

IADSA NEWSFLASH

September 2020

Regulatory news



ASEAN

ASEAN Agreement, Revised timelines

Following the Heads of Delegation meeting that took place early July where a compromise on the agreement text has been reached, the Member States are now working towards the following timeline:

Latest ASEAN HS Harmonisation Timeline

- TMHS Agreements Text Finalisation 7-8 Jul 2020 Virtual
- AMS Legal Scrubbing End Sep 2020
- PWG Task forces Pre-Meetings Oct 2020 ahead of PWG dates yet to be decided
- 33rd TMHS PWG: Endorsement of Agreements 27-28 Oct 2020 Virtual
- National Approval Procedures Apr 2021
- ACCSQ Endorsement May 2021
- SEOM Endorsement June 2021
- AEM Signing July 2021

China

Health Foods: Requirements for literature review

To further strengthen the review of the scientific literature for the registration of health foods, the State Administration for Market Regulation

(SAMR) is consulting on its draft Key Points for Literature Review of Health Food Formula.

The draft paper covers the scientific evidence that is deemed to be acceptable for the literature review in order to support the claimed effect and the product composition.

Change of leadership

The Central Committee of the Communist Party of China has recently decided to appoint Zhang Gong as Party Secretary of the State Administration for Market Supervision and Administration.

Live streaming watched

The State Administration for Market Regulation SAMR has recently launched a public consultation on its draft of Guidelines to Strengthen Online Live Streaming Marketing Activities Supervision.

Under the proposal, advertisement for health foods should not be released in live streaming unless approval has been granted.

Live streaming for Cross-Border E-Commerce (CBEC) related to supplements will also be impacted. Such products should not claim health functions in live streaming as it will be considered advertisement. Interested parties have until 28 August to submit their comments.

Filing: technical requirements clarified for 5 ingredients

The Chinese State Administration for Market Regulation (SAMR) is consulting on the draft of Technical Requirements of Filing Health Food Products related to the use of 5 ingredients.

The draft specifically focuses on the technical requirements and manufacturing techniques for the filing/notification of health food containing:

- Coenzyme Q10 in tablet (oral, lozenge, chewable), granule, hard capsule, and soft capsule.
- Broken Ganoderma lucidum spores in tablet (oral), granule, hard capsule, and powder.
- Spirulina in tablet (oral), granule, hard capsule.
- Fish oil in soft capsule.
- Melatonin in tablet (normal, lozenge), granule, hard capsule, and soft capsule.

The inclusion of the powder form appears to be new and is so far only permitted for Ganoderma lucidum spore health foods.

Gummies & powders under consideration

The State Administration for Market Regulation (SAMR) is considering the authorisation of gummies and powders as possible dosage forms for the notification of vitamin and mineral supplements. Up to now, the approved dosage forms for health food filing/notification include tablets, hard capsules, soft capsules, granules, pills, oral liquids and drops.

India

Mitigating difficulties during lockdown

The Food Safety and Standards Authority of India (FSSAI) has issued several orders relaxing timelines and alternate procedures during the lockdown. Application for renewals of licenses and registrations (LR) expired or expiring since March 2020 are deemed valid until 31 December 2020 without late fee payment. Where LR

services online are unavailable due to internet connectivity, State Authorities are required to adopt offline processing using the standard operating procedure published. It has further asked FDA's of State /Union Territories to implement e-inspections wherever physical inspections are difficult for new LR's. Pre-inspections by submitting videos or live streaming of the premises etc may be conducted for high risk foods.

Labelling monitored

The Food Safety and Standards Authority of India (FSSAI) has recently requested Directors, Regional Offices and Commissioners of Food Safety of all States to ensure strict compliance of the labelling provisions for all products falling under the Standards related to Health Supplements, Nutraceuticals, Foods for Special Dietary Use, Foods for Special Medical Purpose, Functional Foods and Novel Foods.

ITC-HS linked to Indian food code

In a step up to e-governance, the Food Safety and Standards Authority of India (FSSAI) has issued a public notice linking the Indian Trade Clarification based on Harmonized System of Coding (ITC - HS codes) with the Indian Food Category Code (FCS).

