IADSA NEWSFLASH

July 2020

Regulatory news

India

Use of PABA prohibited

The Food and Standards Authority of India has recently reminded companies that nutraceuticals and health supplements containing PABA (Para Amino Benzoic Acid) are not allowed since 2018 due to safety concerns. Products already manufactured / imported shall be withdrawn from the market immediately.

According to FSSAI, several health supplements and nutraceutical products containing PABA are still being sold in the market as well as on e-commerce platforms. Commissioner of Food Safety of States are requested to carry out surveillance and enforcement of the 2018 decision.

Korea

Inclusion of new benefits

The Korean Ministry of Food and Drug Safety has recently updated its Health Functional Food Code to include the following benefits:

- Probiotics: help promote gut health
- Ginseng: helpful to bone health
- Vitamin C: antioxidant properties
- Vitamin E: antioxidant properties

In addition, liquid form probiotics are now permitted for use in health functional products. Until now, only the dry form was allowed.

Fraudulent behaviour

MFDS is cracking down on the sale of foods with illegal Covid advertisements.

Under the Standards for Prohibited Food Labelling and Advertising, business entities in violation of the regulations are subject to the following administrative penalties:

- Suspension of the business licenses for more than two months;
- Revocation of the business licenses or registration;
- Shutdown of the business place
- Financial penalty

Webpages containing illegal content will also be shut down.

CBD: Under discussion

The inclusion of CBD to the cannabis in Food Code, today only applicable to THC, is currently under discussion within MFDS.

The provisions are:

- In hemp seed: CBD: less than 10 mg/kg
- In hemp seed oil: CBD: less than 20 mg/kg

Thailand

Fish oil: alignment with Codex

The Food and Drug Administration (Thai FDA) has recently notified WTO about aligning its national requirements of safety and quality for fish oils with the Codex standard.

The notification specifies that food products containing fish oils shall comply with relevant notifications of the Ministry of Public Health (MOPH).

For example, for food supplements consisting of fish oil, the product shall comply with requirements for safety, quality, labelling and warning statements as specified in the notification of MOPH.

Green light for prebiotic chicory claim

The Thai FDA has recently approved a health claim for the effect of a chicory root fibre to increase Bifidobacteria in the intestine.

The new health claim may be formulated on the packaging according to the Thai FDA guideline: Inulin/Fructo-oligosaccharide/Oligofructose/Short-chain inulin from chicory helps to increase Bifidobacteria in the intestine.

The health claim applies exclusively to the submitter of the application for inulin and Frutalose fructo-oligosaccharides from chicory roots. Uses include dairy, soy-based products, breakfast cereal, beverages without caffeine and food supplements, amongst others.

European Union

Call for use levels of aspartame

As part of its ongoing re-evaluation of the food additive salt of aspartame acesulfame (E 962), the European Food Safety Authority (EFSA) was consulted on the data to be used to estimate total exposure to the two moieties of the additive (aspartame and acesulfame).

EFSA recommended to launch public call for concentration data (use and use levels) for aspartame (E 951) that could complement the data already received for the salt of aspartame acesulfame (E 962) in response to the previous call issued in 2018. The deadline for the submission of data is 1 October 2020. E 961 and E 962 are currently permitted for use in food supplements.

Assessing the presence of nanoparticles

EFSA's Scientific Committee has launched an open consultation on its draft Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. This document sets out information requirements and establishes criteria for assessing the presence of a fraction of small particles. These requirements apply to particles requiring specific assessment at the nanoscale in conventional materials that do not meet the definition of engineered nanomaterial as set out in the Novel Food Regulation (EU) 2015/2283.

This Guidance complements the Guidance on Nanoscience and Nanotechnology adopted by the EFSA Scientific Committee in 2018.

Interested parties are invited to submit written comments by 09/09/2020

E 900 Safe

As part of its re-evaluation programme, the European Food Safety authority has recently reconfirmed the absence of safety concern at the currently authorised uses and levels of dimethyl polysiloxane (E 900).

E 900 is authorised for use in effervescent tablet form, excluding food supplements for infants and young children with maximum level (ML) of 10 mg/l. It is to be noted, that this ML applies to the dissolved food supplement ready for consumption when diluted with 200 ml of water.

A revision the name of the substance to 'poly(dimethylsiloxane)' was also suggested.

No-go for selenite triglycerides

The European Food Safety Authority has recently rejected the use of selenite triglyceride as a new source of selenium for food supplements.

According to the Authority, the information provided to characterise the absorption, distribution, metabolism and excretion of the novel form are mostly derived from studies using doses that were not representative of the potential dietary intake. The data provided also did not allow firm conclusions to be drawn on the fate of the novel food following ingestion.

