IADSA NEWSFLASH

June 2022

Regulatory news

China

Supervision of the blue hat logo

The State Administration for Market Regulation (SAMR) has issued a draft notice regarding the supervision of the health food logo. The document clarifies that:

The logo is specific to health food registered or filed in China.

The logo shall be the pattern specified by SAMR, and shall be marked on the top left of the main display panel of the packaging and shall be clear and easy to identify.

If the surface area of the main display panel is greater than 100cm2, the width of the widest part of the health food logo shall not be less than 2cm. Otherwise, the width of the widest part of the health food logo shall not be less than 1cm.

The specifications of the logo, including the overall proportion, colour and font are also detailed in the notice.

Health food manufacturers and business operators can use the health food logo in production and business operation sites, as well as health food areas and counters.

India

Unit sale price on packaged food labels

Every pre-packaged food will now need to declare the unit sale price, a requirement under new Legal Metrology (Packaged Commodities) Rules. The unit price is to be declared per gram or per kg for net quantities below and above 1kg respectively and similarly for volume declarations. When net quantity is given by number or units, the unit sale price should be per number or unit. The rule comes into effect on 1st October 2022.

Complexity

The Food Safety and Standards Authority of India (FSSAI) has drafted a new framework termed as FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, and Food for Special Medical Purpose, Prebiotic and Probiotic Food) Regulations 2022 which aims to supersede the 2016 regulations.

According to the authorities, this overhaul document is to make the regulations "unambiguous and clear". The main changes include:

Title of the Standard: Functional food and Novel food is dropped - Prebiotic and Probiotic have been added. Definitions are provided for Health supplements and Nutraceuticals, where none were given. Schedules have changed: Sch.IV - 2016 (plant and botanicals) is now Sch.II Sch.Vi - 2022 (nutraceutical ingredients) is now Sch. III. Sch V (a--e) 2016: are now provided as lists; category 13.6 and GSFA equivalent of Table 3 will finally be included in the General regulation on Food Additives. Sch. VII Composition: Apart from drawing ingredients from specific schedules, access to other sources are retained.

Food grade solvents singly or in combination: The scope has been extended.

Health Supplements: Use of all Schedules permitted except Sch. III (nutraceuticals, extracts, isolates enzymes etc). Nutraceuticals allow all schedules (but Sch. III mandatory). Vitamins and mineral usage not to be less than 15% RDA but not more than 1RDA.

Delivery Format: Allowed forms are tablets, capsules, pills, etc, gummies, jelly, bars, biscuits, candies. The latter should however not be presented as conventional foods.

Labelling & Claims: The term Front of Pack will replace Principal Display Panel (PDP)

Under category specific requirements: Health supplements may be allowed to use the other terms Dietary Supplement or Food Supplement.

Claims are aligned with the general regulation (Advertising & Claims)

Malaysia

Updated registration guidance for health supplements

Malaysia has recently updated its guidance document on drug registration covering health supplements.

In Malaysia, health supplements are regulated by the Drug Control Authority (DCA). The products are subjected to pre-marketing approval process. More information about the

composition claims, and other registration requirements can be found in Annex 6 of the new edition.

Taiwan

Calcium L-5-Methyltetrahydrofolate as a source of folate authorised

Calcium L-5-Methyltetrahydrofolate can now be used for supplements sold in capsule or tablet form.

The maximum daily amount of folic acid shall not exceed 800ug.

Warning statements

The Taiwan Food and Drug Administration (FDA) is consulting on the revision of its legislation for the labelling of health food.

Among the changes foreseen, the following warnings for fish oil and red yeast rice:

For health food containing fish oil as raw material: “Please consult doctor first if the product will be consumed by infants, pregnant women, diabetics or those with coagulation disorders and are taking anticoagulants.”

For health food containing red yeast rice: Consuming this product together with lipid-lowering drugs (statin and fibrate drugs) or together with grapefruit may cause liver damage, kidney damage and rhabdomyolysis.

