IADSA NEWSFLASH

May 2023

Regulatory news

India

New Nutraceutical Panel appointed

Food Safety and Standards Authority of India (FSSAI) has appointed its new Scientific Panel on Nutraceutical and Functional Foods which took effect on 1 March 2023. Members have been reduced from 11 to 9. Originally the Panel had 18 members when it was set up.

Special enforcement drive

The Food Safety and Standards Authority of India has been carrying out a special enforcement drive on Nutraceuticals and Health Supplement Products. This enforcement is based on the draft law - Nutra 2022 - which is still awaiting final notification.

Online registration of foreign facilities

Under an order (10 Oct. 2022) foreign food manufacturing facilities of milk and milk products, meat and meat products including poultry, fish and their products, egg powder, infant foods, and nutraceuticals required registration effective 1 February 2023. The Authority has specially provided a website (https://sites.fssai.gov.in/refom/), listing registrations from 31 countries. Most registrations are for milk, dairy, meat, fish, poultry and also for the nutraceutical category.

Hong Kong

CBD officially banned

Since 1 February, CBD has been listed as a dangerous drug under the Dangerous Drugs Ordinance (DDO). Under the DDO, trafficking (including importing and exporting) and sales of substances in contravention of the law will be subject to a maximum penalty of life imprisonment and a fine of $5 million. Possession and consumption of substances in contravention of the DDO will be subject to a maximum penalty of seven years' imprisonment and a fine of $1 million.

Korea

New scheme for foreign facilities

The Ministry of Food and Drug Safety (MFDS) has announced a new registration scheme for foreign food facilities with the aim of intensifying the control of imported foods.

The health functional food will be the first food category subject to the new registration scheme. The trial period will start from April and should end in October.

Importers of health functional foods will be required to submit safety certificates such as HACCP, GMP, ISO22000 when registering the foreign food facilities. For those who do have such certificates, an on-site inspection of foreign food facilities will be carried out by MFDS in the following year.

EU

Member States requested to enforce prohibition of CBD

The European Commission has recently published a statement in the minutes of its February Standing Committee meeting recalling there have been no authorisations for novel food of CBD, other cannabinoids, or products containing either CBD and/or other cannabinoids derived from the Cannabis sativa L. plant. The statement also clarifies that the Member States have the primary responsibility for the correct application, implementation and enforcement of EU legislation.

EU adopts its Green Claims proposal

The EU has recently adopted a Directive on Green Claims with the aim of addressing greenwashing and stop the proliferation of environmental labels.

According to the EU "94% of Europeans say that protecting the environment is important to them personally, and 68% agree that their consumption habits adversely affect the environment in Europe and globally. For this to happen, they need reliable, verifiable information."

The proposal targets explicit claims that:

- are made on a voluntary basis by businesses towards consumers,
- cover the environmental impacts, aspects or performance of a product or the trader itself
- are not currently covered by other EU rules

The proposal requires that the substantiation of environmental claims shall be based on an assessment that meets the selected minimum criteria to prevent claims from being misleading. This includes the need for proven scientific evidence and the need to demonstrate the significance of impacts, aspects and performance from a life-cycle perspective. Requirements for comparative claims are also set out.

Each Member State will be in charge to enforce the provisions. The Commission could also be empowered to adopt specific legislation to complement the requirements on communication for certain types of claims where necessary.

Consumer group calling for ban of climate neutral claims

Misleading 'carbon neutral' claims are rife in the food sector and confuse consumer according to BEUC, the European Consumer Organisation.

BEUC is calling on the EU to ban the use of carbon neutral claims for all products including food and drink.

According to a survey carried out by the Consumer organisation in 2019, over half of European consumers say that sustainability concerns have some (42.6%) or a lot of influence (16.6%) on their food choice.

Mineral oils: MOSH do not pose health concerns

EFSA experts have provisionally concluded that mineral oil saturated hydrocarbons (MOSH) do not pose a health concern. They also confirmed that some substances in the group known as mineral oil aromatic hydrocarbons (MOAH) are a possible health concern.

Relating to exposure from food supplements, EFSA opinions reported that few samples of food supplements (gelatine capsules/tablets) containing various plant extracts, beeswax, emulsifiers, different vegetable oils, etc. were reported with relatively high levels of MOSH (264.1 mg/kg). Assuming an average intake of one capsule per day (one gram) by an adult of 70 kg, the exposure to MOSH would be around 0.004 mg/kg bw.