The inclusion of the substance to the permitted source of selenium in food supplements will therefore have to wait.

New in supplements

The European Commission has recently extended the use of the prebiotic xylo-oligosaccharides (XOS) as a novel food to food supplements at levels of 2g per day.

- The Novel Food is obtained from corncobs (*Zea mays subsp. mays*) via enzyme-catalysed hydrolysis and subsequent purification. The Regulation authorising the extension of use will come into force on 22 July 2020.
- The novel food lacto-N-tetraose LNT has been authorised for use in food supplements at maximum level of 2,0 g/day for young children, children, adolescents, and adults. Data protection has been granted for this new ingredient for a period of five years from the date of entry into force of this Regulation (i.e. 23 April 2020) until 23 April 2025

A step forward for botanical tradition

The European Commission has recently published the Regulatory 'fitness check' (REFIT) report which covers certain aspects of the Nutrition and Health Claims, namely nutrient profiles and 'botanical' claims.

In its report, the Commission highlighted the need "to explore the notion of 'traditional use' in the efficacy assessment of health claims on plants used in foods together with the effects of the co-existence, on the EU market, of Traditional Herbal Medicinal Products on the same plant substances. "

Under the current mandate of EFSA, human studies are considered essential for the substantiation of claims, which implies that tradition is not considered sufficient to underpin the benefit of a botanical to human health.

Kudzu: Root extract is novel

Following a request of the Danish Veterinary and Food Administration (DVFA), the European Commission has recently clarified that the roots, leaves and flowers of Kudzu (*Pueraria lobata*) are not novel in food supplements.

However, since there is no history of consumption in the European Union prior to 15 May 1997, alcohol extract of kudzu (*Pueraria lobata (Willd.) Ohwi)* root is considered as novel food.

Alpha-lipoic acid under review

The European Commission has recently mandated EFSA to carry out a safety assessment of alpha-lipoic acid in supplements under the article 8 procedure. This procedure allows the possibility to prohibit, restrict or put under EU scrutiny the use of substances that could represent a potential risk to consumers.

The request follows safety concerns raised by the Danish National Food Institute and the Belgian Superior Health Council.

Belgium

Cinnamon bark and Basil essential oils: new recommendations

The Belgian Plant Commission has recently issued advice on Cinnamon bark and Basil essential oils in food supplement capsules.

Products not meeting the new recommendations are highly likely to be considered unsafe and be challenged by the Ministry during notification and/or Federal Agency for the Safety of the Food Chain during post-marketing control

Estonia

Blacklisting

The Estonian Veterinary and Food Board (VFB) has recently issued an updated list of products removed from the food supplement database and rejected from notification.

The initiative concerns products that the responsible company has duly notified as required by law, but for which the competent Estonian authority considers these food supplements as non-compliant.

France

Nano being challenged

In a report published in May 2020, the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) takes stock of the presence of manufactured nanomaterials in food products but excluded food supplements from its scope.

"*Whilst certain nanomaterials are used in food supplements, given the lack of information relating to the nature of the nanomaterials used in food supplements and consumption habits, these products were not considered in this report*" said the Agency. The presence of nanomaterials in food supplements will be subject to a risk assessment as part of a subsequent analysis & report.

In its May report, ANSES has identified 37 substances, used as food additives or ingredients, for which it considers that the presence of nanoparticles is proven (7 substances: calcium carbonate, titanium dioxide*, oxides and hydroxides of iron, calcium silicate, tricalcium phosphates, synthetic amorphous silicas, organic and composite compounds) or suspected (30 substances including: aluminium, silver, gold, magnesium phosphate, citrate of ferric ammonium, sodium, potassium and calcium salts of fatty acids, etc.).

Nanomaterials is not a new issue for France. Since January 2020, titanium dioxide (E171) has been banned in food including supplements. The decision was taken as a precautionary measure, as the data collected by ANSES did not provide "new information to remove the uncertainties about the safety of the additive E171".

In the meantime, ANSES has renewed its recommendations to limit consumer exposure by avoiding unnecessary use of nanomaterials in food and by promoting safe products, devoid of nanomaterials.

Ireland

Perspectives on role of BELFRIT

The Scientific Committee of the Food Safety Authority of Ireland considers that BELFRIT alone is not suitable for the Irish market, but in tandem with EFSA Guidance Document and Compendium of Botanicals it is a useful tool for risk assessment and management of botanicals.

