IADSA NEWSFLASH

October 2021

Regulatory news

India

The meaning of Ayurveda Aahar

The Ministry of AYUSH in collaboration with the Food Safety & Standards Authority of India (FSSAI) has published a draft regulation named Ayurveda Aahar, based on the tradition of Ayurveda foods. The draft provisions under the Food Safety and Standards (Ayurveda Aahar) Regulations, 2021 clarify that :

- The manufacture of Ayurveda Aahar shall be established by Food Business Operators in accordance with Schedule 4 of Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation.
- No person shall manufacture, or sell Ayurveda Aahar intended for administration to infants up to the age of 24 months.
- The labelling, presentation and advertisement shall not claim that the Ayurveda Aahar has the property of preventing, treating or curing a human disease or refer to such properties.
- Food Business Operators shall make claims in accordance with the Food Safety and Standards (FSS) (Advertising and Claims) Regulation, 2018. It is however unclear if pre-approval would be required if these are not given in FSS (Advertising &Claims) 2018 or Authoritative texts
- The labelling of Ayurveda Aahar shall be in accordance with the Food Safety and Standards (Labelling and Display) Regulations, 2020, and the specific labelling requirements provided in the regulation.

Ayurveda Aahar shall only contain:

- Schedule A ingredients listed or mentioned in the 68 texts that have been written and published before 1940.
- Natural food additives (around 14) as specified under schedule C of these regulations. This list of additives technically exclude Ayurveda Aahar supplements sold in capsules, tablets or other forms requiring additives not authorised under this law.
- The addition of one or more botanicals listed in 'schedule IV' of Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 shall be authorised.

The addition of vitamins, minerals and amino acids to Ayurveda Aahar shall not be permitted. However, natural vitamins and minerals if present in the Ayurveda Aahar may be declared on the label.

Health regulation amended

India notified its first amendment to the health supplement regulation 2016, which will come into force from 1 April 2022. Previously, under the regulation, a multivitamin and/or mineral product could not be placed on the market if it did not include a food ingredient. Now there are allowed singly or in combination. The restriction of not more than 1x RDA for all dosage forms (tablets, capsule etc.) continues. Claims must additionally be compliant with the general regulation on advertisements. Permitted lists for ingredients and additives have been updated.

EU

Green tea: Restricting its use

The European Commission is consulting on a draft Regulation aiming at restricting the use of green tea catechins in food supplements.

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. Green tea infusions prepared in a traditional way and reconstituted drinks (containing at least 0.12 g dry

mass of extracts from tea in 100 ml) with an equivalent composition to traditional green tea infusions are excluded from the scope of this proposal.

In 2016, Norway, Sweden and Denmark warned against green tea extract supplements. The Commission requested the European Food Safety Authority (EFSA) to deliver a scientific opinion on the safety of green tea catechins under the Article 8 procedure. While EFSA considered that the catechin content of green tea infusions and similar drinks are generally safe, they concluded that there may be health concerns when taken as a food supplement.

A new risk assessment is foreseen within 4 years. Interested parties are requested to perform new studies to determine a dose-response of hepatotoxicity of green tea catechins and to examine the inter and intra species variability.

New labelling requirements for astaxanthin-rich oleoresin from Haematococcus pluvialis algae

The European Commission has restricted the population group for food supplements containing astaxanthin-rich oleoresin from *Haematococcus p*luvialis algae. This decision is based on the recent EFSA opinion reaffirming the safety of astaxanthin-rich oleoresin from *Haematococcus pluvialis* microalgae in food supplements at level of up to 8 mg per day but clarifying that this level was safe for adults and adolescents above 14 years old.

Food supplements containing ≤ 8,0 mg astaxanthin intended for the general population which were lawfully placed on the market before 9 September 2021, may be marketed until their date of minimum durability or use by date. However, food business operators should provide a notice for these food supplements to be displayed at the place of sale informing them that they should not be consumed by infants, children, and adolescents below the age of 14 years.

