IADSA NEWSFLASH

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Regulatory news

ASEAN

Updates from the ASEAN Product Working Group: THMS agreement, ingredient review, & GMP discussion

The key outcomes of discussions are as follows:

THMS Agreement: Indonesia's declaration on protecting their genetic resources continues to create confusion and slow the process of finalising the agreement down. Despite the view of the ASEAN legal services that this declaration would not have legal effect, a number of countries consider it could be a 'reservation' on the Agreement. Since all member countries have not completed their national consultation on the Indonesian declaration, this will now need to be addressed at the next government meeting. Nevertheless, governments continue to move forward on implementing the Annexes and AAHSA is continuing to push for this.

Negative List of Ingredients: The Scientific Committee agreed to carry out a review of the list of ingredients, given that the current list was developed and agreed nearly 10 years ago. There will be no change to the current list prior to the signing of the TMHS Agreement.

GMP: It was agreed that GMP certificates issued by 3rd parties can be accepted in 9 member countries (except Cambodia at this point) as long as they are equivalent to ASEAN GMP Guidelines for TMHS and recognised by the producer's National Regulatory Authority or by international accreditation bodies.

Japan

Japan unveils draft guidelines for tablet and capsule production

The Ministry of Health, Labour, and Welfare has introduced a proposal aimed at ensuring safety and promoting Good Manufacturing Practice (GMP) for products in tablet and capsule forms. The proposal includes two set of guidelines: Guidelines for Self-inspection and Product Design Regarding the Safety of Food Products in Tablet and Capsule Forms (Draft) & Guidelines for Good Manufacturing Practice (GMP) of Food Products in Tablet and Capsule Forms (Draft). The guidelines are aimed to replace the 2005 guidelines, with an official release expected in early 2024.

Philippines

FDA draft guidelines for supplements

The Philippines FDA has issued draft guidelines for the classification of vitamins and minerals in food supplements. These guidelines are based on the ASEAN texts and establish a clear distinction between foods and supplements, which are designed to supplement the diet with nutrients like vitamins, minerals, and other substances. To qualify as food supplements, these products must be available in specific formats such as capsules, tablets, liquids, gels. They must not contain pharmaceutical ingredients and are not permitted to make therapeutic claims. Additionally, the levels of vitamins and minerals in supplements must comply with the limits specified in the guidelines. The guidelines also include transitional provisions, which facilitate the renewal of existing certificates and allow for a period of depletion for existing stocks of labels.

Aligning supplement maximum levels with ASEAN

Thailand has recently aligned its maximum levels for vitamins and minerals in health supplements with ASEAN, which should facilitate trade across the region. While this alignment marks a significant step in harmonising health supplement regulations within ASEAN, the Thai Food and Drug Administration (FDA)

has retained country-specific maximum levels for certain vitamins and minerals. These include vitamins A, D, E, K, Nicotinamide, B6, Folic acid, Calcium, Molybdenum, and Selenium.

EU

Botanicals in focus

The European Parliament has called on the European Commission to promptly review the evaluation of pending botanical claims and remove those with negative evaluations from EFSA. This call potentially impacts thousands of claims. The Parliament voted in mid January in favour of this report for the implementation of Regulation on nutrition and health claims on foods by MEP Tilly Metz. This report aimed to address unhealthy foods on the market, over 2000 on hold botanical claims, and the booming online sale of food and supplements.

The Commission has three months to propose legislation or justify why it will not move forward with measures.

Mineral oil hydrocarbons: Proposed measures under consideration

The European Commission has put forward a proposal that seeks to limit the presence of Mineral Oil Aromatic Hydrocarbons (MOAH) and introduce monitoring for Mineral Oil Saturated Hydrocarbons (MOSH) in foods to address potential risks associated with these substances.

One of the significant aspects of this proposal is the establishment of Maximum Levels (MLs) set at the limit of quantification (LOQ) for food supplements and products containing high levels of MOAH, due to their potential genotoxic and carcinogenic properties. Furthermore, the proposal addresses the need for monitoring of MOSH, particularly in food supplements, as concerns persist about potential health implications if mitigation measures were to be discontinued. An indicative level of 10 mg/kg has been suggested for MOSH in food supplements.

