

IADSA NEWSFLASH

July 2023

Regulatory news



ASEAN

New complexity

The ASEAN Product Working Group on Traditional Medicines and Health Supplements met physically for the first time since the pandemic in July in the Philippines, which has now taken over as Chair for the PWG, with Singapore now moving to Vice-Chair.

Along with their agreement to adopt the TMHS Agreement, Indonesia submitted a Declaration for traditional medicines allowing the country to take measures to protect genetic resources and traditional knowledge associated with these.

The meeting focussed its discussion on whether this Declaration by Indonesia should be considered as a 'reservation' or solely as a 'declaration'. Governments will now need to review the Indonesian declaration in more detail at the national level, which may delay final signing of the Agreement.

Faster market access for DHA supplements

China has recently issued a notice to extend the list of raw materials for supplements subject to filing (notification). The new version includes "docosahexaenoic acid (DHA)" as a new nutrient which would allow DHA supplements to access the market with less time and cost.

The new requirements apply to products targeting the adult population. A minimum daily amount of 200 mg and a maximum value of 1000 mg of DHA is also set. With DHA as a new substance, the following function and interpretation were also added:

Function claim: Supplement n-3 polyunsaturated fatty acids

Interpretation:

- n-3 polyunsaturated fatty acids provide essential fatty acid for human body.
- n-3 polyunsaturated fatty acids in the diet should account for 0.5%-2% of the total energy.
- Helps maintain healthy levels of blood lipids (triglycerides).

The notice also includes the following amendments:

- "casein phosphopeptide + calcium" as a new compound source of calcium (min 200 - max 1000 mg) - suitable group lactating woman
- "hemin chloride" as a new compound source of iron (min 5.5 - max 20 mg) - suitable group lactating woman

- "Vitamin K2 (synthesis method)" as a new compound source of Vitamin K. (min 15 - max 100 mg) - suitable group lactating woman.

India

RDA: extension of compliance date

The Food Authority has extended the compliance date for labelling products conforming with the revised RDA published in 2020. The extension is being given due to challenges faced in reformulating products and unused packaging inventories. It may be noted that the RDA 2020 relates to vitamins, minerals and amino acids notified by directions dated 16th July and 2nd August 2021. The extension is for six months from 1 July 2023.

Taiwan

FDA makes Trans-resveratrol a legal dietary supplement

The Taiwan's Food and Drug Administration (FDA) has recently authorised the use and labeling of a certain type of trans-resveratrol as dietary supplement as so long as the daily intake does not exceed 150 mg/day.

The regulation covers the use and labeling of trans-resveratrol derived from the fermentation of *saccharomyces cerevisiae* strain EFSC4687, a genetically modified brewers' yeast. The ingredient containing trans-resveratrol should have a purity level of 98 per cent and

must go through a purification process to eliminate genetically modified organisms (GMO) or gene segments.

Presence of heavy metal, such as lead and cadmium should be less than one ppm, while that of arsenic to be lower than 1.5ppm and mercury at less than 0.1ppm.

In addition, products containing the substance must be labeled to inform consumers that its use is limited to adults and should be avoided by pregnant or lactating women while people on medications should consult their doctors prior to consumption.

Thailand

Maximum levels introduced.

Thailand has now submitted its draft maximum levels for vitamins and minerals for health supplements to WTO. While Thai FDA has decided to align the maximum levels for certain nutrients with ASEAN, the Authority is still keeping country specific limits for vitamin A, D, E, K, B6, folic acid, nicotinamide, calcium, molybdenum and selenium. The limit for vitamin D has been increased from 5 to 15 mcg.

South Korea

Guidelines for smooth application

The Korean Ministry of Food and Drug Safety (MFDS) updated the Guideline on the preparation of Dossiers for Functional Ingredient Recognition of Health Functional Food so as to help better understand the requirements related to functional ingredient application. The guidelines clarify that applications relate to:

Ingredients not notified in the Health Functional Food Code Addition of functionality or change of the intake amount or manufacturing standards for the functional ingredients.

Addition of functionality, and addition or change of intake amount, manufacturing methods, specifications or other items that may affect the safety or function of listed functional ingredients.

The guidelines recall that functional ingredients are to be compliant with the laws and safety and functionality must be confirmed.

Applications which include the origin, development history, domestic and international recognition and use status, manufacturing method, characteristics of raw materials, traditional use, and toxicity test results among others will be reviewed by MFDS to make sure of the safety of ingredients is secured.