Mass recall

The European Commission has ordered a mass recall of products contaminated with ethylene oxide, also impacting many food supplement companies operating in the European Union. Several new cases have been notified in the European Rapid Alert System in the last few weeks. This concerns food supplements containing certain botanical ingredients, such as spirulina, psyllium, ashwaghanda, moringa, curcuma, bamboo, ginger, fenugreek and pepper. But not only! Food supplements containing calcium are also affected due to the presence of ethylene oxide and/or its breakdown product 2-Chlorenthanol.

The crisis arose in October 2020 with sesame seed from India. Ethylene oxide is not an approved pesticide in the EU but its use seems to be frequent in India.

Although Belgium, Denmark and France have decided to fully implement the EU decision, other Member States have expressed concerns with the systematic recall of all products contaminated. Those countries were notably unhappy with the zero-tolerance approach applied. Some countries highlighted that this approach could contradict the work carried-out on sustainability, reducing food waste and food loss in line with the EU's Farm to Fork Strategy and the Sustainable Development Goals.

In the meantime, controls continue to intensify across the EU.

Czech Republic

Endorsing BELFRIT model for botanicals

The Czech Republic has published a guidance list of botanicals that may be used in supplements. The development of this list was inspired by the BELFRIT list, a common list of botanicals put together by Belgium, France and Italy.

The Czech list is a result of a consensus reached among Ministry of Agriculture, State Agricultural and Food Inspection Authority, State Health Institute, State Institute for Drug Control, Food Chamber of the Czech Republic and CASP.

This development is a major step forward for the Czech Republic and could stir new enthusiasm among EU Member States.

Transition period for Titanium Dioxide

"Given that the Authority did not identify an immediate health concern linked to titanium dioxide (E 171) used as a food additive and in order to allow for a smooth transition, it is appropriate that foods that contain titanium dioxide (E 171) produced before the date of entry into force of the Regulation may be placed on the market until six months after that date. Those foods may then continue to be marketed until their date of minimum durability or 'use by' date." This was the proposal of the European Commission put to a vote late September.

The draft Regulation also includes the confirmation that the additive will remain provisionally on the list of permitted additives but all the provisions for foods will be removed. This decision is to permit Titanium Dioxide to continue to be used in pharmaceutical products for the time being. This will be reviewed in 3 years. It is estimated that today more than 200 000 medicines in EU contain the additive.

Germany

Synephrine: Setting the limits

The Joint Expert Commission, whose office is headed by the Federal Office for Consumer Protection and Food Safety (BVL) and the Federal Institute for Drugs and Medical Devices (BfArM), has recently concluded that products containing synephrine cannot be classified as functional medicinal products.

Regarding the safety of the ingredient in foods and supplements, the Joint Expert Commission concluded that no more than 21 mg of synephrine should be consumed per day in total, which represents a limit at which no significant increase in synephrine exposure is to be expected compared to the intake through foods for general consumption.

For food supplements containing 21 mg synephrine per day, the Joint Expert Commission recommended a warning on the label that no other foods containing synephrine should be consumed.
Synephrine is a natural plant ingredient found in the pulp and peel of various citrus fruits, such as bitter orange.

Italy

New warning statement for *G. Cambogia*

In the light of current scientific evidence, the Italian Ministry of Health has introduced an additional warning statement for the labelling of food supplements containing Garcinia cambogia:

'If, following the use of this product, disturbances arise, for example regarding liver function or the central nervous system, stop taking it and seek the advice of a doctor' (unofficial translation in English)

('Qualora a seguito dell'uso del prodotto insorgano dei disturbi, a carico ad es. della funzione epatica o del sistema nervoso centrale, interrompere l'assunzione e sentire il parere del medico')

Food supplements containing this botanical should comply with the new warning statement provisions no later than 31 December 2021.

Chromium up

The Italian Ministry of Health has recently updated its Guidelines on daily intakes of vitamins and minerals allowing an increase from 200 µg to 250 µg for chromium.

The decision follows a request for mutual recognition presented by a Food Business Operator (FBO), after which the Ministry asked its Committee for a safety analysis, which was favourable.