These developments follow the European Food Safety Authority's (EFSA) updated evaluation of MOHs in food in 2023. EFSA concluded that while Mineral Oil Saturated Hydrocarbons (MOSH) can accumulate in organs, they do not currently pose immediate health concerns. However, the focus remains on MOAH, which consists of MOHs with three or more aromatic rings and is associated with genotoxic and carcinogenic properties. One of the key challenges highlighted by EFSA is the lack of sufficient data on MOAH with one or two aromatic rings in food products. This data gap is driving the European Commission's determination to formulate protective measures.

Nano iron source

Iron Hydroxide Adipate Tartrate (IHAT) has recently been authorised as an iron source for food supplements. IHAT was granted novel food approval in August 2022 and is the first nutrient source in nano form to be authorised, requiring the inclusion of the "nano" label in the ingredient list. The applicant has secured data protection until 28 August 2027.

Impact of QR codes on food labelling

As part of the EU's Farm to Fork Strategy, the Joint Research Centre of the European Commission explored the effectiveness of hybrid labelling in the food industry, which combines traditional labels with digital QR codes. Conducted online with 3,420 participants across Spain, Bulgaria, and Germany, the study revealed interesting consumer behaviour. Participants were presented with two products: one featuring complete information on a paper label and another requiring a QR code scan for additional details. Notably, 37% of consumers never utilised the QR codes, with only 4% consistently scanning them. On average, QR codes were scanned just 24% of the time. Older and less educated consumers were less likely to choose products with QR-coded information. Overall, the study suggests that using QR codes for food information, instead of traditional paper labels, can slow down consumer decision-making and reduce their accuracy in understanding the product, potentially having a negative impact on consumers, according to the Joint Research Center (JRC).

EFSA's latest QPS update

The European Food Safety Authority has recently updated its list of safe microorganisms used in food or feed, known as the Qualified Presumption of Safety (QPS) list.

In the latest update from April to September 2023, no changes were made to the status of existing QPS microorganisms. Out of 71 microorganisms notified to EFSA, 61 were not further evaluated. This included 33 excluded from the QPS list, mostly filamentous fungi, Escherichia coli, Enterococcus faecium, and a bacteriophage. Additionally, 28 taxonomic units already had QPS status. The remaining 10 notifications involved 9 taxonomic units evaluated for QPS inclusion. Some were not recommended due to safety concerns or limited knowledge in food or feed chains. However, three, Chlamydomonas reinhardtii (C. smithii), Clostridium tyrobutyricum and Candida oleophila, were recommended with specific qualifications.

EFSA also clarified that genetically modified strains (GMMs) can be considered for QPS status if their parental or recipient strains are safe, and the genetic modifications pose no safety concerns.

Safe levels set for manganese

The European Food Safety Authority (EFSA) has recently released its opinion on the tolerable upper intake level (UL) for manganese, a critical step for establishing its maximum level in food and supplements. Due to insufficient data to establish a dose-response relationship and identify a reference point for manganese-induced neurotoxicity, EFSA could not set a UL across any population group. EFSA was therefore tasked to identify the highest intake level where there is reasonable confidence on the absence of adverse effects. This safe level of intake was set at 8 mg/day for adults ≥ 18 years (including pregnant and lactating women) and ranged between 2 to 7 mg/day for other groups. EFSA calls for further research on biomarkers, on the relationship between manganese intake and neurological effects, and the need to explore potential toxicity beyond neurotoxicity.

EFSA retains folic acid ULs for all

The European Food Safety Authority (EFSA) has recently reconfirmed the tolerable upper intake level (UL) for folic acid/folate across all population groups, setting the limit at 1000 µg/day for adults including pregnant and lactating women. The ULs apply to the combined intake of folic acid, (6S)-5-methyltetrahydrofolic acid glucosamine, and L-5-methyltetrahydrofolic acid calcium salts. EFSA also affirms that, under normal circumstances, it is unlikely for European populations to exceed these ULs. However, a potential exception exists for those who regularly consume food supplements with high doses of folic acid /5-methyl-tetrahydrofolic acid salts.

