IADSA NEWSFLASH

March 2022

Regulatory news

China

Claims Catalogue modified

The China State Administration for Market Regulation (SAMR) is proposing to remove three health food functions “promoting lactation", "improving growth" and "improving skin lipids" from the Catalogue of health food function for non nutrient supplements currently containing 27 functions. Some of the remaining 24 functions will be slightly modified (e.g. “Losing weight’ replaced by “Help control body fat”)

Among other changes foreseen, SAMR has clarified that the testing methods for the evaluation of health food functions, should be regarded as recommended methods rather than mandatory methods.

Korea

Titanium Dioxide on the table

The Korean Ministry of Food and Drug Safety MFDS is reviewing TiO2 usage, following the EU decision to ban TiO2 in food and supplements. Data at national level is currently being gathered on usage levels, transition periods etc.

Update: Health Supplements Guidelines

South Korea is Consulting on changes to the Health Functional Food Code. Notably, it is proposed to:

Add a new function for ginseng:

The function would read: helpful to improve immunity, recover from fatigue, benefit for bone health, and benefit for liver health”. (Change in bold)
Recommended daily intake for “benefit to liver” : Total amount of ginsenoside Rg1 and Rb1: 28.8mg (equivalent to 2.4g ginseng extract).

Delete Aloe whole leaf from the specified functional ingredient list:

According to the Ministry of Food and Drug Safety (MFDS), the side effect of hepatotoxicity was found after continuous consumption of the aloe whole leaf ingredient for a long time. Therefore, the authority proposed to delete this raw material from the functional ingredient list.

However, the aloe gel still remains a functional ingredient.

Indonesia

Getting in tune with ASEAN labelling requirements

Indonesia FDA (BPOM) launched a consultation on new labelling requirements for health supplements. Generally speaking, the lists of minimum labelling requirements are aligned with the ASEAN labelling guidelines for heath supplements. The New law also proposes the inclusion of mandatory national country specific provisions such as halal label, 2D barcode. In addition, the labelling information shall be indicated both on the primary and the secondary packaging, and shall be directly or firmly printed on the container or the packaging. Stickers can be used when necessary modifications are required after approval by BPOM.

Philippines

Potential restriction of ingredients

The Food and Drug Administration of Philippines is consulting on a draft law aiming to clarify the status of "borderline" products. This draft establishes a list of ingredients some of which are currently widely sold as food supplements in other markets (e.g. CoQ10, glucosamine). According to the proposal, supplements containing these ingredients would be classified as medicines.

As of today, the proposal has now been deleted from the Government portal.

Singapore

Update

Singapore Health Sciences Authority (HSA) has recently updated its Health Supplements Guidelines.

This Guidelines introduces the regulatory requirements of health supplements from the perspective of safety & quality (including prohibited ingredients, contaminants limits, use of vitamins and minerals,

etc.),definition, labeling, advertising, etc.

Notably it is emphasised that:

Health supplements are free of premarket approval or licensing by HSA for their importation, manufacture, and sales in Singapore.

Companies are responsible for the safety of their products. To guide companies, the Guideline includes the list of ingredients prohibited to be added in health supplements, such as substances listed in ASEAN Guiding Principles for Inclusion into or Exclusion from the Negative List of Substances for Health Supplements, and Catalogue of Prohibited/ Restricted Ingredients for Health Supplements (Annex A of the Guideline).

Products should keep to the vitamin and mineral maximum levels that have been agreed at the ASEAN level. However, higher levels may be permitted for adult populations where there are credible authoritative references or expert opinion to show that: a) supplementation over and above the established limits for the general adult population is needed; and b) medical professional's assessment and recommendation on specific patient's additional supplementation needs.

EU

All's well that ends well

In August, The Commission updated its Union list of authorised novel foods to include among others, Calcium L-Methylfolate, a source of folate, which was erroneously not included in the initial Union list of Novel Foods, while the substance was authorised in the EU since 2008. However, the substance was still subject to a new error, the omission of food supplements for infants and young children from the authorised targeted users' group. The error has now been corrected.