The 2022 recommendations on MOAHs still apply. The Commission and Member States agreed at that time to withdraw and, if necessary, to recall products from the market, when the sum of the concentrations of MOAH in food are at or above the following maximum LOQs:

- 0.5 mg/kg for dry foods with a low fat/oil content (≤ 4% fat/oil)
- 1 mg/kg for foods with a higher fat/oil content (> 4% fat/oil)
- 2 mg/kg for fats/ oils
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Analysis and sampling should be done according to the provisions of Regulation (EC) No 333/2007.

UL for vitamin D: No change foreseen

The European Food Safety Authority is expected to publish in July its draft opinion related to the revisions of upper levels for vitamin D. It is understood that the current UL will remain unchanged.

Pyrrolizidine alkaloids: Clarification on batch release criteria

The EU has recently provided clarification relating to the precise way that the content of pyrrolizidine alkaloids (PAs) is to be measured for releasing lots of products and in particular confirming that the following two elements must be taken into consideration: The correction for recovery & the expanded measurement uncertainty.

The document specifies that: " a lot is rejected or not allowed to be placed on the market if the sample, taken in a representative way exceeds the maximum level beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty. This is the case when the analytical result (corrected for recovery if applicable) minus the expanded measurement uncertainty arising from the analysis is above the maximum level. In other cases, the lot is accepted. "

The legal maximum levels refer to the lower bound sum of the 21 PAs specified in Regulation 1881/2006 and that the Level of Quantification will be set at 10 mcg/kg (dried products) and 0.15 mcg/L (liquid products) for each of the individual PAs in the Regulation relating to methods of sampling and analysis of plant toxins that is still under discussion at Standing Committee level.

Clarifying borderline with FSMP

The Court of Justice of the European Union has ruled on the borderline between food supplements and food for special medical purposes (FSMP). In its judgment, the CJEU recalls that these two concepts are mutually exclusive. In determining the borderline between an FSMP and a food supplement, all characteristics of the product need to be taken into account to determine whether it is intended to meet the nutritional requirements of a patient that could not be achieved through regular diet or whether it is intended to supplement the normal diet.

The Court recalled that FSMP are foods intended to meet the specific nutritional needs of patients in relation to a disease, disorder or health condition while the "sole purpose" of food supplements is to supplement a normal diet by being a concentrated source of nutrients or substances with a nutritional or physiological effect. Food supplements are therefore an integral part of the normal diet by supplementing it.

The Court notably highlights that FSMPS must be used only by patients with specific nutritional needs and must be under medical supervision. This ruling arose in the context of proceedings between the Austrian authority and a company marketing product intended to be taken during urinary tract infections on the basis that the ingredients (D-mannose and cranberry) prevent bacteria from adhering to the mucous membranes of the urinary tract. The company classified the products as FSMPs and notified them to the competent authority in Austria. However, the Authority refused to accept the FSMP classification. The Authority took the view that the products could not be classified as foods since D-mannose and cranberry did not exert their effect by ingestions in the digestive tract but acted on the renal excretory organs.

France

Misuse of vitamin D supplements in infants

The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) received three new reports of severe adverse effects (severity level 3, including two life-threatening cases) in infants likely to be linked to the misuse of food supplements purchased on the internet containing 5 000 IU and 10,000 IU per drop of vitamin D. In these reports recorded in nutrivigilance, the intoxication follows the substitution of vitamin D in the form of medicine by a food supplement. This substitution was made on the decision of the parents or following imprecise advice from a health professional.

According to ANSES, the dosage error is linked to confusion between the different forms of expression of vitamin D doses. The concentration of vitamin D in the drug being expressed by ml whereas, in the food supplement consumed, it is expressed by drop.

ANSES noted that these products were purchased on the internet, which increases the risk of dosage error due to a lack of professional advice.

Endocrine disrputors: Adapted labelling provisions for vitamin D3

The French Authorities have notified under TRIS their new proposal for a law specifying how the presence of endocrine disruptors must be labelled, including for nutrients such as vitamin D.

The labelling requirements for indicating on the label the presence of substances that can have endocrine disrupting properties originate from the Public Health Law that establishes lists of such substances. Vitamin D3 (Cholecalciferol) is included in these lists (Table A) because it is also used at high doses as a biocide.

However, the proposed law highlights that due to the nutrient's character and its health benefits, the information on the presence of cholecalciferol (vitamin D3) with endocrine disrupting properties will be adapted and will read: "this substance has health benefits when used according to the precautions and dosage specified on the package leaflet or product labelling. If in doubt, seek the advice of a health professional.' While other substances with endocrine properties should bear the following statements: 'containing a substance or substances with proven or presumed endocrine disrupting properties' (for substances in List I of of Article L. 5232-5) or 'containing a substance or substances with suspected endocrine disrupting properties' (for substances in List I of of Article L. 5232-5).