Proposed amendment to the definition of engineered nanomaterials

The European Commission is to refine the definition of 'engineered nanomaterials' in Regulation (EU) 2015/2283 on novel foods. The changes aim to modernise the existing definition, incorporating scientific and technical advancements. According to the proposal,"engineered nanomaterial" defines a manufactured material produced through various processes, consisting of solid particles with defined physical boundaries. These particles may exist on their own or as identifiable constituents in aggregates or agglomerates. For a material to be considered an engineered nanomaterial, 50% or more of its particles, as per the number-based size distribution, must meet specific conditions regarding their external dimensions. Additionally, materials with certain characteristics, such as a specific surface area by volume of < 6 m2/cm3 or high solubility, are not considered engineered nanomaterials. The proposal provides an18-month transitional period for implementation.

EFSA gives green light to monosodium salt of L-5-MTHF as folate source

The European Food Safety Authority (EFSA) has confirmed the safety and bioavailability of the novel food, monosodium salt of L-5-methyltetrahydrofolic acid (L-5-MTHF). Consumption is considered nutritionally advantageous, provided the combined intake with other folate forms stays below the established Upper Limits (ULs) for various age groups. Produced through chemical synthesis, this novel food is recommended as an alternative to folic acid and other folate sources in various food categories, including supplements.

Belgium

Concerns over sodium chloride supplements

The Superior Health Council in Belgium has issued a negative opinion on the sale of food supplements primarily or exclusively made of sodium chloride (table salt). They found these supplements to be potentially harmful due to their contribution to excessive sodium intake, given that the population already exceeds recommended daily salt limits of 5 g/d. The Council recommended reconsidering the "food supplement" status of such products while suggested that they might be suitable for specific dietary needs under medical supervision. Additionally, they called for regular assessments of salt consumption and encouraged balanced diets with lower salt intake, especially for children.

Introduction of a Nutrivigilance system

The Belgian authorities have recently introduced a Nutrivigilance system through two decrees. This system is specifically designed to address four food categories: food supplements, novel foods, foods for specific groups, and foods fortified with vitamins or minerals. Anyone can report adverse effects related to these categories through an online form or a downloadable PDF sent via email. While citizens and healthcare professionals have the option to report such adverse effects voluntarily, business operators are legally mandated to report any adverse effects.

Upon the receipt of these adverse effect reports, a comprehensive evaluation process is initiated, overseen by a panel of experts. Based on the findings of this evaluation, safety studies may be conducted for specific ingredients, and appropriate corrective actions may be taken on products or ingredients.

Germany

BfR warns against long-term use of high-dose vitamin D supplements

The German Federal Institute for Risk Assessment (BfR) has warned against the long-term use of high-dose food supplements containing vitamin D, emphasising that a balanced diet generally provides sufficient nutrients. BfR argues that while supplementation may be necessary for certain individuals, especially those with limited sun exposure, excessively high doses (e.g. 100 µg or more) can lead to health risks. In addition, prolonged use of such supplements has been associated with adverse effects, including reduced bone density, increased risk of falls, and impaired heart function.

Recognising that sufficient vitamin D levels are not always achieved through the body's own production, BfR suggests supplementation up to 20 µg per day, particularly during winter months for certain population groups.

The German Institute expresses concerns about the widespread availability of vitamin D supplements, both in traditional retail and online markets, with some products containing high doses. BfR strongly discourages the use of such supplements without medical supervision.

Additionally, BfR highlights the insufficient research on the interaction between Vitamin D and Vitamin K, particularly Vitamin K2, and the potential for adverse effects. BfR recommends limiting vitamin K supplementation to 80 µg of K1 or 25 µg of K2 per daily dose. It also warns that vitamin K can weaken certain anticoagulant medications. Older individuals on such medications should only take vitamin K-containing supplements under medical supervision.

Unnecessary CoQ10 supplementation

A recent Q&A from the German Federal Institute for Risk Assessment (BfR) concludes that CoQ10 supplementation is unnecessary. The BfR draws attention to existing scientific uncertainties, especially concerning ubiquinol and ubiquinone forms and note that some studies have

reported occasional undesirable effects, particularly related to the digestive system. However, the current understanding suggests no specific supply recommendations are needed for different population groups.