Call for data on Pullulan

As part of its re-evaluation programme of food additives, the European Food Safety Agency (EFSA) has launched a call for data regarding the use of pullulan E1204. EFSA is looking more specifically for the following information:
1. Safety evaluation strategy and corresponding testing strategy.
This relates to the new 'EFSA Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles' (so-called 'EFSA SC Guidance on particle-TR'). Interested parties and/or stakeholders are requested to provide scientific evidence, supported by data, confirming that the food additive pullulan (E 1204) meets the solubility or the dissolution rate criteria indicated in Section 2 of the EFSA SC Guidance on particle-TR.

2. Technical data

3. Information on production organism

4. Data on use and use levels for food supplements in solid forms.

5. Biological and toxicological data

Regulation on the ban of TiO2 published

The expected Regulation on the ban of the use of titanium dioxide (E171) as a food additive has been published.

Until 7 August 2022, foods produced in accordance with the rules applicable before 7 February 2022 may continue to be placed on the market. After that date, they may remain on the market until their date of minimum durability or 'use by' date.

Belgium

Lutein: half of it

The Belgian authorities have reduced by half the permitted limit of lutein, from 20 to 10 mg/day in supplements.

The new level has been included in a new Ministerial Decree covering food supplements containing substances other than nutrients and plants or plant preparations. This Ministerial Decree abolishes the Ministerial Decree of 19 February 2009 (as amended in 2018).

Levels and conditions of use of the other permitted substances included remain unchanged with the exception of monacolin K, where the name of the substance has been slightly revised as follows: *Monascus purpureus* (red rice yeast) or other sources of monacolin K" to: "Monacolin K sources other than those covered by Regulation (EC) No 1925/2006".

Interpretation & clarification

The Belgian authorities have published two FAQ documents to assist companies regarding the implementation of the Plants Royal Decree and the national notification system known as FoodSup.

The FAQ Document on Plants Royal Decree and the Plants Commission clarifies the conditions of use, information that must be provided for the analysis certifications, methods to be used, difference between LOD and LOQ, derogations, differences with BELFRIT, plant-based infusions, Bach flowers, essential oils. The FAQ also provides information on the Plants Commission and the procedures to obtain an opinion

FAQ Document on Notification System (FOODSUP) clarifies elements specific to the notification system, such as ingredients not found in the list, payment methods, processing time of a file and other information for companies notifying supplements in Belgium

Bulgaria

Alignment with the FS Directive

Bulgaria has recently published a new Ordinance (link) on food supplements. This new legislation transposes the Food Supplements Directive and includes the establishment of minimum and maximum levels for vitamins and minerals in food supplements.

- Annex 1: List of permitted vitamins and minerals
- Annex 2: List of permitted vitamin and mineral sources
- Annex 3: List of maximum daily levels for vitamins and minerals for adults over 18 years of age.

The law also lays down:

- Purity criteria for nutrients intended for use in food supplements;
- The information to be noted in the labelling, presentation and advertising of food supplements;
- Substances which cannot be used in food supplements;
- Plants and parts of plants which cannot be used in food supplements. These include those preparations listed in Annex 5 of the Ordinance No 5 of 2004 on the requirements to be met by herbal preparation centres and herbal stores, those classified as narcotic drugs according to Ordinance on the Procedure for the Classification of Plants and Substances as Narcotic Drugs adopted by Decree No. 293 of the Council of Ministers of 2011 (promulgated in Official Gazette No. 87 of 2011) and finally botanicals listed in Annex III, Part A of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods.

New provisions have also been introduced for the mutual recognition of food supplements lawfully marketed in another Member State.

The Ordinance came into force on 13 January 2022.

France

Mapping out botanicals at risk

The Directorate General for Competition, Consumer Affairs and Fraud Prevention (DGCCRF) has asked its safety agency ANSES to provide scientific and technical support on the most widely reported botanicals in the national 'nutrivigilance' system. The outcome of this report is aimed to assist the French agency in their reflection on botanical food supplements and prioritise the monitoring of certain botanicals and essential oils that could potentially be subject to specific safety assessments and/or legislative measures.

