IADSA NEWSFLASH

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Regulatory news

ASEAN

Signing date

The ASEAN Health Supplements Agreement is scheduled to be signed by the ASEAN Economic Ministers at their meeting in Cambodia from 5-11 September. This is the critical final stage in the ASEAN process that started in 2004. From that point, the focus moves primarily onto implementation by the Member States.

India

Exempt from nutrition declaration

Health supplements were required to declare macronutrient amounts including energy, protein, fat and carbohydrates under the general labelling and display regulation (2020). The Regulation did not specifically address the insignificant contribution of products sold in small, measured quantities or dosage forms. Under a proposed amendment, health supplements, nutraceuticals and foods for special dietary use, "in tablet and capsule format with respect to macronutrients when sources of energy are insignificant" would now be exempted. In addition, the tolerances for label declared nutrients is 20% instead of the previous 10% limit. These changes are in operation from 1 July, while awaiting final publication for enforcement.

Korea

Bringing some glossiness to claims

The Ministry of Food and Drug Safety (MFDS) has recently issued its guideline for the evaluation of new functional claims related to hair health.

Under the Heath Functional Food Act, if a company intends to use a non-permitted functional ingredient or new functional claim, an application should first be submitted to MFDS.

The guideline stipulates that function claims for hair health promotion refer to claims that 'can help maintain a good condition of hair', that are "helpful in relieving physiological hair loss and increase the resilience and glossiness of hair". However, MFDS stressed that claims that mislead consumers into thinking the product can assist in anti-hair loss or has other treatment effects are prohibited.

As for the type of studies required, it is clarified that human studies should take into consideration the hair growth cycle with a minimum duration of 24 weeks. Such studies should be carried out with adults between 18 to 60 with slight hair damage but without hair loss symptoms. The following biomarkers are proposed

- Promotion of nutrients (hair amino acids, such as cystine, methionine, etc.) supply to hair
- Antioxidant and anti-inflammatory effects
- Cell proliferation
- Controls of Hair Follicle Cycling
- Change in hair resilience
- Change in hair glossiness
- Change in hair diameter
- Beneficiary satisfaction
- Evaluation of clinical photography of hair
- Change of hair amount per unit area

Recycling: packaging rules

The Ministry of Food and Drug Safety (MFDS) has issued the Food Sanitation Act setting legal requirements for the use of recycled resources in manufacturing of food packages. Manufacturers aiming to produce containers and packages using the recycled resources, will have to apply for MFDS' recognition to be certified. Requirements for such an application are not yet known.

Hong Kong

CBD to become illegal

A paper from the Hong Kong Security Bureau to the national Legislative Council proposing to list CBD under the Dangerous Drugs Ordinance seems to be under consideration. A transition period of 3 months could be foreseen to dispose or destroy non compliant products.

According to the Hong Kong Security Bureau, since 2019, about one-third of CBD product samples tested were found to contain traces of THC, the main psychoactive compound in marijuana.

It is understood that exemptions would be given to those who have been prescribed CBD-containing products for medical use, or hold a license issued by the Department of Health.

EU

Reviewing consumer's attitude towards sustainable food

The upcoming proposal from the European Commission on a legislative framework for sustainable food systems will encompass a sustainability labelling framework.

The EU Joint Research Centre (JRC) has been asked to review existing evidence on consumer expectations, understanding and behaviour related to sustainability information on food. In addition to scientific publications, the JRC will also review relevant research documents or papers produced by public authorities, academics and businesses, which have not been published in peer-reviewed scientific journals.
This review will include reports and/or other relevant papers with regard to consumer expectations, understanding and behaviour related to sustainability information to consumers on food including claims, labels and logos.

Green tea warning

The final proposal of the European Commission aiming to restrict the use of green-tea catechins, to ensure that foods and supplements containing this substance are safe, is publicly available in all languages.
Catechins are a type of compound found in green tea. In 2018, the European Food Safety Authority issued a scientific opinion that catechins in green tea extracts taken as a food supplement could risk liver injury. This opinion was issued following alerts from Norway, Sweden and Denmark on adverse events reported from consuming green-tea extracts. Under the proposed provisions, green tea supplements should come with warnings and the intake of epigallocatechin-3-gallate (EGCG) should not exceed 800 mg a day. Aqueous green tea extracts containing (-) epigallocatechin-3-gallate which after reconstitution in beverages have a composition comparable to traditional green tea infusions are excluded from the scope of this proposal.
The text has now been sent to the European Parliament for a scrutiny period ending on 7 October 2022. A transition period of 6 months is also foreseen for products not compliant with the new provisions.
This decision to authorise the use of green tea extracts containing-epigallocatechin-3-gallate under the proposed conditions of use and labelling requirements should be revised in four years given the remaining scientific uncertainty related to the hepatotoxicity of the substance.