Importantly, the BfR emphasises health claims on CoQ10, evaluated by EFSA, were not scientifically proven. Therefore, they conclude that advertising using words such as promoting performance enhancement or immune system strengthening is not allowed in the EU. A general authorisation from 2014 in Germany permits up to 100 mg of CoQ10 per daily intake in food supplements, accompanied by a warning advising pregnant women, breastfeeding women, and individuals under 18 to avoid consumption.

Individuals taking coumarin-type anticoagulants or blood pressure medications are advised to seek medical guidance, particularly when considering CoQ10 supplements with daily doses exceeding 100 mg.
BfR reiterates that food supplements are not medicines. Responsibility for safety falls on manufacturers and distributors, emphasising the need for stringent monitoring by state federal food authorities.

Finland

Halved Vitamin B6 UL sparks warning labels for higher-concentration supplements

The Finnish authorities are urging an immediate implementation of warning labels for supplements with levels of vitamin B6 exceeding the revised tolerable upper intake level (UL). This warning must state: "The upper limit of the safe daily intake of vitamin B6 is 12 mg. The amount of vitamin B6 obtained from this product in a daily dose (x mg) exceeds this amount. Not for long-term use. ”The decision should be immediately implemented for information provided by distance sales, and be placed on the label of food supplements in the next batch or within 6 months at the latest. This move aligns with the recent opinion by the European Food Safety Authority (EFSA), reducing the UL of vitamin B6 from 25 mg to 12 mg. EFSA warns that exceeding this value may lead to peripheral neuropathy, causing dysfunctions and pathological changes in the peripheral nervous system, While the Finnish authorities haven't set national maximum levels, they rely on EFSA's ULs as safety guidelines for vitamins and minerals in food supplements.

Italy

PagoPA payment method

The Italian Ministry of Health has introduced a new payment method called 'PagoPA' starting in 2024. This platform allows users to make payments related to notifications of products such as food supplements, foods with added vitamins and minerals, and consultations on novel foods. Payment options on PagoPA include credit/debit cards, bank transfers, and other electronic payment methods. Companies making payments through PagoPA must clearly specify the purpose of their payment, indicating the category of the food product or the nature of the consultation. Additionally, they need to upload the payment receipt to the Italian NSIS electronic system platform for product notifications and consultations.

Guidelines for influencers and future plans

The Italian Communications Authority has released guidelines with the aim to ensure influencers' compliance with the Unified Text on audio-visual media services. These guidelines, which define influencers and establish content standards and sanctions, primarily target influencers in Italy with one million or more followers and a 2% or higher engagement rate. They also introduce a Technical Committee responsible for developing a code of conduct focusing on transparency and recognisability. Importantly, further collaboration involving influencer associations, platforms, and marketing agencies is foreseen to develop a more detailed code of conduct.

Denmark

Updated supplement guidelines

The Danish Food Agency has released new draft guidance for food supplements, replacing the 2019 version and seeking public feedback. This update clarifies definitions for small measured quantities, and restrictions on quantities of certain vitamins and minerals, especially those related to novel foods. The guidance also covers novel food regulations, labelling, probiotics etc.

Norway

Targeting illegal supplements: The Norwegian top priority for 2024

The Norwegian Food Safety Authority has outlined its main priorities for the food sector in 2024. Central to their agenda is the prevention of the sale of supplements containing illegal claims or defective labelling, along with stringent monitoring of growing online supplement sales.

To enforce these regulations, the Authority plans to offer guidance, conduct inspections, and prioritise education for industry stakeholders and consumers alike, stressing the significance of accurate labelling and marketing practices for food products and supplements.

According to the 2020 national inspection project "Illegal Claims about Food Supplements”, a significant portion of the supplement were marketed with medical claims, a practice reserved for medicines and not permitted for supplements. Businesses are urged to familiarise themselves with the rules governing the sale of food supplements, including the addition of ingredients/substances, as well as labelling.

Romania

More botanicals

The Romanian government’s Technical Committee has recently approved 19 more botanicals for use in food supplements.