The list contains ITC-HS codes, food category/subcategory, product description, risk classification, FCS code, reference to standards; all items are expected to have a food end use. Products covered under the FSS (Health supplements, nutraceutical, etc.) Regulations 2016 are also listed; including vitamin, mineral and other premixes. Electronically networked with Indian Customs (ICEGATE) and the Indian Food Laboratories Network (INFOLNET), this feature will facilitate smooth trade and interactions at entry point. The notice has been made available to all food importers for their input.

FSSAI new licensing portal

Since June, the Food Safety Compliance System (FoSCoS) replaces the former Food Licensing and Registration System (FLRS). Towards ease of doing business, the FSSAI has told States to ensure that licensing authorities refrain from repeated clarifications or requests for documents not within the scope of the applications.

In a significant upgrade the new portal has the architecture to link up with several IT based platforms such as FoSCoRIS (food safety compliance through regular inspection and sampling system), InFoLNet (Indian Food Laboratory Network), FICS (Food Import Clearance System) among others. Digitalization of FBO compliance is expected to reduce face to face engagement, consistency in procedures and documentation.

Thailand

Melatonin status clarified

The Food and Drug Administration (FDA) of Thailand has clarified that melatonin is not currently permitted as an ingredient in food or as any food product. This clarification comes in response to the promotion of melatonin-containing supplements through social media to contribute to sleep.



European Union

New step towards pyrrolizidine alkaloids limits

The European Commission has now notified its proposal for setting levels for pyrrolizidine alkaloids (PA) to WTO. The decisions follow a series of opinions from the European Food Safety Authority (EFSA), addressing the risk to public health related to the presence of PA in food. In 2017, the Authority notably published a statement on the risks related to the presence of pyrrolizidine alkaloids in honey, tea, herbal infusions and food supplements.

In order to minimise the risk, the setting of maximum levels in foods is now under consideration by the EU. For food supplements, the following limits are proposed:

- Supplements containing herbal ingredients including extracts: 400 mcg/kg
- Pollen based food supplements: 500 mcg/kg.

Addressing nutrient/additive dual use

The European Food Safety Authority has launched an open

consultation on its draft Statement on the derivation of Health-Based Guidance Values (HBGVs) for regulated products that are also nutrients. This Statement describes the specific considerations that should be followed for regulated products (particularly food additives and pesticides) that are also nutrients to ensure an integrated and harmonised approach for the hazard and risk characterisation, considering the intake from all relevant sources.

"Some regulated products are also nutrients; this can lead to a complex situation in which two assessments, requiring the establishment of HBGVs for the same substance (i.e. a nutrient), are carried out under different regulatory frameworks, using similar but not identical scientific methodological approaches" said EFSA.

This document is important for food supplements especially when the European Commission will resume its work on setting maximum levels for vitamin and minerals supplements.

No to probiotic Bi-07

The European Food Safety Agency (EFSA) has recently rejected an application for the health claim *Bifidobacterium animalis* subsp. *lactis* Bi-07 and the improvement of lactose digestion in individuals who have difficulty digesting lactose.

Two human intervention studies which investigated a single dose effect of Bi-07 on lactose digestion using the hydrogen breath test, as well as on gastrointestinal symptoms were submitted.

While these studies show that consumption of the microorganism increases lactose digestion in individuals with lactose maldigestion, EFSA indicated that the studies provide no evidence that increasing lactose digestion improves the gastrointestinal discomfort in the target group.

Food donation

The European Commission is to amend its food hygiene rules, some of which relate to food donation. The aim is to facilitate redistribution of food whilst ensuring its safety for consumers. The proposal clarifies that:

- Donating food is allowed before the 'use by date,
- Donating food with past 'best before' is allowed.

Companies should also ensure that products are not injurious to health by taking into account the date of minimum durability or the 'use by' date, ensuring sufficient remaining shelf-life, the integrity of the packaging, the proper storage and transport conditions, the organoleptic conditions and ensuring traceability. The Commission has also adopted a Notice providing guidance on food safety management systems to reduce food waste and facilitate safe food donation practices.

Novel Vitamin D2 stimulating discussion on EU harmonisation of maximum levels

The European Commission has recently authorised the placing on the EU market of a vitamin D2 mushroom powder as a novel food. The novel food, for which the authorisation is underpinned by a positive EFSA opinion, is intended to be used in food supplements (15 mcg/day excluding infants) and a number of other food categories.