The report notably identified 54 botanicals and 49 essential oils which are the most reported. Among these Curcuma spp.. Melissa officinalis, Passiflora incarnata. Camellia sinensi, Vitis vinifera, Paullinia cupana, Panax ginseng, Eschscholtzia californica, Piper nigrum, Valeriana officinalis for botanicals and Thymus vulgaris, Rosmarinus officinalis Eucalyptus radiata, Cinnamomum sp.. Mentha piperita for essential oils.

Germany

Legal status of Selenium products

The Joint Expert Commission has recently concluded that it is not possible to classify a food supplement as a medicinal product by function below a dose of selenium that can be absorbed in an appropriate amount through the consumption of general foods.

The Joint Expert Commission assumes that a nutritional-specific or physiological effect at dosages of up to 50 µg selenium per day is sufficient to maintain an adequate selenium supply even with a very low selenium intake from the general diet. As regards food supplements, the Joint Expert Commission does not recognise any nutritional-specific benefit beyond the compensation of deficiency in dosages above 50 µg selenium per day.

Products containing selenium are used as medicines, food supplements, foods for special medical purposes and fortified foods in Germany. The various product categories differ in their intended use. Medicines containing selenium are used to treat a proven selenium deficiency that cannot be remedied in terms of nutrition. Such medicines are only available in pharmacies and require a prescription in doses above 70 µg.

Addressing nutritional gaps

The German Federal Institute for Risk Assessment (BfR) is recommending daily supplementation from 100 up to 150 µg of iodine and 400 µg of folic acid.

According to the latest BfR communication, the general adult population is adequately supplied with folic acid with the exception of women of childbearing age who do not reach the blood folate levels recommended by the WHO to reduce the risk of birth defects, neural tube defects. Among the BfR recommendations, it is indicated that women who want to or could become pregnant should take 400 µg folic acid daily as a supplement in addition to a folate-rich diet. Supplementation should begin four weeks before conception and continue until the end of the 12th week of pregnancy.

As for iodine, according to data collected as part of the national health survey of the Robert Koch-Institute (RKI) "Study on the health of children and adolescents in Germany" (KiGGS) in the years 2014 to 2017, around 30 percent of the adults and 44 percent of the children and adolescents examined are at risk of insufficient iodine intake. For women of childbearing age, the risk is particularly high. Different measures are considered including: exclusive use of iodised table salt or iodised table salt substitute in the household; preference for foods made using iodised table salt, especially bread and meat products ; or a daily supplementation from 100 up to 150 µg iodine (in tablet form) after prior iodine anamnesis.

Now for the next one

Drawing up an algae list is now the next priority of the BfR.

In 2020, Germany published the second edition of its list of botanicals, known as Stoffliste, together with the 1st edition of the list of fungi. The Working Group on the List of Substances has now focused its attention on algae which according to the authorities are currently increasingly being placed on the market as food.

The draft list attached is open for comments until 13 April 2022.

Taking vitamins via food supplements is not useful

"By having a balanced and varied diet, a healthy person can get almost all vitamins in sufficient quantities. Nevertheless, the market for vitamins in the form of food supplements is growing continuously. The diverse range of tablets, capsules and liquids give the impression that a sufficient vitamin intake is not possible from diet alone. However, in most cases taking vitamins via food supplements is not useful. On the contrary: Taking high-dose food supplements in addition to a balanced diet increases the risk of an oversupply of the respective vitamins" Professor Dr.

Andreas Hensel President German Federal Institute for Risk Assessment (BfR) has said.

This BfR statement is based on the findings of a nationwide survey commissioned by the authority to find out how important food supplements are to cover vitamin needs, how often they are consumed and how the population rates their benefits and health risks.

The survey was based on 16 questions, including on frequency of intake of food supplements, suspected deficiencies, and risks and benefits of food supplements. The survey included 1,023 respondents of whom 445 respondents did not take food supplements and 572 respondents took food supplements.

About half of the respondents stated that they often consciously paid attention to an adequate vitamin intake. Fruit and vegetables were considered the most important sources of vitamins by almost all, followed by fish and legumes. Only about one quarter of the respondents considered food supplements to be an important source of vitamin intake.

