Regulatory news

China

Responsible advertising

China SAMR has published its “Interim Administrative Measures on the Review of Health Food, FSPM, Drug and Medical Devices Advertisements”, which will come into force on 1 March 2020. The measures clarify that advertisers are responsible for the authenticity and legality of health foods.

Korea

Mandatory disclaimers for four nutrients

MFDS has announced mandatory disclaimers for four nutrients used in health functional foods.

B-carotene: Smokers shall consult experts before taking this product; If any unusual condition occurs, please stop taking this product and consult experts immediately.

Potassium: consult experts before taking this product if consumers have kidney, gastrointestinal disease, etc. If any adverse reactions occur, stop taking this product and consult experts immediately.

Chromium: consult experts before taking this product if the consumer has diabetes; If any adverse reactions occur, stop taking this product and consult experts immediately.

Regulating the internet

MFDS is tracking online advertising of protein supplements. 2046 websites were screened among which around 60 advertisements were found to violate national regulations. Violations included misleading consumers and misrepresenting ordinary foods as health functional foods. Non-compliant companies will be subject to administrative sanctions.

India

The new FSSAI’s Panel appointees

The Food Safety Authority of India is renewing its Scientific Panels. The membership of the Nutraceutical Panel and the Scientific Committee, that has oversight over all the panels, has been released unofficially.

The new composition of the Scientific Panel for Functional foods, Nutraceuticals, Dietetic Products:

Dr D B A Narayana, Expert Member, Indian Pharmacopoeia Commission, MoHFW
Dr Dinesh Kumar, Scientist, Institute of Himalayan Bioresource Technology, Palampur
Dr G Bhanuprakash Reddy, Scientist-F and Head, Biochemistry Division, National Institute of Nutrition, Hyderabad
Prof H P S Sachdev, Sr Consultant, Paediatrics and Clinical Epidemiology, Sita Ram Bharatia Institute of Science and Research, New Delhi
Dr K Bhaskar Reddy, Professor and Principal, Sri Venkateswara College of Pharmacy, Rvs Nagar, Tirupati Road, Chittoor
Dr Neelam Kier, Chairperson, Sir Ganga Ram Hospital, New Delhi
Dr Puja Dudeja, Director Pensions, DGIFMS, Ministry of Defence
Dr Seema Puri, Associate Professor, Dept. of Nutrition, Institute of Home Economics (University of Delhi), New Delhi
Dr V Thirupathy, Dean, Agriculture Engineering College and Research Institute, TNAU, Kumlur
European Union

Mapping of new genomic techniques

The Council has requested the Commission to submit a study, by 30 April 2021, regarding the status of new genomic techniques (NGTs) covering plants, animals, micro-organisms and derived products obtained by NGTs for agri-food, medicinal and industrial applications.

According to the Council, there has been substantial progress in the development of new breeding techniques, leading to uncertainty on whether those new breeding techniques come under the definition of a GMO and the scope of the Directive on genetically modified organisms or not and, as a consequence, whether products obtained by them should be subject to the obligations laid down in that Directive.

New genomic techniques (NGTs) are understood as techniques that are capable of altering the genetic material of an organism and which have emerged or have been developed since 2001.

Stakeholders have been invited to provide input by 30 April 2020.


Tetrahydrocannabinol: EU over-exposed

The European Food Safety Authority (EFSA) report reveals that the acute reference dose (ARFD) of 1 mcg/kg bw for tetrahydrocannabinol (Δ 9 - THC) is exceeded in the adult high consumers of most hemp and hemp-containing products considered. EFSA particularly emphasises that a higher uncertainty is observed for food supplements due to samples being highly heterogeneous.

Among the recommendations made by the agency, it is suggested that consumption data on real consumers of hemp and hemp-containing products should be collected. Further research to obtain sensitive, validated and Δ 9 - THC specific methods should also be translated to reliable official methods.

Novel Astaxanthin safe in adults

Following a request from the European Commission, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) delivered an opinion on the safety of astaxanthin when used as a novel food in food supplements concluding that astaxanthin is safe for adults at maximum levels of 8 mg/day. This assessment took into account an updated exposure assessment for astaxanthin from the background diet (fish and crustaceans) in combination with 8 mg from food supplements.

Concerns were however raised for children, where the Adequate Daily Intake (ADI) was exceeded by 28% for in children aged 10 to < 14 years and up to 524% in infants aged 4-6 months.


Pyrrolizidine alkaloids: new obligations

The European Commission is finalising its position on pyrrolizidine alkaloid limits (PAs). 400 mcg/kg is proposed for food supplements and 500 mcg/kg for pollen-based food supplements.


Lowerbound concentrations are calculated on the assumption that all the values of the different individual pyrrolizidine alkaloids (or “co-eluted”) pyrrolizidine alkaloids) below the limit of quantification are equal to zero.

It also includes an additional 14 PAs known to co-elute with one or more of the above 21 PA. This list of co-eluted PA is still under discussion and is likely to contain the following PA: Indicine, echinatine, rinderine (possible co-elution with lycopsamine/intermedine), indicine-


A transition period of 2 years should be foreseen to comply with the new provisions.

Can food supplements be organic?

In its recent Frequently asked questions on organic rules, the European Commission has clarified only food supplements produced from agricultural ingredients fall under the scope of Regulation (EC) No 834/2007 on organic production and labelling of organic products and can therefore be labelled as organic.

Food supplements produced from vitamins and minerals do not fall under the scope of organic legislation and cannot be labelled as organic under Regulation (EC) No 834/2007.


