims and can be used if they are accompanied by a related permitted health claim or a related botanical claim from the on-hold list. The guide also provides national interpretations on terms such as resistance, joints, cramps, hangover, and organic claims.

Norway

New guide for public controls

The Norwegian Food Safety Authority has recently developed a new guide detailing the practical aspects of their public inspections. This guide outlines how inspections are planned and executed, the authority's responses to regulatory breaches, such as compulsory fines and infringement fees. It also clarifies the rights and duties of those inspected and steps from investigation to follow-up.

Romania

Botanicals in supplements

The Ministry of Health in Romania has released a consolidated list of plants evaluated in 2023 that may be used in food supplements. This list includes 103 botanical species, with additional specifications compared to the previous list from 2005.

The Netherlands

Empowering good consumer choice through notification

The Dutch Ministry of Health has received an initial report from the Bureau of Risk Assessment & Research (BuRO) regarding the safety of supplements. The report highlights a growing trend in the consumption of various supplements and the absence of specific regulations governing their safety, particularly concerning botanical preparations. Concerns were notably raised regarding potential health risks associated with supplements and their interactions with other substances.

While recognising existing regulations for supplements containing vitamins and minerals, it emphasised the absence of maximum levels and the regulatory gap concerning the category, especially relating to products containing multiple bioactive substances and herbal preparations. Unlike medicines, there is no mandatory notification or registration requirement for supplements in the Netherlands.

The report recommends the implementation of a notification system to enhance safety measures and ensure better consumer and industry awareness. It urges the Dutch Food and Consumer Product Safety Authority (NVWA) to support the establishment and enforcement of such a system.

According to NVWA, such a system could enhance safety by requiring companies to provide authorities with information about their products before market entry, thus empowering consumers to make informed choices. However, the authority acknowledges the need for additional resources and expertise to implement and sustain such a system, indicating forthcoming discussions with the Ministry of Health, Welfare, and Sport about its feasibility and the NVWA's role in its management.

Spotlight on Ashwagandha, Huperzia serrata, and Tabernanthe iboga

In December 2020, the Minister for Medical Care and Sport initiated measures to enhance the regulation and enforcement of food supplements and herbal preparations sold within the country. Central to this initiative was the expansion of the list of prohibited or restricted substances/botanicals, based on risk assessments of commonly used botanicals in the Dutch market.

Following this, risk assessments for three prioritised botanicals: *Huperzia serrata, Tabernanthe iboga, and Ashwagandh*a, were carried out by the National Institute for Public Health and the Environment (RIVM). The assessments, which are now available, have highlighted potential risks associated with these botanicals, particularly concerning pregnant women.

Ashwagandha: While scientific data is limited, there are concerns about possible adverse effects on the liver and on unborn children. RIVM advises caution, especially for pregnant women regarding the consumption of Ashwagandha supplements or tea.

Huperzia serrata: Research indicates various adverse effects, including muscle weakness and gastrointestinal issues. RIVM recommends avoiding products containing Huperzia serrata, especially during pregnancy, due to these potential risks.

Tabernanthe iboga: This herb poses potential health concerns, including heart rhythm disturbances and neurological complications. RIVM advises against using products containing Tabernanthe iboga due to these potential risks.

UK

Addressing allergy risks: Campaign on vegan food labelling

The UK Food Standards Agency FSA has launched a campaign warning about the risks of consuming food labelled as vegan for individuals with allergies. Recent research by the FSA found that 62% of people with reactions to animal-based products, or who buy for someone with such allergies, mistakenly believe that products labelled 'Vegan' are safe to eat. To address this misconception, the FSA updated its Food labelling technical guidance, urging businesses to include a Precautionary Allergen Label alongside vegan labels when cross-contamination is possible.

In an IPSOS study commissioned by FSA titled "Vegan labelling: use and understanding by consumers with food hypersensitivities," it was revealed that many respondents were unaware that vegan products might not be suitable for those with allergies to animal-origin allergens. There was a widespread misunderstanding that the term 'vegan' guarantees safety for individuals with such allergies, leading some to use vegan labelling as a substitute for allergen labelling.

USA

Draft guidance on New Dietary Ingredient Notification Master Files

The U.S. Food & Drug Administration (FDA) has issued draft guidance concerning procedures and submissions for utilising Master Files in new dietary ingredient notifications (NDINs). These Master Files compile information regarding new dietary ingredients, serving as a reference for NDIN submissions by either the file owner or another authorised party. The guidance outlines recommended steps for establishing an NDIN Master File or utilising an existing one. It also addresses the FDA's approach to handling trade secrets or confidential commercial information within the file, emphasising the importance of clearly identifying information exempt from public disclosure.

FDA warning on toxic yellow oleander

The FDA has issued an alert that dietary supplements sold as tejocote root or Brazil seed may contain toxic yellow oleander (Thevetia peruviana). These products can cause serious health problems, including potentially fatal neurological, gastrointestinal, and cardiovascular issues. Despite some voluntary recalls, many of these products are still available. The FDA is evaluating pathways to remove them from the market.

FDA has not identified concerns related to potential genotoxicity of titanium dioxide

In a recent communication, the US FDA has stated that no concerns regarding potential genotoxicity have been identified. The FDA emphasised that titanium dioxide (TiO2) does not

cause cancer in National Toxicology Program (NTP) carcinogenicity studies.