Revision of nano definition

The European Commission (EC) has clarified the definition of nanomaterials in a new Recommendation to align legislation across all sectors in the EU. The new definition should be used in EU and national legislation, policy, and research programs. The Recommendation states:

'Nanomaterial' means a natural, incidental or manufactured material consisting of solid particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates, and where 50% or more of these particles in the number-based size distribution fulfil at least one of the following conditions:

- one or more external dimensions of the particle are in the size range 1 nm to 100 nm;
- the particle has an elongated shape, such as a rod, fibre or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm;
- the particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm;
- in the determination of the particle number-based size distribution, particles with at least two orthogonal external dimensions larger than 100 µm need not be considered.
- however, a material with a specific surface area by volume of < 6 m2/cm3 shall not be considered a nanomaterial.

The new definition replaces the definition published in 2011. Main differences are:

- The general definition is based on size and form only. It does not cover the nano functionality aspect.
- The general definition is limited to solid particles, excluding liquids (e.g. micelles, nano droplets) and gasses.
- The general definition covers not only intentionally manufactured nanomaterials, but also those naturally occurring and (unintentionally) formed during production.
- The general definition introduces a threshold cut-off point at 50%.

France

ANSES call for vigilance on turmeric-based supplements

The National Food Safety Agency (ANSES) warns of the risk of adverse effects associated with the consumption of turmeric-based food supplements. In high doses, this spice can be toxic, especially to the liver said ANSES.
Recently, Italy has recorded around 20 cases of hepatitis involving food supplements containing turmeric. In France, the nutrivigilance scheme has received over 100 reports of adverse effects, including 15 reports of hepatitis, potentially related to the consumption of food supplements containing turmeric or curcumin.
"Curcumin has very low bioavailability, i.e. it is poorly absorbed into the bloodstream and is very rapidly eliminated by the body. Manufacturers have developed various formulations to increase this bioavailability and thereby enhance the effects of curcumin" explains Fanny Huret, coordinator of the expert appraisal at ANSES.
To prevent cases of poisoning, ANSES advises companies marketing food supplements to provide detailed data on the bioavailability of their products

so that a specific maximum daily intake level may be defined. ANSES also stressed that it is not recommended for people suffering from biliary tract pathologies to consume these supplements, because of their choleretic properties. Moreover, there is a risk of curcumin interacting with certain medications such as anticoagulants, cancer drugs and immunosuppressant. The Agency advises individuals taking these medications not to consume food supplements containing curcumin without seeking medical advice. The issue of curcumin will likely land on the European Commission table in view of a new Article 8 procedure. A potential ban or restriction of use could be foreseen at the EU level.

Prevent green washing

A new Decree No. 2022-539 that regulates the communication on carbon neutrality will come into force on 1 January 2023.

It concerns advertisers mentioning the carbon neutrality of one of their products or services in an advertisement or on packaging, by claiming e.g. a "zero carbon", "climate neutral", etc.

These advertisers will be required to carry out annually a greenhouse gas (GHG) emissions assessment of their product or service according to the French standard NF EN ISO 14067, covering the entire life cycle. A summary of this assessment specifying, among other things, the scope, the emission factors chosen and the geographical areas where the emissions take place will need to be accessible by displaying a URL or QR code link.

In addition, advertisers will have to provide a 10-year GHG emissions reduction trajectory for the product or service, to be renewed every 5 years.

The advertiser will be obliged to remove the claims on their packaging if during 2 successive years the emission unit linked to the product or service increases.

The advertiser must ensure that the compensation actions are not unfavorable to ecosystems in place and may only display the statement "compensation carried out in France" if all the compensation projects are carried out there.

Of concern

The French Agency for Food, Environmental and Occupational Health & Safety was again requested by the Directorate General for Competition, Consumption and Fraud Prevention (DGCCRF) to provide scientific and technical support relating to the plants and essential oils that are the most involved in the nutrivigilance cases reported to ANSES.

This request is part of an ongoing reflection by the DGCCRF on the procedures for control/monitoring of food supplements containing plants/plant preparations; the methodology for prioritising the plants that should be subject to such monitoring and, if necessary, future referrals to ANSES or proposals for regulatory work under the so called Article 8 procedure allowing the EU to ban or restrict the use of substances for which there are safety concerns.

ANSES highlighted that between 1 January 2016 and 15 October 2021, 507 cases were evaluated involving one or more food supplements containing at least one plant and for which the Nutrivigilance Working Group concluded minimum possible imputability. In total, for these 507 declarations, 283 different plants are involved. Among these, Melissa officinalis Passiflora incarnata, Eschscholtzia californica, Curcuma spp. As for essential oils, 66 cases were evaluated covering 49 essential oils.

Lithuania

Setting THC limits

Lithuania has notified the European Commission about the draft Order setting maximum levels of tetrahydrocannabinol (THC) in fibre hemp products. A limit of 2 mg/kg is proposed for food supplements excluding those supplements intended for use by infants, children under 18, pregnant and lactating women. A zero tolerance is set for those supplements targeting infants, children under 18, pregnant and lactating women.

This text took into account the work carried out in 2020 by the European Commission on Fibre Hemp, where it reported that foodstuffs containing 0.2% of THC would pose a public health risk and therefore could not be placed on the EU market. In its recent opinion, EFSA determined acute toxicity at 1 µg THC per 1 kg of human body weight.

The new law is expected to enter into force on 1 Jan 2023.