Poland

Food supplements: Update

The Food Supplements Team of the Chief Sanitary Inspector (GIS) in Poland continues its work on establishing maximum levels of ingredients used in food supplements and has published the following four new Resolutions:

- Resolution No. 2/2021 for the use of Rhodiola rosea root preparations in food supplements: Rhodiola rosea root powder can be used in an amount below 216 mg in the recommended daily dose of the product; extract with a concentration ratio of 1,5-5:1 in an amount below 144 mg in the recommended daily dose of the product; extract standardised for the content of rosavins and/ or salidrosides: maximum amount of rosavins, not more than 15 mg in the recommended daily portion of the extract; the maximum amount of salidrosides not more than 5 mg in the recommended daily dose of the extract. In the labeling of food supplements containing Rhodiola rosea, it is recommended to include a warning: "not to be used by children, pregnant and lactating women".
- Resolution No. 3/2021 for the use of *Tribulus terrestris L* . in food supplements: The fruit of the Tribulus terrestris L. can be used in an amount below 3 g per day as calculated in the raw material; the maximum content of saponins may not exceed 200 mg in the recommended daily portion of the product; the entity placing the food supplement on the market should attach a quantitative specification confirming the content of the sum of saponins per the recommended daily portion of the product; it is recommended to include a warning in the labeling of food supplements: "The product should not be consumed in the case of using medicaments for hypertension or diabetes. Do not use in children, pregnant and lactating women ".
- Resolution No. 4/2021 recommending a maximum daily amount of calcium at 1500 mg in food supplements.
- Resolution No. 5/2021 specifying the maximum amount of potassium at the level of 1500 mg in the recommended daily dose in food supplements. Food supplements containing potassium in a daily amount above 1000 mg should include the following warning: "the product is not intended for the elderly, people with kidney disease, insulin-resistant diabetes, hypertension, cardiac arrhythmias".

Note that the opinions of the Team are not legally binding. Like most documents adopted by advisory bodies, the Team's resolutions are issued primarily for the internal needs of GIS and used by inspectors in thecourse of explanatory and control proceedings.

The Netherlands

Do not buy

"Magnesium supplements often contain much more magnesium than is good for you" according to the Dutch consumer Association that calls for consumers to stop buying supplements above 250 mg/day due to its potential laxative effect. A list of 45 food supplements containing more than 250 mg/d has also been published on the Consumer Association webpage.

UK

EU & UK: No divergence on lutein claims

The Nutrition and Health Claims Committee (UKNHCC) has published its verdict on a lutein claim and visual performance confirming the EFSA conclusions of 2014:

" A cause and effect relationship has not been established between the consumption of a combination of 10mg lutein, 2mg zeaxanthin and 10mg meso-zeaxanthin and improved visual performance due to insufficient evidence."

Canada

Clearer labels

As more Canadians rely on Natural Health Products (NHPs) to support their own health, Health Canada has announced proposed changes to the NHP Regulations to make labels clearer and easier to understand. The Health Canada proposal includes four key elements:

A Product Facts table: Product information, such as warnings and directions for use, would be presented in a standardized table;

Clearly and prominently displayed label text: Rules would be introduced to improve NHP label legibility and readability (improved colour contrast and minimum font size requirements);

Labelling of food allergens, gluten and aspartame: Priority food allergens, gluten, and aspartame would be identified in the warning section of the label;

Modernized contact information: A manufacturer may display either an email address, telephone number or website instead of a postal address, as currently required.

Australia

E-commerce sales under scrutiny

With the growth in e-commerce sales and the increase in sale of illegal complementary medicines, the Australian Therapeutic Goods Administration has reconfirmed to the industry that it will progress compliance activity in the sector.

Australia, New Zealand

Titanium Dioxide safety: Pressure is mounting

The release of the opinion of the European Food Safety Authority (EFSA) declaring titanium dioxide unsafe is starting to have an impact on many countries across the globe. In addition to the international Expert Committee on Food Additives (JECFA), a number of governments are now reviewing their scientific opinion on the use of the food additive. These include Canada, Australia & New Zealand, & the UK.