Additionally, the FDA reiterated that TiO2 is permitted within certain specifications and conditions in the US, with a limit of 1% by weight in food products. While foods containing TiO2 typically label it as "artificial color" or "colored with titanium dioxide," such labelling is not mandatory. TiO2, like other colour additives, undergoes pre-market review for safety. Approval requires demonstrating safety through various data, including physical properties, manufacturing details, consumption levels, safety data, and analytical methods.

Furthermore, while the FDA is currently reassessing a Color Additive Petition filed in April 2023, the Agency noted no concerns regarding potential genotoxicity based on available data.

The FDA critiqued the conclusions of the European Food Safety Authority, citing the Joint FAO/WHO Expert Committee on Food Additives' 2023 re-evaluation affirming TiO2's safety based on available toxicological and biochemical data. FDA stressed disagreement from international bodies, including the FDA, FSA, Health Canada, and FSANZ, with EFSA's assessment.

FDA unveils Final NDIN Guidance

FDA has recently issued a Final Guidance titled “Dietary Supplements: New Dietary Ingredient Notification (NDIN) Procedures and Timeframes: Guidance for Industry.” This comprehensive 102-page document is the first instalment in a series of final guidance documents aimed at providing the industry with clearer direction regarding the NDI process.

The process towards the Final Guidance began in 2011 when the FDA issued an initial draft guidance on NDI notification. However, this initial attempt raised criticism from stakeholders. Another effort in 2016 also failed to gain acceptance. Subsequently, collaborative discussions between the FDA and different trade associations led to efforts to simplify and streamline the NDI guidance.

Presented in a question-and-answer format, the guidance addresses key aspects of the NDIN submission and review process. It covers topics such as who is required to submit an NDIN, how the information should be presented, where to submit it, and the subsequent steps after submission.

Australia

TGA Advertising and Compliance Education Plan

The TGA has published a web page outlining the Therapeutic Goods Advertising and Compliance Education Plan for 2024. This plan emphasises several key education priorities:

Education Priority 1: Activities related to import, advertising and supply compliance priorities

Education Priority 2: Publish information on compliance and enforcement actions for transparency of compliance activities and as a deterrent to non-compliance

Education Priority 3: Maintain and enhance fit for purpose educational resources, and participate in training and education opportunities

Education priority 4: Engage with key stakeholders, including members of the TGACC, as partners in education and communication activities

Education priority 5: Maintain and enhance an advertising enquiry management function

Brazil

ANVISA updates its Q&A on food contact materials

The National Agency for Sanitary Surveillance (ANVISA) has recently revised its Q&A document regarding food contact materials, which applies also to food contact materials used in food supplement packaging. The updates cover several key areas, including chemical recycling of plastic materials, biodegradable or compostable packaging, references for updating positive lists, wood and fabric materials for food contact, expanded polystyrene, water boxes, migration tests in cans, use of salts not included in the positive list of additives for plastic materials, and non-greasy dry food.

D-Ribose approved in food supplements

Brazil's Administrative Order 275/2024, amending Administrative Order 28/2018, now includes D-ribose (CAS 50-69-1) as a carbohydrate source in food supplements, subject to specified maximum limits for different age groups and specific populations, except for infants and young children. These maximum limits are outlined as follows: 4-8 years: 0.60 g, 9-18 years: 1.0 g, ≥ 19 years: 2.5 g, Pregnancy: 2.1 g, Lactating women: 2.1 g

Notification for marketing of food supplements

Resolution RDC 843/2024 and Administrative Order IN 281/2024 was recently issued, modifying market access requirements for food and food contact materials under ANVISA's jurisdiction. Notably, as of 1 September 2024, notification of marketing for all food supplements will become mandatory, replacing the previous requirement of municipal-level communication for manufacturing/importation. This notification process requires submission of various documents:

- Notification form.
- Copy of the valid health licensing of the manufacturer(s) that carried out production, quality control and storage activities, located domestically or document that proves regularity with the health authority of the country of origin, in case of manufacturer(s) in foreign territory.
- Stability studies report ensuring the product's nutritional properties are guaranteed throughout the declared shelf life, including post-reconstitution studies for dilution products.
- Report/Certificate of analysis or calculation memorandum demonstrating compliance with composition

requirements as per the specific technical regulation.

Kazakhstan

Rules for dietary supplement advertising

The Ministry of Health in Kazakhstan is strengthening its oversight of dietary supplement advertising. The Committee of Sanitary and Epidemiological Control has proposed regulations for pre-market state registered foods, including therapeutic and preventive dietary foods, products for athletes, pregnant and breastfeeding women, and dietary supplements. These rules require specific information in advertisements, such as the product registration certificate details (date and number). Moreover, the regulations prohibit advertising tactics like referencing endorsements by government officials, making unsubstantiated claims about product uniqueness, safety, or efficacy, comparing products to medications, or suggesting that consumers abandon healthy lifestyles.

Russia

Trade ministry seeks to extend mandatory ID tagging to more categories of dietary supplements

The Ministry of Industry and Trade published for comments draft amendments to the ID Tagging Rules for Dietary Supplements (approved by governmental decree No. 886 dated 31 May 2023), expanding the list of dietary supplements that must be ID tagged before they are placed in the market.

The ministry argues that the current list fails to cover all supplement categories. To bridge this gap, the draft adds the following customs harmonization codes to the list of dietary supplements that must carry ID tags on their retail packaging: 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, 3502 90 700 0, 3503 00, 3802 10 000 0, 3913 10 000 0.

Market operators are responsible for putting ID tags on the product's label and submit information (on ID tagging, product placement on the market, circulation on the market, and withdrawal from the market) to the state information system starting 1 September 2024.

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