EU

ECCG restrictions: Not the industry cup of tea

The European Commission is planning to restrict the use of green tea extracts containing a potentially harmful catechin in supplements and other foods over fears of liver injury, initially reported by Norway, Sweden and Denmark. A daily limit of 800 mg of green tea extracts containing epigallocatechin-3-gallate is proposed. This limit will also be applicable to aqueous green tea extracts used in food supplements.

The proposal has been submitted by the Commission to the Member States for an imminent vote. No transition period is foreseen to allow companies to comply with the new provisions and adapt their labels to include warning statements for vulnerable groups of consumers.

Use of monacolins restricted

The European Commission has decided to ban, without transition measures, the use of monacolins from red yeast rice in food and food supplements for dosages equal to and higher than 3 mg.

The use of monacolins from red yeast rice at lower levels has also been put under scrutiny for a period of 18 months with a decision to restrict or prohibit its use within four years.

In the meantime, monacolins from red yeast rice at doses under 3 mg can continue to be used provided that food labels include special warnings to notably warn persons using cholesterol-lowering medicines to avoid concomitant use of foods containing monacolins from red yeast rice.

Monacolins from red yeast rice have been evaluated at the European level under the so-called Article 8 procedure which allows the EU to prohibit or restrict the use of substances/ ingredients that are associated with a potential risk to consumers.

The decision follows the EFSA conclusions where it was pointed out that severe adverse reactions (e.g. abdomyolysis, hepatitis and skin disorders) had been reported for monacolins from red yeast rice at intake levels as low as 3 mg/day taken for a period of between 2 weeks and 1 year.

The Authority also reported that Monacolin K from red yeast rice via food supplements at varying recommended daily intakes could lead to estimated exposure to monacolin K within the range of the therapeutic doses of lovastatin.

The health claim “monacolin K from red yeast rice contributes to the maintenance of normal blood cholesterol levels”, currently permitted with an intake of 10 mg/day of monacolin K from red yeast will be removed from the Union list of permitted health claims.

Call me vitamin C!

A recent EU judgement (Case C-533/20), the European Court had to clarify whether the list of ingredients must include, in addition to the name of the vitamins concerned, the name of the specific vitamin formulations used in food products.

According to the Food Labelling Regulation (No 1169/2011), when a vitamin is added to a food, it must be indicated in the list of ingredients by its specific name. However the Court pointed out that one of the articles of the Regulation provides that the name of ingredients is to be understood as the legal name of the ingredient concerned, or, in the absence of a legal name, the customary name of that ingredient, or, if there is no customary name or the customary name is not used, a descriptive name.

The Court observes, however, that, in the absence of additional information, that article does not, in itself, clarify what name should be used for a vitamin which is among the ingredients. The Court also emphasised that, to be consistent with the aim of the legislation, information should be clear and easy to understand. It was therefore concluded that considering that the Regulation designates vitamins under names such as ‘vitamin A’, ‘vitamin D’ or ‘vitamin E’, it is under those same names that such vitamins must also be designated for the purpose of their indication in the list of ingredients, and not their chemical names.

Although the nutrition labelling provisions of Regulation 1169/2011 do not apply to food supplements, the ingredient declaration does. Therefore, it is understood that the principles of this judgement would also apply to the labelling of vitamins and minerals in the list of ingredients of food supplements in the EU.

Belgium

B12 content in botanicals

The Belgium Advisory Commission for Plant Preparations has issued earlier this year advice on the determination and labelling of vitamin B12 content in plant products.

In order to determine and report on the effective content of vitamin B12 in plant products, the use of a selective analytical method for the active form of vitamin B12 is recommended (HPLC MS/MS).

As a result of the variability during fermentation processes, the content of vitamin B12 in fermented products also appears to be highly variable. Analysis of each lot of these foods is recommended if vitamin B12 levels are to be reported.

Only the content of the active form of vitamin B12 may be listed on the label.