This publication is the outcome of a request for advice for the FSAI SC to review the applicability of the BELFRIT (BELgium, FRance, ITaly) project to develop a common standard for botanicals. The FSA SC work did not consider the safety of individual botanicals but focussed on their risk assessment as a category of ingredients.

The request in particular addresses the following two questions:

1. Is the safety risk assessment approach used for the botanical species on the BELFRIT list robust and suitable for potential adoption for risk management purposes of these botanicals on the Irish market?*

2. Are there any scientific concerns or considerations that the FSAI should be aware of when considering possible adoption of the BELFRIT list of botanicals and its associated warnings?

Luxembourg

Tracking COVID health claims

The Food Safety Division of Luxembourg has recently published the first results of its control campaign relating to health claims linked to the Coronavirus.

The control campaign ran in April and May and showed only a few non-conformities directly related to COVID.

It was however observed that although products did not necessarily refer directly to coronavirus, websites selling food supplements had blogs on COVID and how people can protect themselves from it. In connection with strengthening of the immune system, a link to products rich in vitamin C was also made.

The campaign covered all Luxembourg operators selling food supplements online.

Latvia

Addressing botanical safety

Latvia has notified a revised new draft Regulation on plants and parts of plants prohibited for use in foods to the European Commission and EU Member States. This contains 61 plants/species generally known for their toxicity.

From 1 January 2021 the use of these plants in food and supplements will be prohibited.

The draft legislation also foresees a list of plants whose use in foods is restricted and a list of other substances with a nutritional value or physiological effect used in food supplements. These annexes have not yet been notified.

The Netherlands

New wakeup call

The Healthcare and Youth Inspectorate (IGJ) in the Netherlands announced that written warnings will continue to be given until 1 July to companies exceeding 0,3 mg of melatonin per day in their products for violations of the Medicines Act.

A market inventory has shown that more than 430 melatonin-containing products are traded on the Dutch market, involving dozens of manufacturers, wholesalers and retailers that are marketed for children and adults. The daily doses of the melatonin-containing products range from 0.1 mg to 20 mg.

The fine for violating the Medicines Act has been raised to 150,000 Euro.

Raising awareness

The Office for Risk Assessment & Research (BuRO) in the Netherlands, has recently advised the Inspector General of the NVWA to widely publicize to manufacturers and distributors the safety risks linked to overdoses of black cohosh preparations and its unsuitability for 5 specific population groups of users (pregnant or breastfeeding women, children, patients with (a history of) liver disease, patients who are or have been treated for breast cancer or other hormone-dependent tumors and people who are hypersensitive to the active components of black cohosh).

According to BuRO, doses of black cohosh extracts up to 40 mg/day can generally be considered as safe for up to 6 months but due to the lack of information on safe use during pregnancy, lactation or children, the safe dose of 40 mg/day does not apply to these risk groups. The use of standardized extracts in accordance with Internationally Accepted Monographs (EMA) has also been recommended.

Switzerland

New Food Regulations come into force

Swiss authorities have approved amendments to various food law regulations, including the law setting maximum levels for vitamins and minerals in food supplements and fortified foods. These changes come into force on 1 July 2020.

The main elements of the changes in this law include:

- The maximum amounts for nutrients, which can have health impacts when the dosage is too high, have been greatly reduced (e.g. zinc (5.3 mg)
- For non-critical nutrients, such as vitamins B1, B2, B12, biotin and pantothenic acid maximum amounts are no longer set.
- Vitamin A is only permitted in the form of beta-carotene.
- The use of boron is now permitted (1 mg per day).

The maximum levels of the following already permitted substances have also been increased:

- Coenzyme Q10: 200 mg (instead of 50 mg)
- Coenzyme NADH: 20 mg (instead of 10 mg)
- Carotenoid lutein: 20 mg (instead of 10 mg)
- L-carnitine: 2000 mg (instead of 1000 mg)
- Eicosapentaenoic acid (EPA) + docosahexaenoic acid (DHA) (as a total): 5000 mg* (instead of 3000 mg)
- Docosahexaenoic acid (DHA): 1000 mg (instead of 250 mg) / 450 mg for pregnant or lactating women. A warning is required for DHA for a daily dose above 450 mg ("Not appropriate for pregnant or lactating women")
- Lactulose is added (10 mg/day).

Finally, a list of plants, parts of plants and herbal preparations not permitted in food is established, as well as a list of edible mushrooms which may only be placed on the market in accordance with specific conditions of use.

Products that do not comply with the changes may still be imported and manufactured until 30 June 2021 according to applicable law, and provided to consumers until the exhaustion of stocks.

United kingdom

Borderline: where it should be drawn

MHRA has recently updated its guide "to what is a medicinal product".

