IADSA NEWSFLASH

April 2021

Regulatory news

China

New dosage forms for Health Food Filing

Gelatinized confection and powder can now be used for health food filing. The China State Administration for Market Regulation has recently updated the list of Dosage Forms and Technical Requirements for Health Food Filing together with the List of Auxiliary Materials. The updated auxiliary materials now include 197 items, 46 of which cannot be used for gelatinized confection and 25 cannot be used for powder. These regulations will take effect on 1 June 2021.

India

Licences: More clarity

The Food Safety Compliance System (FoSCoS) became operational in India in November 2020 replacing the Food Licensing and Registration System (FLRS). FSSAI's order stipulates the document requirements when applying for license/registrations, including renewals and modifications. Basically, documents submitted depend on two broad classifications of the kind of business i.e. non-manufacturing and manufacturing activities. Lists are provided for different activities (e.g. manufacturing, processing, re-labelling, and repacking) and/or for certain product groups (nutraceuticals, novel foods, proprietary foods, etc.). For health supplement and nutraceutical specifications (ingredients as per applicable Schedule), purity criteria adopted for ingredients are to be provided in the prescribed format. Within its continuing efforts to ease doing business in India, the current move ensures consistency and clarity between State Food Authorities and FBO's.

UL for Selenium on the table

The European Food Safety Authority has recently discussed scientific opinion on the revision of the Upper Level (UL) for Selenium (EFSA-Q-2020-00618). The Authority specifically addressed the strategy for the characterisation of a quantitative relationship between selenium intake and serum/plasma levels and possible approaches for addressing infants, children, pregnant and lactating women in the risk assessment. The process of appraising the internal validity of individual studies, related critical appraisal tools and their tailoring to specific research questions was discussed. This mandate was triggered following the EFSA assessment of a selenium rich novel ingredient (EFSA-Q-2018-00796) where the Authority concluded that newly emerging data warrant a reassessment of the UL for selenium.

Thailand

Use of CBD: Clarification

The Ministry of Public Health in Thailand has released a notice clarifying he quality requirements for foods that contain hemp seed. For dietary supplements it is also specified that products containing hemp seed, hemp seed oil or hemp seed protein should be supervised. In addition, dietary supplements containing hemp seed should also be labelled: "This product is prohibited for children, pregnant and lactating women; Allergy sufferers should be aware that this product contains CBD and THC", etc. The THC and CBD limits have been established as follows:

Food supplements containing hemp seed or hemp seed protein: THC 2.0 mg/kg CBD 3.0 mg/kg

Food supplements containing hemp seed oil: THC 5.0 mg/kg CBD 3.0 mg/kg

European Union

Alignment of NF guidance with transparency regulation

In view of the application of the Transparency Regulation as from 27 March 2021, all EFSA administrative guidance documents need to be updated. The Transparency Regulation introduces most specifically provisions in the pre-submission phase and in the application procedure. In particular: general pre-submission advice, notification of information related to studies commissioned or carried out to support an application, public disclosure of non-confidential versions of all information submitted in support of the application and related confidentiality decision-making process, public consultation on submitted applications. The

administrative guidance for the preparation of applications on novel foods.

Prohibition of certain HADs

The European Commission has published the prohibition on the use of certain hydroxyanthracene derivatives (HADs) such as aloe-emodin, emodin and danthron as well as Aloe leaf extracts containing HADs and all preparations containing them, in food and food supplements. This decision was based on the opinion of the European Food Safety Authority (EFSA) where the Authority could not advise on a daily intake of HADs that does not give rise to concerns for human health.

Regarding testing limits, the Commission clarified that in the absence of an EU method of analysis and standardised methods of analysis, 'relevant methods developed and validated with inter or intra-laboratory methods validation studies in accordance with internationally accepted scientific protocols' shall be used for official controls. It is also to be stressed that the Standing Committee on Plants, Animals, Food and Feed PAFF agreed on harmonised limits of quantification (LOQs) for HADs which should allow harmonised enforcement across the EU.

Safety of nutrients with dual use

EFSA has recently published a statement presenting a proposal for harmonising the establishment of Health-Based Guidance Values (HBGVs) for regulated products such as additives or pesticides that are also nutrients. The statement describes the specific considerations that should be followed for establishing the HBGVs during the assessment of a regulated product that is also a nutrient. It also addresses the elements to be considered in the intake assessment; and proposes a decision tree for the risk characterisation of those products. This approach will likely be applied when EFSA updates the UL for certain nutrients.