Mineral oils in foods: call for no tolerance

Following the recent findings of FoodWatch, a consumer group, that claimed that many food products sold in Europe are contaminated with mineral oils, the European Commission services have called for further controls on the presence in food of mineral oil aromatic hydrocarbons (MOAH), which are possible genotoxic carcinogens.

Competent authorities and food business operators are requested to sample and to analyse food products which have been found to contain MOAH, and to perform investigations on the source of contamination (ingredients, food additives, food contact materials, lubricants and others).

Member States and food business operators should also perform controls on the presence of MOAH in microcrystalline wax (petroleum wax, synthetic paraffin) and its potential migration to food, to confirm whether the use of microcrystalline wax in food contact materials is a source of the contamination of food by MOAH. The Commission has specified that if the quantified presence of MOAH in food, including food for infants and young children, is confirmed by an official control, the products concerned should be withdrawn and, if necessary, recalled. This approach should also apply to food supplements, classified as food in the EU.

This measure is taken temporarily until maximum levels are established. Discussion should start following the finalisation of the EFSA opinion expected to be delivered by 31 Dec 2022.

Denmark

Levels go up

The Danish authorities have recently amended their national legislation on the addition of other substances to foods including food supplements.

The amendment notably increases the daily levels for a number of substances including several amino acids, and the limits of Zeaxanthin from Tagetes spp. flower extract (from to 2 mg to 53 mg). D-mannose has also been added to the list of substances that may be used in food supplements.

Germany

Call for e-commerce control

The President of the Federal Office for Consumer Protection and Food Safety (BVL), Friedel Cramer, is calling for legal provisions and structures to address the growth of online food trade.

"There are still no regulations and instruments necessary to enforce consumer health protection in online retail," explained Cramer at the beginning of the 35th German Food Law Day in Wiesbaden."

In view of the growing importance of online trade, I would also welcome it if the European Commission were to establish an EU reference centre for eCommerce control."

This could support the authorities of the EU Member States, for example with online research techniques, methods of online sample procurement or contact with service providers. Cramer also complained about the lack of specific regulations when evaluating food ingredients. Only the framework for the addition of vitamins and minerals to food, including food supplements, is currently regulated. Regulations on maximum and minimum levels of vitamins and minerals are in preparation, but are still missing, Cramer said.

Sweden

Maximum limits for vitamin D and iodine in supplements

The Swedish National Food Administration has recently introduced a proposal to set maximum limits for two nutrients - vitamin D and iodine - in food supplements: 100 microgram (µg) for vitamin D and 200 microgram (µg) for iodine.

According to the authorities, most people get enough vitamins and minerals from their food, but some groups may need extra through supplements. The National Food Administration, for example, recommends vitamin D for the elderly. However, they consider that excessive amounts of certain substances for a long time can be harmful to health. These two substances have been selected because in their opinion there is strong scientific evidence that the consequences of ingesting too high levels can be serious.

The proposed levels have now been notified to the EU and the new text is expected to enter into effect in January 2024. This decision follows the opposition from the Swedish industry to set maximum limits for a broader range of nutrients. In 2020 the Swedish Food Agency presented a new model - influenced by the Irish model - which appeared to be problematic for at least 4-5 different vitamins and minerals according to the Swedish sector. The proposal was abandoned.

UK

CBD - list of credible application

The Food Standards Agency (FSA) has released a list of more than 3,500 food products containing CBD, bringing them closer to being authorised as part of government plans to control this market.

The list released end of March include products that meet the following criteria: They were on the market on 13 February 2020; FSA received an authorisation application for the products before 31 March 2021; FSA has validated the application or agreed that it is sufficiently progressing towards validation. These products can remain on shelves until the agency makes a final decision.

Vitamin D intake to help tackle health disparities

The UK government launched a consultation on how to improve the population's vitamin D intake, after research found that around 1 in 6 adults and almost 20% of children in the UK have vitamin D levels lower than government recommendations.