As for the proof of functionality, the authority will consider the research type and level, the consistency and relevance of results, etc., of human application tests, animal tests, and in vitro studies. For human application tests, the data must be demonstrated to be functional in human bodies by reviewing the appropriateness of the study design and test subjects, the presence of significant results, and whether functionality is achieved at the suggested daily intake.

New applications must be submitted to MFDS along with samples, and an inspection report.



EU

EFSA confirms cut of vitamin B6 UL

EFSA has now released its final opinion on a revised UL for vitamin B6 confirming the interim conclusions of a cut of 50% of the current UL. The UL is reduced from 25 to 12 mg/day. In its opinion, the EU's Food Safety Authority is also suggesting a series of recommendations for future research:

Additional research is needed regarding potential differences in the toxicity profile of the different vitamers of vitamin B6.

Additional research on toxicokinetics and toxicodynamics could help to refine the derivation of an Uncertainty Factor.

Further investigation of the mechanisms of vitamin B6 toxicity is needed and the identification of genetic traits that may influence individual susceptibility.

Additional research is required to investigate the impact of other factors, such as age and sex and

epigenetics, on vitamin B6 neurotoxicity.

Further investigation or analysis of the existing datasets would be needed to clarify the role of high vitamin B6 intake on bone health.

UL on folate to remain unchanged

EFSA has decided to retain the previously established EFSA UL for folic acid for all population groups. The UL of 1000 mcg/day for adults, including pregnant and lactating women therefore remains. The draft opinion is open for public consultation for 6 weeks.

In addition to the opening of the public consultation on the folate UL (see previous update), EFSA also published an external scientific technical report on 'Preparatory work for the update of the tolerable upper intake levels for folic acid/folate' which aims to collect and appraise scientific evidence that could be used to derive an upper intake level for folic acid/folate.

Transition measures clarified for E422, E471, E475 and E476

The European Commission has published guidelines/clarifications on the interpretation of transition measures regarding the new specifications for E422, E471, E475 and E476 aiming primarily to reduce the maximum limits for toxic elements (arsenic, lead, mercury, and cadmium).

According to the document, after 20 January 2024, a product can be sold through until the end of its shelf-life provided that the product is 'finished' and not further transformed along the supply chain.

New guidance on the exposure assessment of food enzymes

The European Food Safety Authority (EFSA) has recently published its guidance on how to estimate the exposure and evaluate the safety of enzymes used in food and feed.

Berberine, Fennel & plant preparations containing hydroxycitric acid (HCA)

The European Food Safety Authority is consulting on the protocols for the safety evaluation of Berberine, Fennel and plant preparations containing hydroxycitric acid (HCA). This evaluation is based on the request of Member States to initiate the so-called Article 8 procedure:

Berberine: The French authorities have provided a scientific assessment carried out by the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) on the safety of use of berberine-containing plants as ingredients in food supplements. In its opinion, ANSES concludes that the consumption of food supplements made with plants or plant preparations containing berberine can pose risks including gastrointestinal disorders, hypoglycemia and hypotension.

Plants containing hydroxycitric acid: The Spanish authorities have raised concerns regarding a potential risk to consumers (liver injury) linked to the consumption of the pericarp of the fruit of *Garcinia gummitutta* (L.) Roxb. containing HCA on the basis of a risk assessment conducted by the Spanish Agency for Food Safety and Nutrition (AESAN).

Fennel: The German authorities have raised concerns regarding a potential risk to infants and young children linked to the consumption of fruit preparations from bitter and sweet fennel, mainly due to the presence of estragole in these preparations, on the basis of a report by the German Federal Office of Consumer Protection and Food Safety and a risk assessment by the German Federal Risk Institute for Risk Assessment (BfR) of fennel teas for infants.

Concerns about use of probiotic claims

In a recent meeting of the EU Member States and the European Commission, Austria requested clarification from the French authorities on the permission given to the food supplement sector for the use of the term probiotics in France. Concerns were raised that several Member States were allowing this term while it is currently prohibited in Europe. The Commission reminded countries to take action to ensure conformity of their market with EU rules. Noting

the divergent views in the room, a suggestion was made to address this topic in a working group.

EGCG: When to apply labelling requirements

The European Commission was recently asked by Belgium to clarify whether the labelling requirements * for epigallocatechin-3-gallate (EGCG) in green tea extract would also apply to green tea used for flavouring purposes. The Commission clarified that the requirements were only applicable for EGCG used for nutritional and physiological purposes and therefore not applicable to flavourings.