During the voting procedure, the Netherlands however voted against this authorisation. The Dutch authorities were indicating that the vitamin D2 mushroom powder as a novel food was to be used as a new source of ergocalciferol which was not the purpose of the novel application. The Dutch authorities therefore felt it was not appropriate to specify individual food categories to which the NF may be added.

The Netherlands took also the opportunity of the discussion to call upon the European Commission to resume its work on setting maximum levels for vitamins and minerals in food supplements and fortified food by referring to a letter recently sent by 19 Member States (including The Netherlands) to the new DG SANTE Commissioner Ms. Kyriakides.

Belgium

Botanicals: A change of mind

The Belgian Plant Commission has issued new advice on three botanicals that could impact the placing on the market of food supplements containing them.

1. *Cananga odorata*: A reduction of the daily amount of safrole from 3 mg to 0.6 mg is advised. This decision is in line with the recent recommendations

of the Commission to limit the safrole content to maximum 0.6 mg for the essential oil of *Cinnamomum verum* J. Presl. (bark)

2. *Cotinus coggygria*: This botanical is currently considered to be a dangerous plant unless the analysis shows that the preparation does not contain a detectable amount of ptaquiloside. The Commission has recently indicated that this current derogation would no longer be application due to the high level of tannin content that poses a risk to health when used in supplements.

3. *Rhus* spp. This botanical is also currently considered to be a dangerous plant, with conditions for derogation: 'Only the use of small amounts of non-concentrated fruit is allowed in the preparation of meals'. However the Commission has now highlighted the potential allergic reactions due to urushiols and high tannin content, concluding that use of *Rhus* spp. in food supplements poses also a risk to health. The current derogation for use of this botanical in food supplements is therefore now questioned.

In all three cases, although the legislation has not yet been amended, these opinions will likely be considered for new food supplements containing these botanicals during the notification process.

Germany

Warning against too much vitamin D

Intake of high dose of vitamin D is not necessary from a nutritional point of view said the German Federal Institute for Risk Assessment (BfR).

In its recent opinion 'Vitamin D: intake of high-dose food supplements unnecessary', BfR explains that is possible through the intake of high-dose vitamin D supplements that a risk of overdose is observed. This overdose could also lead to a risk of hypercalcaemia due to an increased calcium levels in the blood serum.

The BfR recalls that EFSA has established an Upper Level (UL) of 100 µg for vitamin D, whereby the UL value includes the intake of all vitamin D sources (via supplements, the normal diet and enriched foods). Therefore, when taking high-dose vitamin D supplements, there is a risk that this value can be exceeded in combination with the other intake sources. The BfR concluded that if enough time is spent outdoors and the skin is adequately exposed to the sun while

having a balanced diet, a good supply of vitamin D can be achieved without taking vitamin D supplements. A daily intake of vitamin D preparations with doses of 50 µg or 100 µg is not necessary from a nutritional point of view.

Pyrrrolizidine alkaloids (PAs): Supplement source of concerns

While the European Commission is about to pass a law setting new provisions regarding the levels of pyrrrolizidine alkaloids (PAs) in food supplements, the German Federal Institute for Risk Assessment (BfR) is reiterating the need to continue reducing the levels of 1,2-unsaturated PA in all food groups by improving cultivation, harvesting and cleaning methods. This applies particularly to food groups such as herbs / spices and food supplements. According to BfR, food supplements may be a major contributor to the total intake of 1,2-unsaturated PAs. They therefore recommend that consumers are aware of this.

France

No to miracle products

In a recent post on its website, the French General Directorate for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF) has alerted consumers to be vigilant against operators taking advantage of the Covid-19 pandemic. The warning targets specifically food supplements claiming to prevent or cure the disease. These claims often refer to boosting the immune system or preventing viral infections of the respiratory tract, and sometimes even fraudulently claiming they are 'approved by the WHO', said the Authority.

Promises that consumers can be cured of serious illnesses or their symptoms are misleading under the Consumer Code, which provides for sanctions against those who are found guilty. Sanctions could entail imprisonment for a maximum of 2 years and/or a fine of € 300,000.