Switch of responsibility

Responsibility regarding the notification of food supplements has recently been transferred from the Directorate-General for Competition Policy and Consumer Affairs (Ministry for the Economy) to the General Directorate for Food.

Plants containing HAD under scrutiny

The French Agency for Food, Environmental and Occupational Health & Safety, ANSES, has recently released a new note on identification of plants and plant parts likely to contain hydroxyanthracene derivatives (HAD) used in food supplements.

In that note, the Agency confirms that the current labelling requirement are justified for:

- Aloe (A africana, A arborescens, A ferox, A macroclada, A perryi, A plicatilis, A vera).
- Cassia (C fistula)
- Chamaecrista (C nomame)
- Frangula (F alnus = F dodonei = Rhamnus Frangula, F purshiana)
- Rhamnus (R alpina, R cathartica)
- Senna (S alexandrina = Cassia senna = Cassia angustifolia = Cassia acutifolia, S italica = Cassia italica, S obtusifolia = Cassia obtusifolia, S occidentalis = Cassia occidentalis, Senna tora = Cassia tora)
- Morinda (M citrifolia, M officinalis) (subject to further definition of the safety profile)
- Picramania (P antidesma)
- Reynoutria (R Japonica = Fallopia japonica = Polygonum cuspidatum, R multiflora = Fallopia multiflora = Polygonum multiflorum)
- Rheum (R australe = R emodi, R officinale, R palmatum, R rhabarbarum = R undulatum, R rhaponticum, R x hybridum)
- Rumex (R acetosa, R acetosella, R alpinus, R conglomeratus, R crispus, R longifolius, R obtusifolius, R patientia, R sanguineus)
- Saussurea (S costus = S lappa = Aucklandia costus)

The labeling must bear a warning advising against the use by children under 12 years old, pregnant and breastfeeding women and a statement advising against prolonged use. The amount of anthracene derivatives expressed as sennoside B must be less than the pharmacological dose (15 mg).

This French initiative could potentially lead to EU discussion on further restrictions/ ban on the use of the botanicals in supplements.

Rhodiola spp.to be included in the EU CITES legislation

EU is now aligning with CITES with the inclusion of Rhodiola species in the EU CITES Regulation.

Rhodiola spp. is included in Annex B with the annotation: "Designates all parts and derivatives, except: (a) seeds and pollen; and (b) finished products packaged and ready for retail trade.". This means that Rhodiola ssp. used as raw material will be subject to the restrictions applying to annex B: The introduction into the EU is subject to completion of the necessary checks and the prior presentation at the border customs office at the point of introduction of an import permit issued by a management authority of the Member State of destination.

There is no transition period. The Regulation will apply from the 3rd day after its publication.

Tightening up

Since in consignments of Gotu Kola (Centella asiatica) and Mukunuwenna (Alternanthera sessilis) from Sri Lanka a high rate of non-compliance with pesticide residues legislation has been detected during official controls, the European Commission will increase the frequency of identity and physical checks to be performed on those consignments entering the EU to 50 %. Increased controls are also implemented for certain other plants, vegetables, nuts and fruit and commodities known to be contaminated with ethylene oxide (such as locust bean and guar gum).

Curcumin: FS exemption

Turmeric extracts of the rhizome of Curcuma longa L, containing up to 95% of curcuminoids (also referred to as curcumins) are not considered to be novel food when used in food supplements. A history of consumption in the EU has been demonstrated for such an extract in food supplements. Use in foods remains subject to novel food authorisation.

Finland

Ashwagandha potential ban

Finland is considering to ban the use of Ashwagandha in food supplements. The decision is based on an opinion from a neighbouring country, Denmark, where the use of the botanical is already prohibited in supplements.

Turkey

New Health Claims published

The Ministry of Health has recently published the long-awaited Health Claims regulation. This text was expected since the shift of responsibility from Ministry of Agriculture (MinFaL) to the Ministry of Health in December 2018.
The new provisions are similar to the version in place under the responsibility of the Ministry of Agriculture's previous health claim regulation. Flexibility is given to brand names built as health claims which was a major topic of discussion in the workshop IADSA attended at the end of last year. Guidance on approved claims and conditions of use, including guidance on flexibility in the use of health claims, should be published shortly.

Procedures for new health claims applications are not yet covered in the new regulation.

Sweden

Maximum levels abandoned

While the European Commission has resumed its work to harmonise maximum amounts of vitamins and minerals in foods and supplements in all EU Member States, Sweden has this week announced the withdrawal of a national proposal on maximum levels for supplements.