**Should not be consumed if you are consuming other products containing green tea on the same day. Should not be consumed by pregnant or lactating women and children below 18 years old. Should not be consumed on an empty stomach.*

Help!

EFSA has recently created a LinkedIn community to find information, updates on the developments of IT tools, alerts on new training material and events, frequently asked questions, etc. It is also intended that the LinkedIn group should allow applicants to interact with other peer applicants, laboratories, and research representatives.

Connecting nutrивigilance systems

The European Food Safety Authority EFSA is aiming to explore the possibility of building a community of knowledge to interconnect information from nutrивigilance systems and potentially toxic plant-based substances in food supplements. In 2021, food supplements have been identified as a category of focus by the Emerging Risks Exchange Network (EREN) following safety concerns raised by the EFSA Scientific Committee and Advisory Forum.

EREN has recently suggested that the focus should be on: Work on Selective Androgen Receptor Modulators (SARMs); making use of the nutrивigilance systems in place for emerging risks identification; focus on plant-based food supplements; making use of the EFSA Compendium of Botanicals to map food supplements made of plants containing substances with QSAR/read-across predicted toxicity; exploring the possibility to

build a community of knowledge on food supplements; connecting EREN and StaDG-ER members interested in emerging risk identification in this field.

The EREN programme for 2023 includes a 2-year project to be outsourced as an external EFSA grant/procurement for the creation of a community of knowledge on plant-based food supplements with the following two tasks:

To identify nutrивigilance systems in and outside Europe and analyse information correlating food supplement intake and adverse health effects.

Use the EFSA Compendium of Botanicals, identify plant-based substances of concern with predicted toxicity (i.e. no experimental evidence), trace back plant species containing these substances, and whether these plants have been used in/as food supplements (and at which level).

Tackling Food waste: Act now

Stella Kyriakides, the European Commissioner for Health and Food Safety, has called for a better commitment of industry to address food loss and waste.

In a communication to the European Industry, Kyriakides highlighted that only a small number of companies (30 out of 488 signatories to the EU Code of Conduct on Responsible Food Business and Marketing Practices) committed to this goal.

The EU Code includes an aspirational objective to halve per capita food waste at the retail and consumer level by 2030 and reduce food losses along the food production and supply chains, in line with the UN Sustainable Development Goal Target 12.3.

To help companies in their efforts, different platforms have to be created.

EU Platform on Food Losses and Food Waste which aims to support all actors in defining measures needed to prevent food waste; sharing best practice; and evaluating progress made over time.

EU Food Loss and Waste Prevention Hub allowing the sharing of resources, latest developments and good practices.

Scientific hub

EFSA has launched a new hub 'Food Risk Assess Europe (FRAE)' which is an open access repository of selected scientific articles from national food safety agencies across the EU. FRAE provides English abstracts and summaries where needed. The articles can be filtered by country and language.

EFSA Compendium: Revision

EFSA aims to finalise the toxicity characterisation of naturally occurring substances found in botanicals and of possible concern for human health by October 2023. Among the 2701 plant species screened, 1537 substances were considered as substances of concern.

The new version of the EFSA Compendium COMBO database is expected to be released early 2024.

The Compendium has been developed as a tool to help risk assessors and risk managers to assess the safety of plant-derived products. However, as stressed on the EFSA website, "it has no legal or regulatory force and it may not be used as support or evidence in any disagreement or dispute pertaining to the legal classification of products or substances".

France

Botanical supplements: interaction and side effects

According to the French scientific assessment agency for food and nutrition (ANSES), botanicals in food supplements may pose a risk to consumers. Some of them can interact with medicines and supplements do not always have the right instructions for use. "Taking these supplements is not necessarily adapted to the needs of consumers and can even have "serious effects"" said ANSES.

Following the publication of an opinion in April taking into account the relevance of extending the warnings from medicinal plants to food supplements, ANSES has created a spreadsheet for 118 plants, addressing the potential interactions and contraindications. For example, supplements based on buckthorn bark are strictly contraindicated for people with heart or kidney failure.

In the opinion, ANSES also calls for European harmonisation of lists of plants, parts of plants, uses and levels authorised in food supplements, as well as restrictions and warnings governing their use. A nutriviigilance system extended to the European Union is also proposed.