Argentina

Changes to food supplement regulation

The National Commission of Foods (CONAL) has opened for public consultation a proposal to update the Argentinian Food Code to include ß-hydroxy-ß-methylbutyrate (HMB) and Beta-alanine (ß-ALA) for use in food supplements, according to the identity and purity specifications from the Food Chemical Codex, USP and other pharmacopoeias. For HMB, a daily intake of 3g per portion or a single unit of no more than 300 mg is proposed. For (ß-ALA) a daily intake of 2 g per portion or single unit of no more than 300 mg is proposed. Final date for comments: 9 October 2021

Sanitary registry on supplement label

Argentina has mandated the inclusion of the number of the National Food Product Registry (known as RNPA) on food supplement labels. The measure (Resolution 26/2021) impacts all food products, including food supplements.

For those products registered before 17 August 2021, a period of 3 years is granted to adapt labels, i.e. until 17 August 2024.

New botanicals

The National Commission of Foods (CONAL) opened for public consultation two proposals to update the Argentinean Food Code.

The first seeks to update Article 1192 in order to include two new herbs for infusions:

- Urtica Dioica as herb for infusions, with a maximum limit of 5 g per day
- Aloysia Polystachya (Griseb.) Mold. (Verbenaceae)

The second consultation proposes to include new vegetable species in Article 888. The proposal seeks to include: Geoffroea decorticans and fruits from Plinia cauliflora.

According to the food supplement regulation, any herbs and vegetables permitted in food products can be used in food supplements, in addition to the list of specific herbs allowed in food supplements.

Vegan & Vegetarian

The National Commission of Foods (CONAL) has opened for public consultation a proposal to include rules for the use of the claims "vegan" and "vegetarian" in the Argentinean Food Code. The proposal foresees the following conditions for each claim:
Vegan: Permitted in products that do not contain ingredients of animal original and/or their derivatives

(including additives and processing aids)

- The following wording for vegan would be allowed: “vegan” (in English itself), “only with ingredients of vegetal origin”, “100% vegetal” or other similar
- At the time of the registration of the product the interested company must submit all the documentation that proves compliance with being vegan
- It would not be permitted to use the term vegan if the company declares the possibility of cross-contamination with allergens of animal origin.

Vegetarian: Permitted in products that do not contain ingredients of animal origin and/or their derivatives (including additives and processing aids), except for the following ingredients and their derivative components: milk, dairy products, egg and egg products obtained from alive animals, honey and bee-derived products

- The following wording for vegetarian is permitted: “veggie” and similar
- At the time of the registration of the product, the interested company must submit all the documentation that proves compliance with being vegetarian.

Extension of supplement list

Lutein, zeaxanthin, resveratrol, coenzyme Q10 and lycopene are now permitted for use in supplements.

So far these substances have been accepted on a case-by-case basis for each applicant company, but are now authorised in any food supplement.

The identity and purity criteria are accepted from the Food Chemical Codex and/or United States Pharmacopoea and/or other pharmacopeias (although not specified, it has been clarified that references from the European Food Safety Authority, Authority of Public Health Agency of Canada, British Pharmacopoea and Japan Pharmacopoea have been considered). No maximum limits are established.

In addition, Argentina has recently approved coralline algae, goji berry and rosehip as new botanical ingredients under the Argentinean Food Code. Under the Argentina food supplement regulation, plants listed in the Food Code can be added to food supplements.

Ecuador

Revised definition

Ecuador has recently amended its food supplement regulation covering a revised definition for the category. Food supplements should contain nutrients in significant quantities with a nutritional and physiological effect. They can contain vitamins, minerals, proteins, amino acids, probiotics, concentrates and plant extracts alone or in combination, animal or human hormones and others as long as its use as an ingredient and its concentration is justified by the regulatory agencies of high sanitary surveillance.

Other amendments recognising EFSA, US FDA, and other international authorities have also been made.