Ireland

Step-by-step safety approach for VM supplements

The Food Safety Authority of Ireland (FSAI) has published a step-by-step guide to the assessment of the level of vitamins and/or minerals in food

supplements. This practical guide follows the publication of the 2018 Report of the Scientific Committee of FSAI on a risk assessment approach for evaluating the safety of vitamins and minerals in food supplements in Ireland. Until EU harmonised maximum levels of nutrients for use in food supplements are established, FSAI recommends that this guidance be used by companies intending to market their products in Ireland, in order to establish their safety.

Notably, the new publication provides clarity on the upper intake level and maximum safe level for vitamins and minerals in food supplements in Ireland. Maximum safe levels are in particular set for 7 nutrients, namely: vitamin A 1700 µg, vitamin B6 20 mg, vitamin C 1800 mg, vitamin D 75 µg, beta carotene 8 mg, folic acid 500 µg, magnesium 250 mg.

The Netherlands

Caffeine - first steps towards EU action

The Dutch authorities may request the European Commission to look at limits of caffeine in food supplements. The recent assessment of the Dutch Institute for Public Health and the Environment (RIVM) reveals that the consumption of caffeine food supplements could result in excessive dietary caffeine intake that can greatly exceed the amount of caffeine ingested from the diet for adults and adolescents.

Effects on the central nervous system (such as an increase of sleep latency and decrease of sleep duration, anxiety, perceived exertion during exercise) and the potential 'masking' effect of caffeine on alcohol intoxication was particularly emphasised.

According to RIVM, the conditions are met to initiate the Article 8 procedure allowing the EU to prohibit, restrict or put under scrutiny the use of the ingredient.



Australia

Pre-approval no longer required for ads

Medicine ads in television, radio, print media, cinema, billboards or other

public displays ('specified media') no longer require pre-approval following parliamentary changes to the Therapeutic Goods Act 1989 (the Act). The changes came into effect on 1 July 2020.

The Therapeutic Goods Administration (TGA) continues to regulate advertising content and there is now greater responsibility on advertisers to ensure their advertising is fully compliant. There are sanctions and penalties for advertising that does not comply with the Act and the Therapeutic Goods Advertising Code.

New Zealand

Consultation on influencer guidelines

The Advertising Standards Authority (ASA) of New Zealand has developed AdHelp guidance to support responsible advertising and the requirement for Influencers to clearly identify advertising content to their audiences.

The ASA is inviting influencers, agents, agencies, advertisers, media, consumers and any other interested individuals or organisations to review the consultation document and submit their views on the proposed guidelines and submission questions. Deadline for submissions is 5 August 2020.



Israel

PAH, new limits

The Ministry of Health has notified WTO about its revised maximum levels for Polycyclic Aromatic Hydrocarbons (PAHs) compounds to be apply to different food categories, including food supplements containing herbs, algae, fungi and lichens, propolis, spirulina among others. Proposed limits are as follows:

- Benzo(a)pyrene: 10 µg/kg
- Sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene: 50 µg/kg

The proposed date of entry into force is to be determined.



USA

Disclosing bioengineered foods

U.S. Department of Agriculture (USDA) Agricultural Marketing Service (AMS) has recently issued final guidance addressing the validation of a refining process and selection of acceptable testing methods. This guidance aims to allow compliance with the national mandatory standard for disclosing foods that are or may be bioengineered.

The Standard requires food manufacturers, importers, and certain retailers to ensure bioengineered foods are appropriately disclosed. Bioengineered foods are defined as those that contain detectable genetic material that has been modified through certain lab techniques and cannot be created through conventional breeding or found in nature.

The implementation date of the Standard was 1 January 2020, except for small food manufacturers, whose implementation date is 1 January 2021. The mandatory compliance date is 1 January 2022.

Qualified health claims for cranberry and UTI

The U.S. Food and Drug Administration has announced, in a letter of enforcement discretion, that it does not intend to object to the use of certain qualified health claims regarding consuming certain cranberry products and a reduced risk of recurrent urinary tract infection (UTI) in healthy women.

The agency however concluded that there is limited and inconsistent credible scientific evidence to support a qualified health claim for cranberry juice and limited credible scientific evidence to support a qualified health claim for cranberry dietary supplements. That said, the following claims has been included for supplements:

- “Limited scientific evidence shows that by consuming 500 mg each day of cranberry dietary supplement, healthy women who have had a urinary tract infection (UTI) may reduce their risk of recurrent UTI.”