Guide to Environmental Claims

The new edition of the practical guide to environmental claims is now available.

Intended for consumers, the guide aims to provide keys to understanding the various claims used: For example: What does "organic" or "natural" mean? What to expect when choosing a "recycled" product?

The Guide to Environmental Claims has been published just after the results of the Government survey dedicated to checking environmental claims on 1100 companies between 2021 and 2022. It appeared that a quarter of the companies checked had claims which were not substantiated.

UK

Easier!

The Food Standards Agency (FSA) and Food Standards Scotland (FSS) are launching a new system for businesses to make applications for 12 regulated products which include new additives, Novel foods, new Flavourings, PARNUTs and which required authorisation before they can be sold in the UK.

The approval process for regulated product applications broadly comprises four stages. 1. Validation, 2. risk assessment, 3. risk management, and 4. authorisation. The FSA expects to receive approximately 350 application each year. The new system is introduced as being more efficient and easier for applicants.



USA

FDA reorganisation

In a recent update to reorganise the agency's human foods program, FDA has announced the relocation of the current Office of Dietary Supplement Programs (ODSP) within a new Office of Food Chemical Safety, Dietary Supplements, and Innovation. According to the FDA Proposed Human Foods Program (HFP) Organization Chart, the Office of Food Chemical Safety, Dietary Supplements, and Innovation will work to modernise and strengthen oversight of food chemical safety, advance dietary supplement safety, and enable the HFP to support and effectively regulate food ingredient innovation. The US trade associations have expressed concern at this proposal.

Environmental Defense Fund call to revoke titanium dioxide in foods

The Food and Drug Administration has announced that they have filed a colour additive petition, submitted by the campaign group Environmental Defense Fund, et al., proposing that FDA repeal the colour additive regulation providing for the use of titanium dioxide in foods.

Expand access to dietary supplements through Health Savings Accounts

Bipartisan legislation has recently been introduced in the House of Representatives to amend the Internal Revenue Code (IRC) to include dietary supplements as a qualified medical expense. This change would allow Americans to use Health Savings Accounts (HSAs) or Flexible Spending Accounts (FSAs) to purchase dietary supplements.

The legislation is supported by IADSA members American Herbal Products Association, Council for Responsible Nutrition and United Natural Products Alliance.



Australia

Quality of probiotics

TGA is seeking feedback on the proposed new 'Guidelines for the Quality of Listed Probiotic Medicines.

The purpose of the Guidelines is to help companies meet the regulatory requirements to ensure the quality of their probiotic medicine is acceptable under the Therapeutic Goods Act 1989 (the Act); and to assist them by providing relevant applicable legislation related to ensuring the quality and stability of probiotic medicines.

The Guidelines will apply to probiotic medicines with an AUST L or L(A) number that are listed on the Australian Register of Therapeutic Goods (ARTG).

The Guidelines do not apply to medicines with therapeutic activity attributed to distinct ingredients that are inactivated, non-viable microorganisms and/or their components (known as postbiotics or paraprobiotics). If a postbiotic is a distinct active ingredient within a probiotic medicine, then these Guidelines apply to the probiotic ingredients.

New Zealand

Therapeutic Products Bill passes Parliament

The New Zealand Therapeutic Products Bill passed its third reading in the New Zealand Parliament on 19 July 2023 and will become operational in September 2026.

The Bill establishes a new framework for the regulation of food supplements as therapeutic Natural Health Products and requires the establishment of a new Regulator to administer what will become the new Act.

Secondary legislation around the practicalities of the regulatory regime such as allowable ingredients and product claims, are yet to be developed but will need to be in place by 1 September 2026.

Until late 2026, the existing Medicines Act 1981 (and Medicines Regulations) and Dietary Supplementary Regulations 1985 remain in force.



Egypt

Maximum levels for VMs

The National Food Safety Authority (NFSA) Drug Authority (EDA) of Egypt have released a white list for the permitted levels of vitamins and minerals in food supplements. Supplements containing higher levels are regarded as medicinal products.

South Africa

Business as usual

SAHPRA has issued a Guideline on a Roadmap and Transitional Process for Regulation of Category D Medicines which now includes supplements.

This document establishes the roadmap and general overview for the regulatory pathway of Category D medicines, including licensing and submission of applications for their registration following the implementation of the General Regulations, and applies to medicinal products for human use (DS and HS).