The review comes ahead of the UK health disparities white paper due to be published later this year, which will set out action to reduce disparities between different places and communities and address their causes.

Dr Tazeem Bhatia, Interim Chief Nutritionist at OHID (Office for Health Improvement and Disparities), said: "I welcome this call for evidence as part of OHID's continued drive to improve health outcomes and tackle health disparities. We want to improve the dietary health of the population and this includes supporting everyone to maintain sufficient vitamin D levels to support strong and healthy bones and muscles."

In the UK, people obtain the majority of vitamin D from sunlight on their skin during the spring and summer, as dietary sources of vitamin D are limited. Current advice is for all adults and children to consider taking a daily 10 micrograms supplement of vitamin D between October and March. Some at-risk groups are advised to consider taking a supplement throughout the year. However uptake is low with only 1 in 6 adults reporting taking a daily supplement.

The Netherlands

Glucosamine/ Chondroitin and creatine claims: Caught up

Numerous food products have recently been challenged by the Dutch authorities (NVWA).

In their recent reports, NVWA revealed that more than 60% of online stores did not meet the legal requirements for the use of claims of Glucosamine/ Chondroitin and 74% of the 43 web shops assessed traded products containing creatine with illegal claims.

While the authorities noted that the number of medical claims seems to have decreased (pain-relieving and stiffness' and' against osteoarthritis of the knee'), many unauthorised health claims were still being used (e.g. glucosamine provides lubrication to the joints', 'for flexible, resilient muscles and joints').

The reports also re-iterated that product descriptions such as 'glucosamine is an important as a building block of cartilage tissue' should also be regarded as health claims as confirmed in 2017 by the Appeals Tribunal (Court case no. 19/463).

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.

USA

NAC: A step forward

FDA has released its draft guidance on N-Acetyl-L-Cysteine (NAC), indicating its intent to "exercise enforcement discretion with respect to the sale and distribution of certain products that contain NAC and are labelled as dietary supplements".

The enforcement discretion policy would apply to products that would be lawfully marketed dietary supplements if NAC were not excluded from the definition of "dietary supplement" and that are not otherwise in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Lawful dietary supplements include compliance with all applicable regulations, including: Potential health claims and structure/function claims, labels, and labelling (21 CFR Part 101-Food Labeling), Good Manufacturing Practices (21 CFR Part 111-Dietary Supplement GMPs), FSMA and potentially, Preventive Controls for Human Foods, Foreign Supplier Verification Programs, Produce Safety, or Intentional Adulteration Food, Drug, and Cosmetic Act (adulteration or misbranding).

Enforcement discretion will extend until either a notice-and-comment rulemaking to allow the use of NAC or the FDA denies the Citizen Petition. So far FDA indicated that no safety-related concerns during the ongoing review have been identified.

Increase Safety Information About Dietary Supplement Marketplace

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires manufacturers and distributors who wish to market dietary supplements that contain "new dietary ingredients" to notify the Food and Drug Administration about these ingredients at least 75 days before introducing the product into the market.

Generally, the notification must include information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing a new dietary ingredient will reasonably be expected to be safe under the conditions of use recommended or suggested in the labelling.

The FDA is aware that since the requirement was established, some dietary supplement firms have marketed products for which a premarket NDI notification was required, but never submitted. To address this issue, a revised draft guidance has been issued for public consultation.

This includes enforcement discretion policy which relates solely to the failure to submit an NDI notification.

Along with this draft guidance, the FDA is also developing a new submission pathway through the CFSAN Online Submission Module to

provide a dedicated approach for stakeholders to electronically submit their late notifications.

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 duty 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.

New York State Senate passes age-restriction bill

The New York senate has recently passed a bill related to establishing restrictions on the sale of over-the-counter diet pills and dietary supplements for weight loss or muscle building. This bill aims to prohibit the sale of over-the-counter diet pills or dietary supplements for weight loss or muscle building to people under 18 unless properly prescribed by a health care provider. It exempts certain protein powders, protein drinks and foods.