This decision follows the opposition from the Swedish industry to set maximum limits. In 2020 the Swedish Food Agency presented a new model - influenced by the Irish model - which appeared to be problematic for several nutrients according to the Swedish sector. The proposal was not adopted at that time but a new slimmed down proposal with only two maximum values for vitamin D and iodine was presented in 2022 aiming to be implemented in 2024. This new proposal has also now been withdrawn.

Vegan labels: Getting confused

Many people have a worse understanding of labelling than they think - and vegan labelling is confusing. A recent survey carried out by the Swedish Food Agency reveals that most people are satisfied with how the food is labeled - even though they don't always understand what the labelling means.

The participants in the survey often have different ideas about what the terms vegetarian, vegan, vego, plant-based, lacto-vegetarian or lacto-ovo-vegetarian mean. Almost all concepts are unclear to consumers and many find it particularly difficult to understand what lacto-vegetarian and lacto-ovo-vegetarian mean.
Many people say that they often look for origin marking, especially when they are going to buy products they have not bought before. They also wish to receive information about the origin of a number of different products where there is currently no requirement for origin marking.
The survey is a follow-up to a survey from 2014 and has been carried out with focus groups, surveys, and in-depth interviews. The new survey shows largely the same results as the previous one.

New Zealand

Hope!

The New Zealand government has been consulting on the draft Therapeutic Products Bill that aims to regulate supplements as Natural Health Products. It is now more than 20 years that the IADSA member association (Natural Health Products NZ) has been working with the government to try and achieve a workable system. It is understood that the new Bill should in principle not disrupt the market and will allow health benefit claims.

South Africa

Government releases its new direction for supplements

In 2022 the Courts suspended the regulations on Complementary Medicines (including supplements) following legal challenge. The Minister of Health was given 12 months to put a lawful and valid regulatory framework in place. A proposal has now been issued to address the issues identified by the Court.

The new proposal has removed the definitions of complementary medicine and health supplements and only refers to Category D, namely classes 33 and 34.

Class 33 has not changed and includes: CMs Discipline specific traditional claims including aromatherapy, homeopathy, phytotherapy, TCM, unani, Western herbal, combination and other herbals.

Class 34 has not changed and includes amino acids, amino-saccharides, animal products, carotenoids, enzymes, fats, minerals, polyphenols, probiotics, saccharides, vitamins, multi-substance and other substances.

However, there are fears that some products may be classified as medicines which would impact the requirements to place them on the market.

USA

FTC warning companies

The United States Federal Trade Commission (FTC) has announced that it has sent a letter to almost 700 companies involved in the marketing of OTC drugs, homeopathic products, dietary supplements and functional foods, informing them of the penalties for violation of the prohibition on deceptive or unfair practices under Section 5 of the Federal Trade Commission Act.

Under FTC law, companies must back up claims about what their product can do with reliable evidence. If a company makes a claim about the health or safety benefits of a product, that claim must be based on scientific evidence.

FTC has in the past issued similar reminders on a range of topics to attempt to establish that marketers have actual knowledge of the unfairness or deceptiveness of making unsubstantiated health claims.

New Directory of Dietary Supplement Ingredients

The U.S. Food and Drug Administration (FDA) has recently unveiled a new directory of ingredients used in products marketed as dietary supplements.

According to FDA, the directory is intended to be a one stop shop of ingredient information that was previously found on different FDA webpages. At present, the only ingredients listed are those about which FDA has expressed concerns or taken enforcement actions.

It is clarified that the directory is not intended to be a comprehensive list of all ingredients used in products marketed as dietary supplements and may not include all actions the agency has taken with respect to a particular ingredient.

Restrictions for supplements removed

A Colorado Senate Bill (SB 23-176) "Protections For People With An Eating Disorder" has been amended to remove restrictions to the sale of dietary supplements marketed for weight management. Similar bills targeting dietary supplements have recently been vetoed by governors in the states of New York and California.

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Brazil

All in one

Following the decision of ANVISA's Board of Directors, all permitted additives are compiled under a single act, including those for food supplements.

The recent text IN 211/2023 includes the following annexes: Technological functions of additives (Annex I), Technological functions of processing aids (Annex II), Maximum limits and conditions of use of additives authorised for use in food by category (Annex III), Maximum limits and conditions of use of processing aids authorised for use in food (Annex IV)

Novel food process

ANVISA will be receiving comments until the end of July on the proposal to update the procedures for novel foods and ingredients, mainly the safety and authorisation assessment foreseen in Resolution 16/1999 and 17/1999. ANVISA has recognised that the regulation and process for novel foods and ingredients is outdated and aims to modernise and accelerate it.