Astaxanthin under review

The Commission is currently consulting the EU Member States on astaxanthin following the 2020 EFSA opinion on the safety of the substance as novel food. The 2020 opinion has revealed that the ADI of 0.2 mg/kg bw was exceeded by 28% in children aged 10 to 14 years and up to 524% in infants aged 4–6 months. Options under consideration are: a) Keep the current intake reference value and adjust only the labelling on packaging (e.g. should not be consumed below the age of 14 years); b) reduce the intake reference value so that it is suitable for the whole population; c) leave the existing intake reference value without comment.

Food Supplements Directive: A few changes

The European Commission has now included the substances nicotinamide riboside chloride and magnesium citrate malate in Annex II to the Food Supplements Directive (Dir. 2002/46/EC), permitting their use in the manufacture of food supplements. The substances have received a favourable scientific assessment by the European Food Safety Authority (EFSA) and are both included in the EU list of novel foods.

The new measure also amends the units for copper in Annex I to align them with those required for labelling purposes. A transition period of 18 months is foreseen to adapt labels.

Guide to Mutual Recognition

The mutual recognition principle ensures market access for goods that are not,or are only partly subject to EU harmonisation legislation. It guarantees that any product lawfully sold in one EU country can be sold in another. This is possible even if the food does not fully comply with the technical rules of the other country.

A guidance document has now been published by the European Commission to explain the various aspects of this regulation, including the mutual recognition declaration for businesses and the assessment of goods by national authorities. This document also offers information on support services provided by SOLVIT centres and Product Contact Points.

Probiotics back on Member States' agenda

Denmark's Minister for Food, Agriculture and Fisheries has set out to work with Spain and other EU countries to change the EU regulation to allow the use of the word "probiotic"on labels. The term probiotic is considered a health claim according to the EU claims regulation. However, some Member States have taken a flexible approach allowing the use of the term subject to specific conditions of use. These include Italy, Greece, Poland, Czech Republic and most recently Spain.

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France

Nutrivigilance goes online

The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) has launched a new online reporting website for their nutrivigilance scheme (https://www.nutrivigilance-anses.fr/nutri#!).

ANSES recalls that to ensure the accuracy of the information provided, healthcare professionals (doctors, pharmacists, dieticians etc) are responsible for reporting adverse effects, as well as dieticians, manufacturers or distributors.

Individual consumers can also report adverse effects online, but ANSES highlights that it is nevertheless recommended to contact a healthcare professional so that they can make the declaration.

Since the launch of the nutrivigilance scheme in 2009, over 5,000 declarations have been recorded, with an average of 1,000 declarations per year in recent years.

Germany

VMs limits updated

The German Federal Institute for Risk Assessment (BfR) has said "Food supplements are not necessary for the predominantly well-supplied population". In its recent update on recommended limits for the use of vitamins and minerals in food supplements and fortified foods in Germany, the German Institute has turned down the beneficial role of supplements and fortification by emphasising that additional intake of micronutrients beyond what is required is not expected to have any positive health effects. No addition to fortified foods of vitamin K, nicotinic acid, chloride, phosphorus, zinc, copper, manganese, boron and silicon is for instance proposed.

The updated BfR proposal will be on European table in the context of EU discussions that have been resumed regarding the harmonisation of EU maximum limits for food supplements.

Acute reference dose as basis for assessing hemp-containing products

The German Federal Institute for Risk Assessment (BfR) has recently confirmed that the toxicological assessment of hemp-containing foods should be carried out on the basis of the ARfD of 1 microgram Δ9-THC/kg bodyweight (BW) derived by the European Food Safety Authority (EFSA) in 2015.

In 2018, the BfR came to the conclusion (Opinion No. 034/2018, 08 November 2018) that the THC guidance values recommended by the former Federal Institute for Health Protection of Consumers and Veterinary Medicine (BgVV) in 2000 are no longer suitable for the assessment of hemp-containing foods according to current standards.

The Netherlands

St John's wort: Warning

The National Institute for Public Health and the Environment (RIVMN) advises caution when using herbal preparations containing St John's wort.

Food supplements and tea containing St. John's wort can have harmful effects on health, according to RIVMN. St John's wort can reduce the effect, for example, of certain medicines prescribed for fungal or viral infections and cancer (chemotherapy).

St John's can also enhance the effect of, for instance, antidepressants or sedatives. RIVM therefore advises consumers not to combine herbal preparations with medicines.

St John's wort in peril

Following the recent safety concerns on St John's wort in herbal preparations raised by the Dutch National Institute for Public Health and the Environment (RIVM), the Ministry of Health, Welfare and Sport (NVWA) is considering to proceed with a legal restriction or ban in addition to a compulsory label warning statement.