The use of food additives that appear in the General Standard for Food Additives Codex Stan 192, in the regulation of the European Union and/or US FDA, as well as those approved by other agencies with a high sanitary surveillance will also be accepted.

Nicaragua

Changes of responsibility

The Ministry of Health has published a Resolution that requires that organisations that import, distribute and market supplements must now register products at the Pharmacy Directorate, and not the Department of Natural Artisan Products and Nutritional Supplements, as has been the case. The resolution entered into force on 13 August 2021.

Belarus

More flexibility for distance selling

Distance selling of supplements containing macronutrients, such as protein, fats, carbohydrates, and fiber will now be permitted in Belarus under the new Decree No.363 of last June.

The document specifies requirements to be provided to consumers in print and electronic catalogues, brochures, advertisements, leaflets, photos etc. The decree also lists information that should be placed on the main page of an online store.

The law however still prohibits distance selling, including online-commerce, of dietary supplements that are used to support the body’s functional activity within its physiological range, namely supplements containing biologically active substances, vitamins, micro-elements, minerals, amino acids, live microorganisms and/or their metabolites that 'have a normalisng impact on the composition and biological activity of the bacterial flora in the human gastrointestinal tract’.

Ukraine

Alarming definition

The Ministry of Economy has proposed to define dietary supplement as a source of vitamins and minerals only.

Under the draft regulation, dietary supplements would be defined as food consumed in small quantities in addition to the normal food ration as a concentrated source of vitamins and minerals, in tablets, capsules, dragees, powders, liquids or in other forms.

It is understood that the draft, published for comments in July, excludes the possibility to add ingredients other than vitamins and minerals in supplements.

The bill also proposes to expand some terminology and definitions including flavouring agents, food additives, novel foods, novel traditional food, claims, disease risk reduction claims, health claims, nutrition claims, falsified food, food imitating another analogous food (imitation food) etc.

Antimonopoly Committee alarmed at sales of pharmaceuticals under guise of dietary supplements

The Ukrainian Antimonopoly Committee initiated a meeting with representatives of the State Medicines Service to discuss dietary supplements. There are repeated calls by the supplement industry to put an end to the practice of marketing medicines containing active pharmaceutical ingredients as dietary supplements. Medicines that contain certain active agents are put on the market using two different paths: some as medicines and others as dietary supplements. The agencies agreed to further cooperate in order to regulate this practice.

Russia

New guideline updates nutrient intake recommendations

Russia's Chief Sanitary Doctor has adopted the new Guideline Standards of physiological requirements for energy and nutrients for various population groups in the Russian Federation (MR 2.3.1.0253-2021).

The new document (attached) expands the nomenclature to include such terms as adequate intake levels, biodiversity, glycemic index (GI) of foods, microbiome, intestinal microbiome, essential nutrients, mono- and disaccharides, added sugars and naturally occurring sugars, saturated fatty acids and trans fats.

The new document also introduces new physiological norms for macronutrients and revises adults' physiological intake of micronutrients, including:

- For Vitamin C, 100 mg/day instead of 90
- For Vitamin D, 15 micrograms/day (600 ME) instead of 10
- for persons aged over 60, 20 micrograms/day (800 ME) instead of 15
- For phosphorus, 700 mg/day instead of 800
- For magnesium, 420 mg/day instead of 400
- For potassium, 3,500 mg/day instead of 2,500
- For chromium, 40 micrograms/day instead of 50.

For children aged over 1 in different age groups:

- The physiological need for Vitamin D has been increased from 10 to 15 micrograms/day;
- The physiological need for phosphorus, potassium, iodine and fluorine have been specified.

The document also introduces a recommended trimester-based intake of vitamins and minerals for pregnant women whilst the previous version only identified the recommended intake for women in the second half of pregnancy.

IADSA
International Alliance of Dietary/ Food Supplement Associations

International Alliance of Dietary/Food Supplement Associations
International Non-Profit Organisation
Gridiron Building, One Pancras Square, London, N1C 4AG, United Kingdom
Website: www.iadsa.org