The Netherlands

Pyrrolizidine alkaloids: Alignment with EU

The Dutch authorities have recently amended their national legislation to align with the Commission provisions setting maximum levels of pyrrolizidine alkaloids in tea and herbal infusions, food supplements and other foods (Commission Regulation (EU) 2020/2040 which entered into force on 1 July).

Turkey

2 in 1

The Ministry of Food Agriculture and Livestock (MinFAL) which is in charge of food supplements has been consulting on a draft regulation combining the two current texts regulating supplements in Turkey. The proposal aims to re-establish the procedures and principles regarding the production, preparation, processing, storage, import, advertisement, and placing on the market of food supplements on the market. It also includes limits for vitamins and minerals and a range of other ingredients.

Claims relief!

The long-awaited list of health claims in Turkey permitted for use in supplements is now under public consultation.

The Ministry of Health who took over the responsibility of health claims from MinFAL, the Ministry of Food Agriculture and Livestock, is consulting on two documents: "Draft Guideline on the Use of Health Declarations" and the “list of health claims”.

In 2018 a legislative amendment changed the way health claims should

be supervised. The responsibility related to the use of health claims in the advertisement, promotion, and labelling of foods and food supplements was passed into the hands of the Turkish Pharmaceuticals and Medical Devices Agency ("TİTCK") within the Ministry of Health ("MoH").

Since this time, the future of the Health Claims Regulation remained uncertain. A conservative approach was initiatively considered.

USA

Mandatory product listing: Imminent?

The U.S. Senate is considering two separate bills that would create a new requirement for mandatory product listing (MPL) for all dietary supplements marketed in the United States. One of these is found in section 811 of S. 4348, the Food and Drug Administration Safety and Landmark Advancements Act of 2022 (FDASLA), which will be the focus of a markup in the Senate Health, Education, Labor, and Pensions (HELP) Committee on Tuesday, June 14, 2022. The other is standalone legislation recently introduced by Senator Durbin (D-IL) and Senator Braun (R-IN), S. 4090.

In 2019, FDA estimated the US market contains more than 50,000 dietary supplement products and perhaps as many as 80,000 or even more, compared to an estimated 4,000 products in 1994 when Congress passed the Dietary Supplement Health and Education Act (DSHEA).

Dietary supplements are not subject to pre-market approval. Manufacturers have generally the obligation to notify FDA before marketing new dietary ingredients (NDIs) in their products under a provision in DSHEA intended to ensure supplements containing the NDIs are reasonably expected to be safe. S.4348 - FDASLA Act of 2022 S.4090 - Dietary Supplement Listing Act of 2022.

FDA releases finalized NAC enforcement discretion guidance

The Food and Drug Administration (FDA) has released a final guidance announcing a policy of enforcement discretion for products containing N-acetyl cysteine (NAC). This final guidance is not substantively different from a draft guidance previously released in April this year. FDA states that it is releasing the enforcement discretion guidance as the agency considers regulatory action to include NAC in the definition of dietary supplement.

Australia

Testimonials and endorsements in advertising

The TGA has published new guidance on the use of testimonials and endorsements in advertising.
The guidance aims at clarifying the intention of the updated Section 24 of the Therapeutic Goods Advertising Code 2021 (the Code) that began on 1 January 2022 and is expected to be fully implemented by 30 June 2021.

E-commerce priority

Australia's Therapeutic Goods Administration (TGA) has published its compliance priorities for imports, advertising and supply. The list of priorities for 2022/2023 includes seven compliance priorities including goods associated with COVID-19, medicinal cannabis, sports supplements and unapproved goods on e-commerce platform.
TGA is particularly concerned that some unapproved complementary medicines being advertised and sold through online stores and e-commerce platforms use unlawful testimonials and unsubstantiated claims to advertise the products.
TGA is working with relevant online stores and e-commerce platforms and taking enforcement action where appropriate including where non-compliance is identified.

Nitrosamine, informing manufactures

The Therapeutic Goods Administration (TGA) has recently published an updated web page in relation to Nitrosamine impurities in medicines. This includes detail on sources, acceptable intake limits and testing.

'Long-term exposure over a period of years to nitrosamines that exceed certain levels can increase the risk of developing cancer' said TGA who has set acceptable intake (AI) limits for many nitrosamine impurities to ensure products remain both safe and of high quality.

The limits are used to determine if regulatory actions are required for affected products.

Argentina

Botanicals: Obsolete list

Argentina has recently revoked its permitted and banned botanicals in food supplements.This resulted from the latest update of the food supplement regulation issued at the end of 2020, which modified article 1381 of the Argentinean Food Code and introduce a revised list of botanicals.This initiative is part of ANMAT's simplification of processes and regulations.

El Salvador

Post registration guidance

On 23 June the National Directorate of Medicines published in the Official Gazette a series of guides on post-registration procedures for pharmaceutical products, which includes nutritional supplements. These include the following:

- Guide to request the free sale certificate
- Guide to authorise post registration modifications: specific documentation to be submitted depending on the modification made
- Guide to authorise advertising and promotion
- Guide to verify good storage practices