While the information on the interface with food supplements and the application of mutual recognition has not changed, a new section providing guidance on the classification of CBD has been included, pointing out the potential classification of the substance as medicine.

Australia

Reclassification

The Australian Therapeutic Goods Administration is proposing to declare under section 7 the Therapeutic Goods Act 1989 that sports supplements containing ingredients not acceptable for food (e.g. medicinal ingredients or substances include in the World Anti-Doping Code Prohibited List) and/or that are presented like medicines (e.g. in capsules, tablets or pills) are to be regulated as medicines, rather than foods. The proposed date of entry into force is September 2020.

South Africa

CBD down-scheduled

The Minister of Health has amended in May the scheduling of cannabidiol (CBD). Government Gazette 43347 specifically states that CBD has been reviewed and is now officially a Category D, SO Complementary Medicine with relevant low risk claims.

USA

More time to make changes

Compliance enforcement with the new Nutrition and Supplement Facts labelling requirements will be extended to the end of the year, which makes the new target date for enforcement 1 Jan 2021.

Resuming domestic on-site inspections

FDA has announced that it plans to resume on-site domestic inspections in the week of 20 July 2020.

Prioritized domestic inspections will be pre-announced to FDA-regulated businesses. This will depend on the data about the coronavirus' trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments.

Acknowledgment of supplement value

During its recent Draft Advisory Report Meeting, the 2020 Dietary Guidelines Advisory Committee (DGAC) affirmed the importance of supplementation with iron, vitamin D and folic acid for pregnant women, recognizing the role of supplement products in meeting adequate nutrient intakes and supporting overall health and well-being.

The report however discourages the use of supplements for women who are lactating, noting that prenatal supplements are specifically formulated to meet the high iron requirements of pregnant women. In addition, the Committee does not advise routine iron supplementation for breastfed infants without iron deficiency.

Argentina

4 new ingredients to be included in the food supplements regulation

The National Commission of Foods has opened for public consultation a proposal to include in the food supplements regulation lutein/zeaxanthin, coenzyme Q10, resveratrol and lycopene. Currently, these ingredients are permitted on a case by case basis, depending on individual company applications. The proposal states that there is enough evidence of their physiological and/or nutritional role and that the proposed concentrations of use in food supplements have no therapeutic function. According to the draft, these ingredients would need to comply with the specifications from Food Chemicals Codex and/or United States Pharmacopeia and/or other pharmacopeia.

Coral red algae and edible mushrooms as food ingredients

The National Commission of Foods has opened for public consultation two proposals to include in the Argentinean Food Code. The first seeks to include the use of coral red algae or Phymatolithon calcareum (Pallas) or Lithotamnium calcareum, while the second proposal includes the use of 21 edible mushrooms (Ascomicetes and Basidiomicetes) whether wild or cultivated. Purity and identity specifications are provided in each proposal.

Brazil

New food additive in iron supplements

ANVISA has recently included sucrose esters of fatty acids (INS 473) in the list of permitted food additives for food supplements, foreseen in Resolution RDC 239/2018. This substance can now only be use as an emulsifier in iron supplements as tablets, gums, dragees, capsule, gelatine capsules, tablets and chewable forms. The maximum limit is 7 g/100 g. It can be used alone or in combination with sucrose oligoesters, Type I and Type II (INS 473a), and sucroglycerides (INS 474).

Guatemala

Rules for food supplements under medicinal Law

The Department of Regulation and Control of Medicines and Related Products from the Ministry of Health issued Version 1 of Technical Standard No. 14-2020 that establishes the requirements for the registration of food supplements under medicinal law. The text ratifies the requirements already set out for those food supplements regulated as medicines regarding the minimum and maximum limits of vitamins, minerals and other ingredients. The only change to existing requirements is that interested companies must now submit the additional information requested by the sanitary authority within a maximum period of 6 months, not in 1 year as has been the case.

A separate initiative is expected from the Ministry of Health's food regulation division to ratify the rules for food supplements placed on the market under food law.

Currently, in Guatemala food supplements can be classified as food or medicines depending on their composition and intended use.

Peru

GMP Equivalent Documents

The sanitary authority in charge of the control and surveillance of medicines, including food supplements, issued Resolution N° 026-2020-DIGEMID-DG-MINSA which approves the "List of Equivalent Documents to the GMP Certificate". As of now, food supplement companies can submit one of the following documents if they do not count with a GMP Certificate:

- HACCP certificate,
- ISO certificate related to the manufacture of food supplements,
- Attestation for Exportation (only for food supplements from Switzerland and Monaco),
- Free Sale Certificate (only for food supplements from the United Kingdom).