The Dutch authorities also aim to address their concerns with EU Member States via the so-called Article 8 procedure of Regulation 1925/2006 which could lead to restriction of use or a ban across the EU. Under Article 8, if a harmful effect on health has been identified in respect to certain substances, those substances should be prohibited or allowed under specified conditions of use. If the possibility of a harmful effect has been identified relating to certain substances but scientific uncertainty exists, those substances should be placed under EU scrutiny with a view of further evaluation within four years subject to which such substances might be generally allowed, allowed under conditions of use, or prohibited.

USA

Recognition of vitamin D role

Representative Glenn Grothman (R-WI) has introduced a House Resolution (H. Res. 116) that recognizes the potential role vitamin D may play in decreasing the severity of COVID-19. The resolution called on the Centers for Disease Control and Prevention and the Food and Drug Administration to update existing guidance and to issue new guidance that encourages vitamin D intake during the COVID-19 pandemic.

Import alert for higenamine supplements

The U.S. Food and Drug Administration (FDA) has published an Import Alert relating to dietary supplements and bulk dietary ingredient that contain higenamine.

Higenamine is an ingredient listed on FDA's Dietary Supplement Ingredient Advisory List ("DSIA List") which is intended to alert the public when the FDA identifies ingredients that do not appear to be lawfully included in products marketed as dietary supplements.

According to FDA, there is inadequate information to "provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury."

Companies for which an import alert has been issues will be added to the Red List. To be removed from the Red List, information must be provided to the Agency to demonstrate that the firms have resolved the conditions that gave rise to the violation.

Proposing age restriction

California Assembly member Cristina Garcia has introduced Assembly Bill 1341, which would prohibit retailers from selling dietary supplements for weight loss and over-the-counter diet pills to under 18s.

The bill would require a retail establishment to limit access to such products and to determine which products will be subject to those access limitations. The bill would also require the development of a health-related notice regarding those products to be posted each purchase counter. The bill, commencing 1 July 2022, would make a violation of these provisions by a retail establishment subject to a civil penalty of no more than $1,000.

Argentina

Green light for Aloe

Argentina has given its green light for the use of aloe vera from the leaf/stem of *Aloe barbadensis Miller* and *Aloe arborescens* species, with an aloin maximum limit of 0.1 mg/kg in food and beverage.

Under the recent update of the food supplements regulation, supplements can contain botanicals and plants listed in Article 1381 of the Argentinean Food Code and all other plants defined in the Argentinean Food Code. The recent inclusion of aloe vera in Chapter XI of the Code therefore gives this authorisation to use aloe vera under the above conditions in food supplements.

Control of labels

A system for the Control of Labels (SiFIRE) of food and beverages has recently been created.

The control of labels will be performed by the Sub-Secretariat of Actions for Consumer Defence and labels must be submitted to the TAD platform where registrations are submitted. The following Information should be provided including:

- Label in colour for each presentation of the product
- Details of the manufacturer/importer
- Brand, product denomination, country of origin, description and composition of the product
- Complete information of the components, raw materials, additives, methods of production and packaging, along with their properties or indications of use.

SiFIRE aims to avoid non-compliance with applicable regulations. The Sub-Secretariat of Actions for Consumers' Defense must provide a reply within a period of 10 administrative business days after the request is submitted. This measure will begin to apply on 1 May 2021.

Food additive specifications

Continuing with its work to update specifications for food additives, Argentina has now updated the identity and purity specifications for 19 food additives foreseen in Article 1398 of the Argentinean Food Code. JECFA, European Union and Food Chemical Codex references have been considered, with JECFA specifications prevailing.

List of additives covered by the update:
Acetic acid (INS 260), Adipic acid (INS 355), Alginic acid (INS 400), Ascorbic acid (INS 300), Benzoic acid (INS 210), Citric acid (INNS 330),Phosphoric acid (INNS 338), Fumaric acid (INS 297), Gluconic acid (INS 574), Erythorbic acid (INS 315), Lactic acid (INS 270), Malic acid (INS 296), Sorbic acid (INS 200), Tartaric acid (INS 334), Agar (INS 406), Alpa-tocopherol (INS 307), Aluminium and potassium sulphate (INS 522), Ammonium alginate (INS 403), Ammonium bicarbonate (INS 503ii)

Brazil

Novel food catalogue

The Brazilian National Agency for Health Surveillance (ANVISA) has announced the creation of a Database of approved novel foods, which are regulated by Resolutions 16/1999 and 17/1999.

More ingredients to come

ANVISA's Board will consult on an updated list of permitted ingredients, maximum limits, permitted claims and other labelling requirements for food supplements. The proposed changes include:

- 25 new sources of nutrients, bioactive substances, enzymes and probiotics to be included in the list (if approved, the list will total 451 permitted ingredients)
- Inclusion of melatonin with specific conditions
- Amendments to the name and CAS number of 2 substances
- Inclusion of a warning statement for inositol
- Amendment of the daily minimum limit of folic acid in pregnant women

In addition, ANVISA has issued the 7th version of the Q&A document on food supplements.