As regards the intake frequency, 16% of respondents reported taking food supplements daily, 11% several times a week. About one third of the population takes vitamins via food supplements at least once a week. As regards the diagnosis or suspected vitamin deficiency, the highest was reported in vitamin D with 57%, followed by vitamin B12 with 35% and vitamin C with 15%, vitamin B6 11%, folic acid 11% and vitamin K 9%.

Most frequently, respondents spontaneously mentioned the compensation of a deficiency as a potential health benefit of food supplements. These results were more or less consistent with responses to the question of what vitamins respondents typically took from food supplements, where they indicated that the vitamins typically taken are:

vitamin D (45%),
vitamin B12 (36%),
vitamin C (32%),
multivitamin products (28%),
vitamin B6 (13%),
vitamin K (12%) and
folic acid (11%).

As the main health risk of taking food supplements, respondents mentioned a potential overdosage. Among the non-consumers of food supplements 59 % rated the likelihood of an oversupply as high when vitamins via food supplements were taken daily. Among the consumers of food supplements, this figure was lower: at 42 %.

As discussion continues at the EU level on establishing maximum levels of vitamins and mineral, it is probable that the survey results will be used by the German government as a basis to support their case for a more restrictive approach to setting levels.

Poland

Tightening rules

The Polish Government Legislation Centre has received a draft ordinance which aims to introduce a list of banned substances applying to all foods.

The substances listed in this resolution include: yohimbine hydrochloride (yohimbine group),methystine pepper (Piper methysticum),pancreatin, ibutamoren, DMAA, ligandrol, ostarine andarine, RAD-140 (testolone), and monkey tamarind (Mucuna pruriens). The proposal is based on two resolutions (Resolutions No. 6 and 9 /202) already banning the use of these ingredients in food supplements.

Selenium and Molybdenum limits

The Polish Food Supplements Team of the Chief Sanitary Inspector (GIS) continues its work on establishing maximum levels of nutrients for food supplements and has published the following new resolutions:

1. Resolution No. 7/2021 specifying the maximum amount of selenium at the level of 200 µg in the recommended daily dose in food supplements intended for healthy adults.

2. Resolution No. 8/2021 specifying the maximum amount of molybdenum at the level of 350 µg in the recommended daily dose in food supplements intended for healthy adults.

3. Resolution No. 9/2021 amending the negative list of substances not permitted for use in food supplements established in the Resolution No. 6/2021 by adding: testolone (RAD-140),andarine, monkey tamarind (Mucuna pruriens).

Alpha lipoid acid: Aligning with EU

The government's Polish Food Supplements Team has set up a maximum daily level of piperine in food supplements at 2 mg for adults. The label should also include a warning "not for use in children, pregnant and lactating women".
The authorities also foresee alignment of national rules related to alpha-lipoic acid (ALA) with EU law. Resolution No. 3/2016, stipulating that the content of alpha-lipoic acid in food supplements in individual forms should not exceed 600 mg for the racemate (R, S) and 300 mg for the active form of the (R) enantiomer, has therefore been repealed.
In 2021, in its opinion on the relationship between intake of Alpha-lipoic acid and the risk of insulin auto-immune syndrome (IAS), EFSA concluded it was not possible to determine a maximum amount because it is not possible to determine a safe dose since the symptoms and their severity differ per person.

During the last EU discussion, the Commission and Member States indicated that a total ban of the substance would not be appropriate (i.e. inclusion in the prohibited list, given that very few people are at risk and the symptoms are reversible). A warning on the label of products containing ALA is currently being considered.

Luxembourg

Listed

Following numerous recalls since September 2020 of products contaminated with ethylene oxide, the Luxembourg food safety authorities have published a list of affected products, among which 21 food supplements. The list will be updated when the authorities become aware of new contaminated products. The ethylene oxide crisis arose with sesame seed from India. Ethylene oxide is not an approved pesticide in the EU but its use seems to be very frequent in India and in other part of the world.