Supplement Your Knowledge

The U.S. Food and Drug Administration has launched a new initiative, Supplement Your Knowledge, to build awareness about supplements and help educate, inform consumers, educators and healthcare professionals.

South Africa

Uncertainty ahead

The Supreme Court of South Africa has issued a judgement regarding the regulation of health supplements under complementary medicines regulations.

This judgement concludes that the regulations are unlawful to the extent to which they applied to complementary medicines which are not deemed to be medicines (ie they applied to health supplements).

The South African Health Product Regulatory Agency (SAHPRA) has been given 12 months to correct the situation.

Given that the current regulatory framework has been the subject of years of discussion, this judgement now creates considerable confusion in the market place about the status of products and the future evolution and whether supplements will remain the responsibility of SAHPRA. These issues and next steps are being considered by the South African association, HPA.

GCC, Kingdom of Saudi Arabia Yemn

Ban of titanium dioxide on the table

The Gulf Standards Organisation has decided to ban the use of TiO2 in all Gulf countries. The decision has recently been notified to WTO by the Kingdom of Saudi Arabia, Yemen, Qatar, Oman, the State of Kuwait, Kingdom of Bahrain, United Arab Emirates.

Saudi FDA has recently issued a national circular stating that TiO2 is banned from usage in food products. In addition, existing registrations of food products containing this additive will be stopped. All legal measures will be taken by 21 October 2022 for non-compliant products.

In Yemen the ban is expected to enter into force on 25 September 2022.

Ecuador

Notification: a few changes

Ecuador proposes changes to the guidelines for food supplement notification.

The National Agency for Sanitary Regulation, Control and Surveillance (ARCSA) opened for public consultation the third update of the instructions for registration, re-registration and/or modification of the sanitary registration/notification of foods and food supplements, which is carried out through the Ecuadorian Single Window (VUE). These changes do not introduce new rules but amend the instructions for market access.

Honduras

Fine-tuning FS Law

The Honduras Agency of Sanitary Regulation (ARSA) has established a list of vitamins and minerals and their conditions of use permitted in supplements.

The new regulation also defines the forms permitted for use which include capsules, tablets, powder, solutions, syrups.

It also clarifies that products containing natural extracts with pharmacological activity are to be classified as medicinal natural products.

Supplements with a shelf life of more than 24 months must provide stability studies performed in Zone IV.

Labelling must be in compliance with the provisions of the Central American

Technical Regulation for General and Nutritional Labelling (RTCA).

Mandatory waring statements are required on the product labels:

a. "This product should not be used for the diagnosis, treatment, cure or prevention of any disease and is not a meal supplier";

b. "Do not use in pregnant women, nursing women or in children" except for those food supplements that are directed specifically at these populations, which must then indicate: "use under medical supervision";

c. "Keep out of reach of children".

In Honduras, food supplements are defined as food products whose purpose is to replace, add, complement or increase the intake of nutrients in daily food. Food supplements are presented as a concentrated source of nutrients and/or other substances with a physiological or nutritional effect, alone or in combination, including compounds such as vitamins, minerals, proteins, amino acids, plants, plant concentrates and extracts, probiotics, bioactive substances or other nutrients and their derivatives.

Peru

Updated list

On 6 April, the Directorial Resolution 025-2022-DIGEMID-DG-MINSA List of Vitamins, Minerals and other nutrients allowed in the manufacture of dietary products was issued. This updates the list from 2013 foreseen by Resolution 177-2013 -DIGEMID-DG-MINSA.

Sources of the following vitamins and minerals have been added:

- one new source of folic acid
- three sources of choline
- one source of niacin
- one source of chrome
- two sources of iron
- six sources of magnesium
- one source of silicon
- one zinc source

At the same time, some sources were removed, for example:

- Certain sources of phosphorus
- One source of sodium

The list of permitted nutrients was also modified as follows:

- L-carnitine, L-ornithine alpha ketoglutarate, taurine and L-seline as amino acids and other nitrogenous compounds, have been added
- A positive list of fatty acids, dipeptides and peptides, flavonoids and carotenoids, polysaccharides and oligosaccharides, and other substances, which were not previously considered, have been added.