In case of companies interested in presenting other document not listed on the list above, a prior assessment must be requested to the General Directorate of Medicines, Supplies and Drugs (DIGEMID).

SIECA

Promoting supplementation

The Nutrition Institute of Central America and Panama (INCAP) has published a technical opinion regarding the use of food supplements by health and other essential staff in the frontline during the COVID-19 pandemic. According to INCAP, there is only scientific evidence to support the use of vitamin C, vitamin D and zinc supplements in the prevention of common colds, respiratory infections in people of different ages and also to accelerate recovery. Regarding the use of supplementation with other micronutrients, the document

indicates that current scientific evidence is not sufficient to support their use in the prevention of respiratory diseases.

Belarus

Traceability system for sport supplements

The Belarus government Resolution 312 of 25 May 2020 amends the order for inspecting the quality and safety of dietary supplements.

In January 2019, the Belarusian government adopted the provision for the procedure and conditions of inspecting the quality and safety of dietary supplements and foods for special use intended for athletes. The EEC Board's Resolution 187 of 29 October 2019 reads that the Belarusian requirement for additional conformity assessment for such products establishes a barrier to EAEU-wide trade.

The new version of the draft resolution is significantly abridged and replaces mandatory conformity assessment with monitoring the quality and safety of domestic and imported dietary supplements and sport foods by way of ensuring their traceability on the market.

According to the Union's regulation CU TR 021/2011 on safety of foods, traceability of foods is "the possibility of identifying, in documentary form (in the form of hard-copy and/or electronic media), the manufacturer and subsequent owners of products on sale, with the exception of the end user, as well as identifying the place of origin (manufacture) for foods and/or alimentary raw materials". Belarus is likely to require submission of documents for every batch of goods brought to their market.

EAEU

First amendments to safety regulation

At its May session, the EEC Board decided on the procedure to introduce Amendment 1 to CU TR 021/2011 on food safety (adopted by the EEC Council's Resolution in August 2019). Among other issues, the amendment applies to bring the list of plants whose use in dietary supplements is prohibited (Addendum 7) in line with the latest version of the Uniform Sanitary Requirements (Addendum 6). The amendments entered into force on 11 July 2020. Within the grace period, to last until 11 July 2021, manufacture and sales of foods under the previous requirements will be permitted in the EAEU. Sales of foods released onto the market prior to the end of the grace period will be permitted until their manufacturer-defined expiry date.

Mandatory GMO symbol

26 June 2020 marked the end of the grace period for the latest amendments to CU TR 022/2011 on food labelling as applied to the labelling of foods involving GMO foods. Such foods will now have to be labelled accordingly (the relevant EEC Council resolution came into force in December 2018).

The labels of GMO foods will have to have, alongside the EAC marking, a GMO symbol of the same size.

If a food manufacturer does not intentionally use GMO, the content of GMO, less than 0.9%, will be viewed as inadvertent presence. Such products will not be considered as GMO products, and will not have to be marked as such. GMO foods released onto the market before 26 June 2020 without proper labelling may continue to be marketed until their expiry date.

Russia

Harsher penalties for falsified supplements

The following two laws were adopted on 1 April 2020:
- Federal Law 89-FZ on amending the Administrative Violations Code;
- Federal Law 95-FZ on amending Article 238.1 of the Criminal Code.

Both laws are aimed at introducing harsher penalties for sales of falsified dietary supplements with the use of the media or electronic or telecom networks, including the internet Both laws came into force after their publication.

Distance sales at hand

Pharmacies and individual entrepreneurs licensed to engage in pharmaceutical activity have now the right to sell dietary supplements through distance selling.

As per the law, distance retail sales of over-the-counter medicines may be performed by pharmacies which hold corresponding licences and permits issued by federal executive bodies authorised to supervise the health care system. It will be for the government to establish the issuance procedure for such permits, as well as requirements for approved pharmacies, the sales procedure and the rules governing the delivery of sold medicines.

Ukraine

Aligning with EU food contact materials provisions

In May 2020, the Ukrainian Ministry of Economic Development, Trade and Agriculture posted on its website a draft law "Requirements for food contact materials and articles" for public discussion.

At present, Ukraine has no legislation governing the safety of food contact materials and articles used in the manufacture, marketing and use of foods. The association agreement with the EU mandates that the country brings its laws in line with EU legislation, including requirements for chemicals migrating from packaging materials to foods.

Should the proposal be passed into law, it will come in effect within six months of official publication. Until the relevant state registries have been set up and launched, food contact materials and articles permitted in the EU will be similarly permitted in Ukraine.

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