Warning about product legality

Food safety officials in Luxembourg have issued a warning after a company in the United States contacted residents about dietary supplements.

The Food Safety Unit of the National Health Directorate said it has learned of an incident in which an unnamed business based in the United States approached people in Luxembourg on social media to recruit them to sell their products in Europe. Initial contact was accompanied by scientific articles aiming to show effectiveness of the products.

These food supplements have "questionable" claims and are potentially non-compliant with European regulations, according to the authority.
The Food Safety Unit said anyone accepting such a proposal would take responsibility for ensuring compliance with the requirements of food law. It urged people to remain vigilant in the face of such offers.

Norway

Consumers mislead

According to the Norwegian Food Safety Authority, many dietary supplements in Norway have illegal labels with misleading claims.
The Norwegian Food Safety Authority has examined 50 dietary supplements sold on the Norwegian market. The result was that nine out of ten examined dietary supplements were illegally labelled with claims that give the impression that they can prevent, treat, or cure disease.
"We have found many serious violations of the regulations for labeling. None of the examined products meet the requirements of the regulations. It is worrying and unacceptable that the companies do not follow the regulations, which are there to protect consumers," the Norwegian Food Safety Authority stated.

The Norwegian Food Safety Authority has controlled the use of medical claims and illegal use of health claims on product packaging, in marketing on websites, in newspapers, magazines, advertising magazines, TV, and social media. Both linguistic and pictorial claims were considered.
The audit focused on the following three areas: brain and/or memory bones, bones and/or joints and stomach and/or digestion.

Switzerland

Ti02: Ban spreading

The Federal Office for Food Safety and Veterinary Affairs FSVO has recently prohibited the use of titanium dioxide as a food additive. The ban comes into force on 15 March 2022 and is subject to a six-month transition period.

The decision to ban titanium dioxide in Switzerland is based on an updated safety assessment of this substance by the European Food Safety Authority (EFSA)

In May 2021, EFSA concluded that genotoxicity concerns could not be excluded. Therefore, the safety of titanium dioxide as a food additive can no longer be guaranteed. FSVO stated.

According to the FSVO, transposition of the EU law in Switzerland will allow Swiss and EU citizens to benefit from the same level of protection. It will also facilitate trade with the EU.
A Q&A has also been published on the FSVO homepage providing answers to consumers on questions related to the use of the additive.

Switzerland recommending vitamin D supplements for over 65s

The Swiss Federal Food Safety and Veterinary Office is widely distributing a flyer recommending over 65s to take vitamin D supplements in addition to a balanced diet.

Importantly, the government highlights the benefits of vitamin D not only for bone health but also to support the immune system, brain and heart health.

This Swiss development is an encouraging step forward. It is also an indicator that some of the barriers preventing government recommendations on supplements could be overcome in some parts of the world.

UK

TiO2: Divergence

The UK Food Safety Authority (FSA) has decided to launch their own review of the safety of titanium dioxide (E171).

The decision follows the outputs of the discussions from the UK Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) and the Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM).
In its interim report (link), the COT reiterated that on balance, the weight of evidence did not support the conclusions drawn by the European Food Safety Authority (EFSA) (link) .
The COT also agreed with the comments of the COM with regards to risk communication. The COM notably indicated that "EFSA conclusions were not justifiable based on the available evidence and this may create unnecessary concern for the public."

The COM also questioned the quality of the dataset and robustness of some of the studies used by the EFSA panel to draw its conclusions and noted that the overall data considered by EFSA were heterogenous. It was also noted that until relatively recently, the specification of E171 was poorly defined, which contributed to uncertainty in evaluation. The COM suggested that if practicable, restricting the amount of nanoparticles in the specification for E171 might reduce any potential genotoxicity risk.

As next steps, the FSA Secretariat is expected to present the available database on the genotoxicity of titanium dioxide to the COM. No clear timelines have been announced.

In the EU, of which the UK is no longer a member, the use of the food additive has now been banned with a six-month phasing out period ending on 6 August 2022.