The Netherlands

Consumer awareness: Supplements & Social media

The Dutch Authorities has released a video aimed at consumers emphasising that supplements are generally unnecessary for most individuals, except for specific vulnerable groups like pregnant women or the elderly. The video highlights the risks of consuming multiple products simultaneously and advises caution when combining supplements with medications. The video provides several recommendations, including: Always read the product label, be careful when purchasing supplements through social media channels. Be vigilant when taking

supplements alongside medications. Avoid products that make extravagant claims.

UK

Guidelines for health claims in supplement ads

The UK Advertising Standards Authority (ASA) has released guidelines regarding health claims in supplement advertisements. In essence, the ASA emphasises that supplements fall under the category of food, not medicine. Therefore, advertisers are prohibited from making medicinal claims, such as for influenza, COVID-19, clinical vitamin deficiency, Alzheimer's disease, memory loss, anxiety, and hangover prevention, unless their products are licensed as medicines. Advertisers may include General Health Claims (GHCs) in their ads, but only if they are accompanied by Specific Health Claims (SHCs) that have been authorised and listed on the Great Britain Nutrition and Health Claims Register. SHCs must accurately represent the authorised claims and must not imply a different interpretation. Advertisers are also required to provide evidence that their product aligns with the conditions specified in the SHCs. The use of customer testimonials does not exempt advertisers from compliance. Such testimonials should avoid prohibited claims and should be accompanied by appropriate SHCs when GHCs are promoted.

USA

FDA issues warning against fraudulent diabetes products

With the growing number of people diagnosed with diabetes, there has been a surge in the illegal sale of products that falsely claim to prevent, treat, or cure diabetes according to the U.S. Food and Drug Administration. Consequently, FDA strongly recommends avoiding these products for a range of reasons: They might contain harmful or ineffective ingredients, and some may be falsely labelled as non-prescription drugs or dietary supplements while containing hidden prescription drugs. They also state that using such products can also pose risks by causing people to delay or stop effective diabetes treatments.

FDA initiates peer review for NAC safety Evaluation

The FDA has completed its safety review of N-acetyl-L-cysteine (NAC) and added it to the Peer Review Agenda. This follows a citizen petition requesting the FDA to rule that NAC is not excluded from the definition of "dietary supplement."

FTC issues warnings to trade associations and influencers for social media posts on aspartame and sugar

The Federal Trade Commission (FTC) has issued warning letters to two trade associations and 12 health influencers regarding insufficient disclosures in their Instagram and TikTok posts endorsing the safety of aspartame or the consumption of sugar-containing products. The influencers, including dieticians, failed to adequately disclose that they were hired to promote the safety of aspartame or the consumption of sugar-containing products.

The FTC's notice includes penalty offences concerning misleading endorsements. The recipients could face penalties of up to $50120 per violation for future failures to disclose unexpected material connections. They were also asked to contact agency staff within 15 days and detail any actions taken or that will be taken to address the concerns.

The FTC's action aligns with its recent revision of the Guides for Endorsements and Testimonials.

Australia

Distinction between therapeutic goods and food for sport supplements

The Australian Therapeutic Goods Administration (TGA) has recently issued guidance to address the regulatory framework governing sport supplements. This aims to shed light on the distinction between sport supplements classified as either therapeutic goods or food products. TGA stresses that supplements may fit into one of two possible regulatory schemes: foods or therapeutic goods. Under the law, a product can either be a food or a therapeutic good, but not both. To facilitate better understanding, the TGA has provided a printable Fact Sheet addressing vital information for importers and sellers.

Argentina

Significant fee surge

Argentina has introduced a significant registration fee increase due to chronic inflation through ANMAT Disposition 25/2024, affecting food supplements. The main change is a substantial increase in the registration fee, rising from 50,560 Argentinean Pesos to 202,300 Argentinean Pesos (around 205 USD).

Gluten-free labelling & food availability

Argentina has updated its regulations regarding gluten-free labelling. The key change is the removal of the phrase "Without TACC" (SIN TACC in Spanish, meaning without wheat, oats, barley, and rye) from gluten-free claims (gluten free"/"free of gluten"/"does not contain gluten) and related logo. Additionally, establishments such as schools, hospitals, restaurants covered under Law 26588, are now required to offer gluten-free food options or menus.