Uruguay

Guidance to supplement companies

Since the regulation for food supplements has not yet been published, the Ministry of Health has issued a Communication Letter stating that food supplement companies must comply with the following requirements:

a) Use as reference for GMP in their manufacturing plants the US GDA CFR 21, part 111

b) The companies authorised by the Ministry of Health as food importers, that present applications to register food supplements, in addition to the Free Sales Certificate and the corresponding technical documentation, must indicate if the manufacture of products in the country of origin is carried out in facilities that exclusively produce food supplements and food products, or are pharmaceutical plants.

c) If the food supplements to be imported are made in pharmaceutical plants, the GMP certificate issued by the competent health authority in the country of origin will be accepted, and must be provided with the product registration application (it must be mentioned which sanitary standard applies in the country of origin).

d) Food supplements produced in pharmaceutical plants that produce antibiotics, hormones, cytotoxic substances and/or biological preparations will not be accepted.

e) If the food supplements to be imported are made in plants dedicated to their manufacture or in plants that manufacture also food products, a GMP certificate to manufacture food supplements issued by the sanitary authority in the country of origin, mentioning the sanitary standard applied (compared with the US GDA CFR 21, part 111). Alternatively, proof of registration of the company and/or proof that the establishment is subject to periodic inspections by the competent sanitary authority. Reference should be made to the sanitary standard that applies to companies in the country of origin, in order to be able to assess that there is reasonable equivalence between this and the reference standard for food supplement manufacturing. In addition, documentation must be submitted from the company of origin indicating that it complies with subparts E and F of the aforementioned standard, endorsed by the Technical Director of the company in Uruguay.

EAEU

No veterinary control for supplements

On 1 April, the Eurasian Economic Commission's Board published resolution No. 52 dated 29 March 2022 amending the Uniform Veterinary Requirements for Goods Subject to Veterinary Surveillance amending the list of goods subject to veterinary control. The following foods are now excluded from the unified list:

- vitamin, mineral or vitamin and mineral complexes (premixes);
- dietary supplements;
- flavors and flavoring agents;
- foods based on protein concentrates and isolates (of animal and vegetable origin) and their mixtures;

- food fibre and additives (including complexes);
- foods for special dietary purpose, including baby foods;
- foodstuffs intended for infant food production as feedstock;
- sugar icing, pastes and fillings for confectionery.

The requirements come into force on 28 September 2022.

Towards harmonized levels of biologically active substances for children aged 1.5 to 17

In March, the Working Group on draft amendments to Union's regulations (TR TS 021/2011 On food safety and TR TS 027/2012 On safety of foods for special dietary purpose) that introduce special requirements for dietary supplements, closed their discussions and finalized the draft document.

The Group notably agreed to introduce recommended daily intakes of vitamins, vitamin-like substances, and minerals for children aged from 1.5 to 17. The new levels will be used in manufacturing and labelling of dietary supplements.

The finalized amendments will now be reviewed by the Commission's Consultative Committee before being further sent to EAEU member states for the internal state approval.

Russia

ID tagging guidelines agreed

The Ministry of Industry and Trade has approved guidelines on a pilot ID tagging of dietary supplements.

The Russian governmental decree No. 673 dated 29 April 2021 approved the procedure for a pilot project in Russia to ID tag dietary supplements and also introduced the list of dietary supplements to be included in the pilot.

The document sets out:

- Details of applying ID tags to dietary supplement packaging;
- Instructions for pilot participants on how to submit information on the marketing of dietary supplements into the state information system;
- Specifics of the ID tags used for dietary supplements.

The pilot was originally scheduled to run from 1 May 2021 until 31 August 2022. The draft governmental decree extends the period until 28 February 2023.