There has been no concession yet from SAPHRA on the challenges raised by the industry. In essence, requirements appear to be comparable to current law.



Argentina

Hemp under consideration

Argentina proposes to authorise hemp derivatives in food products, which would be then permitted in food supplements. From 14 July to 12 August, the National Commission of

Foods (CONAL) will receive comments on the proposal to authorise the use of hemp derivatives. The proposal seeks to approve:

- Under Article 917 of the Argentinean Food Code Cannabis sativa L. seed as an edible seed, with no more than 1% of THC for food use
- The addition of Article 1407 tris in the Argentinean Food Code to include hemp seed flour, with a minimum protein content of 20%
- The addition of Article 536 bis hemp seed oil.

Hydrolysed collagen in supplements

Argentina proposes to include hydrolysed collagen in the regulation for food products. From 13 July to 12 August, the National Commission of Foods (CONAL) will be receiving comments on the proposal to include hydrolysed collagen in the Argentinean Food Code, under Article 1417. The proposal seeks to authorise hydrolysed collagen only in food supplements, and not in conventional foods. Although this has been approved on a case-by-case basis and products are already in the market containing hydrolysed collagen, this was under the "novel food" procedure. If the proposal is approved, it would be allowed as ingredient in food supplements without prior authorisation of the ingredient. It would need to comply with the conditions and specification for collagen included in the current Article 1417.



Russia

Bill on supplement education

In April, a draft text amending the federal law on education in the Russian Federation and introducing mandatory notification of educational programmes and events was submitted to the State Duma (the Russian Parliament).

The bill reads that individuals and legal entities which provide education on the use of dietary supplements will be required to:

Inform participants on the goals and objectives, timeline, forms, venue, target audience, and organizer;

Notify federal authorities about the educational activity no later than 14 business days ahead of the event scheduled date.

The bill defines educational activity as an activity that is not subject to the state education licensing, and is aimed at disseminating knowledge and experience, developing skills, abilities, values, and competencies in the areas of intellectual, cultural, creative, physical and/or professional development of individuals. The authors of the document believe that the notification procedure will help prevent potential misuse of trainings and seminars by those acting in bad faith, while also providing the public with additional guarantees and protection.



Global

JECFA conclusions on the safety of titanium dioxide to be addressed later this year

JECFA, the international Scientific Expert Committee administered jointly by FAO and WHO, is expected to address the safety of the food additive titanium dioxide (INS171) in the final quarter of 2023, with publication of its opinion in early 2024.

Following the conclusions of the European Food Safety Authority (EFSA) that titanium dioxide can no longer be considered as safe when used as a food additive, the Codex Committee on Food Additives (CCFA) supported in 2021 the request of JECFA to re-evaluate its safety. While the new JECFA specification for titanium dioxide was established in 2012, it was noted that the last toxicological assessment was conducted in 1969. The conclusions of JECFA are highly anticipated to address the discord around the safety of titanium dioxide.

The EU ban of titanium dioxide in food (including food supplements) came into force in early 2022 with a 6-month transition period and was based on the EFSA conclusion that a genotoxicity concern could not be ruled out. However, the EU decision was dismissed by other agencies including the Food Standards Australia & New Zealand (FSANZ), Health Canada and the UK Food Standards Agency (FSA). Those countries have not introduced a ban of the additive in their respective countries.

Safety of aspartame re-confirmed

The Joint FAO/WHO Expert Committee for Food Additives (JECFA) and the International Agency for Research on Cancer (IARC) have been concurrently assessing the risks associated with aspartame. The assessments of the health impacts of the sweetener have recently been released by the two organisations.

On a positive note, JECFA has reaffirmed aspartame's safety by confirming there is no sufficient reason to change the previously established acceptable daily intake (ADI) of 0-40 mg/kg body weight for aspartame. This should help the Codex Committee on Food Additives (CCFA) to reconfirm the provisions for the sweetener in many food categories including food supplements.

Based on the conclusions of the IARC, aspartame will join the World Health Organisation's watchlist of substances that are considered to be "possibly carcinogenic to humans" (known as Group 2B) based on limited evidence it might cause cancer (specifically liver cancer) in people. IARC also notes there is limited evidence for cancer in lab animals and limited evidence related to possible mechanisms for it causing cancer. To put this into context, Group 2B (possibly carcinogenic to humans) includes very hot beverages over 65 degrees and pickled vegetables, and the higher risk Group 1 (carcinogens) includes processed meat.

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