References from the European Union, Australia, New Zealand, Canada and the United States have been consulted.

The proposal seeks to include:

- A revised definition for novel foods and ingredients, as follows: *"foods and food ingredients without a history of safe consumption in Brazil obtained from plants, animals, minerals, microorganisms, fungi, algae or synthetically, including, but not limited to, those that:*

  a) have a new or intentionally modified molecular structure;
  b) consist of or have been produced from cell cultures or tissue cultures;
  c) have undergone significant modifications;
  d) have been subjected to an unconventional production process that implies significant modifications;
  e) are obtained from plants by fermentation, extraction or selective concentration, used for technological purposes in order to modify the physical, chemical, biological or sensory characteristics of food, provided that they do not qualify as a food additive;
  f) are made of nanomaterials;
  g) are a source of nutrients and non-nutrients for use in conventional foods;
  h) are constituents of dietary supplements not provided for in Normative Instruction - IN 28/2018, or another that may replace it;
  i) are composed of nutrients and other substances for enteral formulas not provided for in Resolution RDC 22/2015, or any other that may replace it;
  j) are composed of nutrients for foods intended for infants and young children not provided for in Resolution RDC 42/2011, or any other that may replace it; or
  k) are constituents authorized only for use in dietary supplements and special purpose foods, if they are to be used in other foods.

- A definition for exposure assessment, risk

assessment, bioavailability, risk characterisation, adverse effect on health, food purpose, therapeutic purpose, among others
- A definition for history of safe consumption
- More specifications are given for the documentation to be submitted
- New requirements for novel foods and ingredients containing GMOs
- The development of a list of approved novel foods and ingredients that would allow any company to use them according to the conditions approved.

Argentina

Proposed arsenic limit for edible algae

The National Commission of Foods (CONAL) has opened for public consultation a proposal to establish a maximum limit for inorganic arsenic in edible algae. The proposal seeks to include under Article 921 of the Argentinean Food Code a maximum limit for inorganic arsenic of 1 mg/kg. The authorities note that this limit is based on international references such as Australia, New Zealand and Taiwan. Food supplements are ruled by Article 1381 of the Argentinean Food Code, which establishes that all permitted ingredients listed in the Argentinean Food Code can be added to food supplements, meaning that edible algae can be used. Final date for comments: 11 May 2023

Panama

Setting up regulation for food supplements

The Ministry of Health has opened to public consultation a proposal to regulate the registration of food supplements with therapeutic properties under the competence of the National Directorate of Pharmacy and Drugs, in order to replace Resolution 550/2019. They had already submitted a proposal in February 2021 that had failed to advance.

Law 1/2001 and its modification through Law 97/2019, constitute the regulatory framework for pharmaceutical products, including food supplements with therapeutic properties.

The proposal foresees:

- That those supplements that do not exceed the dietary reference intakes are not the responsibility of the National Directorate of Pharmacy and Drugs (meaning that it would be the minimum limit for nutrients)
- That if those supplements that exceed the dietary reference intakes from the National Institute of Health from the United States, or that contain probiotics or prebiotics alone or combined with vitamins and minerals are the responsibility of the National Directorate of Pharmacy and Drugs; extracts of animal origin or enzymes alone or combined with vitamins and minerals; extracts of plant origin combined with vitamins and minerals; the bioactive substances listed in Annex 2 combined with vitamins and minerals.
- Establishes a list of permitted bioactive substances and amino acids with maximum limits. However, for vitamins and minerals, although it is mentioned that the Upper Level should be considered, it is not described in the proposal which ULs would be considered
- List of accepted pharmaceutical forms
- Requirements for registration, including the presentation of stability studies in zone IVb
- Labelling requirements, including warning statements
- Use of claims: only those that are supported in the registration file will be allowed, subject to the approval of the Ministry of Health.

Ukraine

Food Supplement law as new priority

On 18 March 2023, the Cabinet of Ministers published a resolution (No.221 of 14 March 2023) approving the Plan for the Cabinet's Priority Actions for 2023.

The plan requires the Ministry of Health to draft among others the following laws:
On biological safety and biological security in line with the One Health approach.

On biocides ensuring a high level of protection for the health of humans, animals and the environment against harmful organisms by developing rules for placing on the market and use of biocidal products; adaptation of the national regulations to international law and EU law on pesticides and biocidal products.

On foods for special dietary purpose, dietary supplements, and food additives in line with EU law.

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