- “Consuming 500 mg each day of cranberry dietary supplement may help reduce the risk of recurrent urinary tract infection (UTI) in healthy women. FDA has concluded that there is limited scientific evidence supporting this claim.”
- “Consuming 500 mg [X capsules/tablets/soft gels] each day of [this identified cranberry dietary supplement] may help reduce the risk of recurrent urinary tract infection (UTI) in healthy women. FDA has concluded that there is limited scientific evidence supporting this claim.”

CBD Guidance for industry under review

The U.S. Food and Drug Administration has recently submitted its “Cannabidiol Enforcement Policy” draft guidance for industry to the White House Office of Management and Budget. While its content has not yet been released, it is expected that the draft could be particularly relevant to CBD and dietary supplements.



Brazil

New Formula statement

On 3 September ANVISA issued Resolution RDC No. 421/2020 which mandates the statement “New formula” on the label of foodstuffs and food supplements where products have changed their composition. Normative Instruction IN No. 67/2020 provides the specific technical rules. According to ANVISA, the objective of this new regulation is to provide more information and safety to the consumer, especially those suffering from food allergies.

Food supplements must bear the statement “New formula”, “New composition” or “New recipe” in case of changes on:

- the list of ingredients (including food additives)
- the nutrition information
- the allergen declaration
- the declaration of the presence of lactose

- the mandatory warning statement “contains gluten” or “does not contain gluten”.

Product labels must carry the statement “New formula” for at least 90 days after the implementation of the changes, and it must appear in the main panel, in capital letters, in bold and contrasting font, with a minimum height of 2mm. The regulation will take effect on 1 September 2021.

Ecuador

Cannabis rules for supplements

The National Agency for the Regulation, Control and Sanitary Surveillance (ARCSA) have launched a draft resolution that would introduce rules for products containing cannabis or its derivatives, including in food supplements. The text proposes:

- The derivatives to be approved as food ingredients would be hulled cannabis seed, cannabis seed protein powder, and cannabis seed oil.

- This limits the delta-9-tetrahydrocannabinol (THC) content in final products to 3%. A certificate by an accredited laboratory (ISO 17025) must be provided.

- Companies interested in using any other parts of the non-psychoactive cannabis plant except for the seeds, should submit the history of safe consumption from the country of origin and the corresponding scientific evidence issued by an international reference agency indicating its safe use as food ingredient.

- Restrictions on labelling are proposed (non-therapeutic effects, images, etc).

Peru

Basic criteria for claims

Ministry of Health has recently established Criteria for the Promotion and Advertising of Pharmaceutical Products, Medical Devices and Sanitary Products. This impacts food supplements, often defined as dietetic products and regulated under pharmaceutical law in Peru.

This new regulation specifies that: Nutrition claims must not be false, ambiguous, misleading.

Dietetic products cannot indicate they have therapeutic effects like medicines.

It must not be stated, suggested, or implied that the consumption of dietetic products can replace a balanced and varied diet that provides adequate amounts of nutrients in general.

So far there is no specific regulation for the use of nutrition and/or health claims in Peru, but this new rule provides some basic criteria similar to other regulation in the region.

It will be effective 90 days after publication on 6 October 2020.



Russia

Laying legislative groundwork for food ionisation

A Bill on amending certain legislative acts related to the ionisation of agricultural and food products passed its first hearing in the lower house of the Russian parliament.

The document amends the laws on the development of agriculture, on plant quarantine, on quality and safety of foods products, on consumer rights protection and on veterinary services to legalise ionisation of raw materials and final products.

Eurasian Economic Union EAEU

New amendments to food safety come into effect

Amendment 1 to CU TR 021/2011 on food safety came into effect on 11 July 2020. The amendment notably aligns the list of plants prohibited for use in dietary supplements with the latest adopted version of the Uniform Sanitary Requirements. Within the grace period until 11 July 2021, manufacture and sales of foods meeting the requirements in effect prior to the coming-into-effect of Amendment 1 will be permitted within the EAEU. Sales of products released onto the market within the grace period will be permitted until their expiry date as defined by the manufacturer.