Australia

Updating evidence guidelines for listed medicines

The Therapeutic Goods Administration (TGA) is seeking feedback on the updated 'Listed medicines evidence guidelines – How to demonstrate efficacy for listed medicines' (the

Guidelines), which is intended to replace the existing 'Evidence guidelines – Guidelines on the evidence required to support indications for listed complementary medicines v 3.0, January 2019'.

Listed medicines do not undergo pre-market assessment but are subject to post-market compliance reviews that determine whether these medicines comply with the relevant regulatory requirements for listing. This includes holding the appropriate evidence to substantiate the indication(s) being made for the medicine and being able to demonstrate to the TGA that the efficacy of the medicine is acceptable.

The purpose of this update is to enhance the readability and utility of the Guidelines; clarify the way the TGA interprets and analyses the different types of evidence; and clarify specific technical concepts that have been problematic or unclear in the existing Guidelines. The update of the Guidelines is not intended to change the regulatory requirements for listed medicines and will not change the existing requirements to substantiate indications.

Improving access to medicine adverse event data

TGA is seeking feedback, via an online survey, on a proposal to improve sponsor access to extract de-identified medicine adverse event data to support their pharmacovigilance (PV) obligations.

There is currently no ability for sponsors to automatically view or export de-identified adverse event data held in TGA systems. Instead, sponsors seek to access relevant data by manually searching the public Database of Adverse Event Notifications (DAEN) - Medicines and through email requests to the TGA.

Both of these methods are considered inefficient for sponsors and the TGA, resulting in delays in access to important safety information.

TGA is consulting sponsors to seek their advice for developing such functionality.

Amygdalin and hydrocyanic acid: proposed amendments to the Poisons Standard rejected

Australia has ruled against changing the permitted levels of amygdalin and hydrocyanic acid (HCN) that can be present in supplements and TCM products. TGA concluded that they are "substances of such danger to health as to warrant prohibition of sale, supply and use"

Currently, absence of amygdalin and conformity with an HCN restriction of maximum 1 microgram per litre or kg (1 part per billion) has to be demonstrated. It is understood that it is generally considered extremely difficult to achieve.

Update to listed medicine ingredients

TGA has recently updated its list of new Therapeutic Goods (Permissible Ingredients) covering 22 changes. The changes includes:

New ingredients and specific requirements that apply to that ingredient

Changed ingredients with the original requirements and the new or changed requirements.

Deleted ingredients if applicable.

The list can be found at this link: https://www.tga.gov.au/update-listed-medicine-ingredients-january-2022

USA

Qualified Health Claim for Magnesium and Reduced Risk of High Blood Pressure

The US FDA has announced it is allowing, for conventional foods and dietary supplements, three qualified health claims for magnesium and high blood pressure provided that the claims are appropriately worded to avoid misleading consumers and that other conditions for the use of the claim are met.

The three qualified claims read as follows:

"Inconsistent and inconclusive scientific evidence suggests that diets with adequate magnesium may reduce the risk of high blood pressure (hypertension), a condition associated with many factors."

"Consuming diets with adequate magnesium may reduce the risk of high blood pressure (hypertension). However, the FDA has concluded that the evidence is inconsistent and inconclusive."

"Some scientific evidence suggests that diets with adequate magnesium may reduce the risk of high blood pressure (hypertension), a condition associated with many factors. The FDA has concluded that the scientific evidence supporting this claim is inconsistent and not conclusive."

South Africa

Cannabidiol: Guideline

South African Health Products Regulatory Authority (SAHPRA) has updated its guideline for applications related to the registration of complementary medicines containing Cannabidiol.
Annexure 4 has been developed to guide the use of the substances when used in Complementary Medicines as Health Supplements.

Argentina

Registration fee up

The National Administration of Medicines, Food and Medical Devices

(ANMAT) has updated the fees for the registration of food products, including food supplements. The fee is generally updated annually based on the inflation rate and dollar exchange rate in Argentina. For example, the fee to register a food supplement was increased from 16,240 Argentinean Pesos (approximately 85 USD) to 20,450 Argentinean Pesos (approximately 108 USD).