Brazil

New rules for Novel Foods

Brazil has issued Resolution RDC 839/2023, updating rules for novel foods and ingredients. Key changes include revised definitions, introduction of risk-related definitions, stricter documentation requirements, and requirements for GMO-containing products. ANVISA aims to enhance transparency by making safety assessments public. The Resolution takes effect on 16 March 2024.

Changes to food supplement additives

Brazil has approved changes to the additives allowed in food supplements through Normative Instruction IN 267/2023, which amends IN 211/2023. These modifications include:
New additives /New limits:

Trisodium phosphate INS 339(iii) at 5000 mg/kg in liquid food supplement and 2200 mg/kg in solid forms.

Sodium polyphosphate INS 452(i) 2200 mg/kg in solid forms.

Modifications of the list of processing aids for food supplements, particularly enzymes and enzymatic preparations.

Introduction of fatty acid mono- and diglycerides (INS 471) as a lubricant in solid and semi-solid supplements (excluding those for infants and infants) in Annex IV of IN 211/2023.

These changes came into effect on 1 January 2024.

El Salvador

Chewable forms prohibited in new regulation

El Salvador has recently approved a new regulation through the Salvadoran Technical Regulation Agency (OSARTEC), known as RTS 67.06.02:22, related to foods for special diets, supplements, and probiotics. Prior to this regulation, these products were not subject to specific food laws and were instead governed by medicinal regulations.

For supplements, this regulation introduces the following provisions:

A requirement for supplements to contain a minimum of 15% of the recommended daily value for vitamins and minerals in the manufacturer's recommended serving size.

Establishment of maximum levels for vitamins and minerals, ensuring they do not exceed the tolerable consumption levels established for various age groups. If these levels are exceeded, such supplements will be classified as pharmaceutical products under medicinal regulations.

A prohibition of chewable and jelly forms for supplements.
Introduction of specific provisions for supplements designed for athletes, including limits on caffeine levels and other nutrient specifications.

A clarification that supplements should not have therapeutic properties.

A mandate that supplements must be taken orally exclusively.

Specifications are also given for the use of other ingredients like amino acids, fatty acids, glutathione, lactoferrin, flavonoids, carotenoids, nucleotides, and others.

Companies must seek product registration before marketing, with the registration remaining valid for a period of 5 years.

Inclusion of labelling requirements, including general warning statements and specific warnings depending on the product's composition.

General guidance on claims is also provided given the absence of an established list of permitted health claims. If health claims are used, scientific substantiation through human studies must be provided.

The regulation does not provide specific specifications for additives in supplements.

Azerbaijan

New import requirements

A recent import regulation in Azerbaijan has made it mandatory for dietary supplements to undergo state registration, as detailed in Cabinet of Ministers' Decree No. 442 of 11 December 2023. This regulation, in alignment with the Food Safety Law of 5 May 2022 (No. 523), requires:
food manufacturers to obtain approval from Azerbaijan's Food Safety Agency (AQTA), and imported food and feed products to be accompanied by a safety certificate to issue in accordance with the law of the exported country.

Novel foods, food additives, feed additives, dietary supplements, and natural mineral waters are all now subject to state registration.

Importers who are engaging in this process for the first time are obliged to submit electronic notifications via the national system, known as Avtomatlaşdırılmış Qida Təhlükəsizliyi İnformasiya Sistemi (AQTİS).

Additionally, the decree emphasises that imported food and feed must comply with Azerbaijan's labelling requirements (e.g product name, ingredients list, best-before date, and instructions for use).

Uzbekistan

Food Safety Regulations: New labelling requirements for supplements

Uzbekistan's Ministry of Health released in December a revised version of the national law on food safety, for public feedback.

This updated draft expands government oversight across all stages of manufacturing, processing, storage, transportation, sales, imports, exports, and disposal of foods. Notable changes in the document include the introduction of new terms such as "food contaminants," "foods for special dietary use," and "minimum levels of quality criteria". Changes also include the requirement for dietary supplements to bear a clear indication in Uzbek emphasising that they are not medicines. Furthermore, foods containing genetically modified organisms (GMOs) must now carry distinct labelling as GMOs.

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