Ecuador

Green light for hemp

The National Agency for the Regulation, Control and Sanitary Surveillance (ARCSA) approved by Resolution on 10 February ARCSA-DE-002-2021-MAFG the Technical Standard for the regulation and control of finished products for human consumption that contain non-psychoactive cannabis or hemp, and its derivatives. The standard applies to processed foods, food supplements, pharmaceutical products, medical devices and cosmetic products that contain non-psychoactive cannabis or hemp, or their derivatives in their formulation.

Chapter VI foresees provisions for food and food supplements, including:
Maximum THC content should not exceed 0.3% in the finished product
The use of therapeutic claims on the label and advertising is not allowed
GMP certificate must be presented at the time of the registration
The use of cannabis or hemp and its derivatives is not permitted in products intended for infants, young children and children below 12 years old.

Nicaragua

Creation of new Sanitary Authority

Nicaragua has announced the creation of the National Sanitary Regulation Authority. This new body will operate under the Ministry of Health. It will be in charge of regulating, controlling and coordinating regulations and standards for foods and beverages, nutritional supplements, medicines, vaccines, biological products, natural medicines, cosmetics, medical devices and other products. The Directorate of Food and Beverages Regulation will be the competent authority for food related matters within the Authority, replacing the General Directorate of Sanitary Regulation.

Colombia

Supplements in gyms on the move

Bill proposing to regulate the marketing of food supplements in gyms moves forward in the Congress.
Bill 181/2020 filed in the Chamber of Deputies in July 2020 by representatives from the political party Colombia Renaciente (opposition) and a group from the governing party, proposes to regulate the marketing of food supplements in gyms and any commercial establishment where sports activities are practiced.
According to the Colombian legislative process, bills undergo two major discussions. At the first discussion that took place on 18th March 2021, the bill received a positive vote. Now it should be voted at the second discussion.
The bill focuses on ensuring that:
All food supplements marketed in gyms and commercial establishments where sports activities are practiced must be listed in the sanitary registry of INVIMA.

Gyms and commercial establishments where food supplements are marketed must make available a health-care professional or nutritionist.

New Zealand

Current law in place for another 5 years

The Food (Continuation of Dietary Supplements Regulations) Amendment Bill has passed its third reading and is now awaiting Royal Assent. This will extend current dietary supplements regulations for another five years, from 1 March 2021 to 1 March 2026.

Uzbekistan

Pre-market approval for new dietary supplements and food additives

A resolution drafted by the Service for Sanitary and Epidemiological Welfare and Public Health of Uzbekistan introduces the procedure for authorization of new dietary supplements and food additives to be placed on the market.

The document supersedes the Cabinet Resolution 131 on adopting the provision on authorising procedures within the system of the Uzbek sanitary and epidemiological service of 30 April 2016, which currently regulates the issuance of import and manufacture permits for novel specially introduced biologically active agents which are dietary supplements that have not been manufactured in

Food contact packaging draft rules

Draft technical regulation on safety of food contact packaging drawn up by Uzbekistan was proposed for public discussion on 5 February 2021.
The document introduces requirements for the safety and labelling of packaging and closures, as well as requirements for packaging conformity assessment and identification.
Additionally, the document introduces the sampling procedure and testing requirements. The document also introduces mandatory identification symbols for packaging materials for labelling purposes. The public discussion ended on 20 February 2021.

Russia

Testing ID tagging

The Russian government's draft resolution on conducting an experiment involving ID-tagging of dietary supplements was submitted for public comments on 8 February 2021.
The experiment is aimed at:

Information that would allow for identifying a dietary supplement as a sales unit; testing efficiency of the ID tagging mechanism in prevention of illegal imports, manufacture and sales of illegal products, and in increasing tax and duty collection; assessing the efficiency of the information system to be used in the experiment; drafting proposals related to future amendments to Russian legislation regulating the dietary supplement market; analysing the feasibility of introducing mandatory ID tagging for dietary supplements.

By 1 May 2021, the information system operator is to draw up the information system requirements.

By 15 May 2021, the Ministry of Industry and Trade and Rospotrebnadzor are to draft and adopt guidelines for conducting the experiment and its schedule. The draft document contains a list of dietary supplements under the relevant FEACN code which are subject to ID tagging as part of the experiment, irrespective of whether they are finished goods or ingredients for use in the food industry. The experiment will be conducted from 1 April 2021 to 1 March 2022.