New additives for supplements

The National Commission of Foods (CONAL) opened for public consultation a proposal to include in Article 1398 from the Argentinean Food Code polyethylene glycol (INS 1521) and polyvinyl alcohol (PVA) – polyethylene glycol (PEG) graft copolymer (INS 1209) for use in solid food supplements as coating or glazing agent. This was recently included in the Codex GSFA.

The proposal seeks to authorise the use of the additives only in food supplements in solid forms, including capsules and tablets, except for chewable forms, and except for those food supplements destined for infants and young children. The proposed limit for polyethylene glycol (INS 1521) is 7g /100g and for polyvinyl alcohol (PVA) – polyethylene glycol (PEG) graft copolymer (INS 1209) is 10g/100g.

Brazil

Amendment to tocopherol provisions

The National Agency for sanitary Surveillance (ANVISA) opened for public consultation a proposal to modify the maximum limits of tocopherols for use as additives in food supplements. The text proposes:

In liquid food supplements:

To reduce the maximum limit for D-alpha-tocopherol (INS 307a), mixed concentration of tocopherols (INS 307b) and DL-alpha-tocopherol (INS 307c) in liquid food supplements containing bioactive or fat-soluble substances from 300mg/kg to 0.2g/100 ml (except for those containing fish or algae oil).

To maintain the maximum limit for D-alpha-tocopherol (INS 307a) in liquid food supplements containing bioactive or fat-soluble substances of 0.6g/100ml only in fish or algae oil, alone or in combination with other authorised antioxidants

To maintain the maximum limit for DL-alpha-tocopherol (INS 307c) in liquid food supplements containing bioactive or fat-soluble substances of 0.6g/100ml only in fish or algae oil, alone or in combination of other authorised antioxidants

In solid food supplements:

To reduce the maximum limit for D-alpha-tocopherol (INS 307a), mixed concentration of tocopherols (INS 307b) and DL-alpha-tocopherol (INS 307c) in solid food supplements containing bioactive or fat-soluble substances from 1500 mg/kg measured in the fat content to 0.2g/100g measured per 100g of final product.

Additives: Make it easy

The National Health Surveillance Agency (ANVISA) has launched two new tools intended to help companies in understanding the permitted food additives and processing aids and their conditions of use in all food categories, including food supplements. The tools were developed based on the existing regulations, intended to facilitate the identification of substances, conditions of use, technological functions and maximum permitted limits. In addition, the tools provide quantitative information on the number of authorized food additives and processing aids, by food category and technological function. In this sense, it is important to clarify that information on enzymes authorized for use as processing aids are presented in a specific panel, also available on ANVISA's website.

Additives : Update

Brazil has recently updated its list of additives for food supplements:

Beeswax (INS 901) with stabilizing and thickening function, at quantum satis limit, only for liquid content in gelatinous capsules (subcategory 14.1 of Annex I of Resolution RDC 239/2018)

Beeswax (INS 901) with stabilizing and thickening function, at quantum satis limit (subcategory 14.2.1 of Annex I of Resolution RDC 239/2018)

Basic methacrylate copolymer (INS 1205) with glazing function at a limit of 10g / 100g (subcategory 14.2.1 of Annex I of Resolution RDC 239/2018)

Sucrose fatty esters (INS 473) with stabilizing function at a limit of 0.1g / 100g, with conditions of use (subcategory 14.2.1 of Annex I of Resolution RDC 239/2018)

Oligoesters of sucrose type I and II (INS 473a) with stabilizing function at a limit of 0.1g / 100g, with conditions of use (subcategory 14.2.1 of Annex I of Resolution RDC 239/2018)

Polysorbate 80 (INS 433) with stabilizing function, at a limit of 0.9g / 100g (subcategory 14.2.1 of Annex I of Resolution RDC 239/2018)

Calcium carbonate (INS 170i) with coloring function, at quantum satis limit (subcategory 14.1 and 14.2.1 of Annex I of Resolution RDC 239/2018)

Steviol glycosides (INS 960) with a sweetening function, at a limit of 0.024g / 100ml and different conditions of use according to the subcategory (subcategory 14.1 and limit of 14.2.1 of Annex I of Resolution RDC 239/2018)

Stearic acid (INS 570) with lubricant function and limit quantum satis

Many of these provisions have recently been agreed by Codex CCFA thanks to IADSA efforts to move pending provisions to completion in the Codex step process.

The changes were effective on 3 January 2022.

Colombia

Hemp: Green light

Colombia has given the green light for the use of hemp. The new regulation applies to the cultivation and harvest of cannabis, the process for obtaining the cultivation license and specific rules for its use as an ingredient in food supplements, food and beverages, among others.

For supplements, the regulation foresees the use of cannabis vegetal components, seeds and non-psychoactive derivatives. Ingredients obtained from the cannabis plant that are not included in the references adopted in Annex 3 of Decree 3863/2008 (and its modifications)

must be assessed by the Specialised Commission of Phytotherapeutic Products and Dietary Supplements from the National Institute for Medicines and Food Surveillance (INVIMA).

In particular:

THC limits should be established by the Ministry of Health in addition to a specific regulation for the use of CBD in the category

Manufacturers of food supplements containing cannabis ingredients must submit a certificate with the THC and CBD content

GMP certificate will also be requested

THC percentage must be declared on the label of the food supplement. In addition, images related to the authorised parts of the plant used will be permitted on the label

Claims related to cannabis ingredients must be authorised by the Specialised Commission of Phytotherapeutic Products and Dietary Supplements from INVIMA

Until the Ministry of Health issues a regulation for the use of cannabis ingredients in the category, CBD content must be non-detectable in the analysis.

Costa Rica

Authorising Hemp

On 2 March, the Costa Rican President signed Law 10.113 which approves the medicinal use of cannabis and the use of hemp as a food ingredient. The law seeks to regulate and allow the access and use of cannabis and its derivatives exclusively for medicinal and therapeutic use and authorises the production, industrialisation and marketing of hemp for industrial and food use. The President committed to issue a regulation to implement the Law this year. Since food supplements are covered by food regulation, it is expected that the use of hemp derivatives could be approved for the category.

Ecuador

Hemp: Another 6 months

The National Agency for Regulation, Control and Sanitary Surveillance (ARCSA) has authorised as an emergency measure, the use of hemp and its derivatives in food supplements, food, cosmetics and medicines. Since emergency measures are valid for 12 months, on 3 February 2022 ARCSA decided to extend it for another 6 months, meaning, August 2022. According to Resolution ARCSA-DE-2022-003-AKRG, any emergency measure from any country of the Andean Community of Nations is valid for 12 months and could be extended to 18 months. So far, the applicable regulation for the use of hemp ingredients continues to be Resolution ARCSA-DE-002-2021-MAFG.

Belarus

Supplement imports from the West banned

Under the Belarusian Council of Ministers Resolution 700 'On special measures with regard to individual types of product bans', imports of a range of products from the EU, the USA, Canada, Norway, Albania, Iceland, the UK, Montenegro, North Macedonia and Switzerland takes effect.

The list of banned products includes foods under FEACN codes 1901 90 and 2106 90, including food supplements. The ban came into force on 1 January 2022 and will stay in force for six months.

Ukraine

Ukrainian Health Ministry seeks to restrict sales of dietary supplements through pharmacies

In November 2021, Ukraine's Health Ministry published for comments a draft decree on amending the list of goods which can be sold by pharmacies.

As per the current list of products, Ukrainian pharmacies are allowed to sell: Functional foods, foods for special dietary use (including infant foods, foods for athletes and the elderly), dietary supplements; drinks not ascribed to dietetic or infant foods; diabetic foods; individual foods in original factory packaging such as chewing gum, chocolate bars, drops and dragees, biscuits; leaven and fibre.

The ministry believes some dietary supplements currently on sale in Ukraine contain active pharmaceutical ingredients which have therapeutic or prophylactic pharmacological, immunological or metabolic effect on humans, whereas accompanying information states that they are not medicines, which contradicts the Ukrainian law on medicines.

The draft decree calls for harmonizing the terms contained in the list in legislation and preventing sales of dietary supplements with therapeutic effect through pharmacies.

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