Novel requests

The European Commission has recently received 6 new novel food applications for supplements: Pasteurised Akkermansia muciniphila Ashtaba sap powder

Cannabidiol derived from chemical synthesis

3-fucosyllactose

Blend of Tamarindus indica seeds and Curcuma longa rhizome extracts

Synthetic trans-Cannabidiol


Green light for vegan friendly vitamin D source

The European Food Safety Authority (EFSA) has recently concluded positively on the safety of a novel vitamin D2 mushroom powder used as a
food supplement for individuals above 1 year at a level up to 15 mcg vitamin D2/day.

The new ingredient is produced from Agaricus bisporus mushrooms that have been exposed to UV light to induce the conversion of provitamin D2 (ergosterol) to vitamin D2 (ergocalciferol). The novel food contains levels of vitamin D provided by vitamin D2 in the range of 1,000-1,300 mcg/g.


Refreshing the list of microorganisms qualified as safe

EFSA has recently released its three-year summary update of the latest QPS (Qualified Presumption of Safety) list.

The QPS list is a list of microorganisms that are considered to be safe as a defined taxonomic group (mostly species level). For microorganisms that are included in the list, no further safety data would be required (except what is specified in the QPS entry itself). Microorganisms not considered suitable for QPS would remain subject to a full safety assessment.


Italy

Tetrahydrocannabinol: Put a cap on it

Italy has set values on total tetrahydrocannabinol (THC) in food for the purpose of official control, namely:

- Hemp seeds, flour obtained from hemp seeds: 2.0 mg/g
- Oil obtained from hemp seeds: 5.0 mg/kg
- Supplements containing hemp-derived foods: 2.0 mg/kg

Maximum limits of total THC are defined as the sum of the concentrations of the substance (-) - trans- Δ9 -THC and of the precursor inactive acid (Δ9 -THCA-A).

The analysis method must refer to the provisions of the -Recommendation (EU) no. 2016/2115 of the Commission of 1 December 2016 on monitoring the presence of Δ9 -tetrahydrocannabinol, of its precursors and other cannabis derivatives in food.

France

TI02: where the ban begins

The French ban on the food additive titanium dioxide (E171) took effect on 1 January, meaning products containing the additive can no longer be placed on the French market.

The decision followed a study published by the French Agricultural Research Institute (INRA) on the food additive E171. It highlighted the development of pre-tumorous damage in the colon of rats fed with TI02 nanoparticles.

The European Commission is still contemplating what actions to take. Meanwhile, a number of MEPs have written to the new Commissioner for health and food safety Stella Kyriakides asking to apply the precautionary principle and extend the ban to the whole of the EU arguing that both EFSA and ANSES have raised concerns.

Germany

Red yeast rice: No go

The German Federal Institute for Risk Assessment BfR recommends against the use of food supplements with red yeast rice.

In its opinion published in January, the Institute advises that the such products should only be taken after medical consultation or under medical supervision.

The European Commission is still reflecting how to regulate products containing red yeast rice. It is currently considered to ban products containing more than 3 mg Monacolin K. It is also considered to put under Union scrutiny the use of Monacolin K at levels less than 3 mg/day.

BCCAA in combination

The German Federal Institute for Risk Assessment (BfR) has derived orientation values for tolerable daily intake for the intake of leucine, isoleucine and valine, individually and in combination:

Leucine: 4.0 grams per day
Isoleucine: 2.2 grams per day
Valine: 2.0 grams per day

BCCAA (total): 8.2 grams per day (corresponding to the sum of the individual BCAA)

The BfR findings also suggest that BCAA should not be taken individually, but in combination. Due to insufficient data, it was not possible to derive orientation values for tolerable daily intakes of the BCAA in isolated form for children, adolescents, pregnant women and breastfeeding women.

The BfR therefore recommends these groups of people to avoid the intake of isolated BCAA from food supplements or sports nutrition, for example.

People with reduced kidney function and those who follow a diet with a low protein intake are also excluded from the derived orientation values. A doctor should be consulted before taking relevant isolated amounts of these amino acids.


Belfrit vs Stoffliste? Revised German list of botanicals

The German BVL (Federal Office of Consumer Protection and Food Safety) has published a draft of the 2nd edition of its botanical Stoffliste, a alternative version of the Belfrit list that was developed by Belgium, France and Italy. This publication comes with three revised Excel Annexes (2 updated lists of plants (A-K and L-Z) and 1 list of mushrooms. The new list has been elaborated with support from the Austrian and Swiss authorities and is currently open for public consultation.

https://www.bvl.bund.de/DE/Arbeitsbereiche/01 Lebensmittel/01_Aufgaben/07_Stofflisten/Kommentieren/1m_stoffliste_kommentieren_node.html

Poland

Work in progress

The Polish Chief Sanitary Inspectorate continues its work on establishing maximum levels of micronutrients for food supplements and has published further resolutions adopting maximum daily levels for vitamin B6 (18 mg), magnesium (400 mg), iron (general adult population: 20 mg, pregnant women: 30 mg) and copper (2 mg). The resolutions are issued by the Polish Team for Food Supplements, an opinion-making and advisory body of the Chief Sanitary Inspector. They are available at the following link:

Upgrading system

With the aim to improve the supervision of products on the market, the Polish Chief Sanitary Inspectorate is launching a new online notification system for food supplements and other food categories subject to notification. The new tool should allow preliminary verification of product compliance. While it will not eliminate the need for further explanations and proceedings, it will however flag unlawful products which should help reduce the risk of violation of regulations and criminal penalties.

At the time of launch, the system will have around 2300 ‘rules’ relating to ingredients banned in food, acceptable chemical forms and ingredients for which the authorities have set maximum levels in food supplements. Further criteria will be gradually completed in the future. The new system should become operational between 30/01/2020 and 03/03/2020.

The Netherlands

Botanical safety: Data, data, data

The National Institute for Public Health and the Environment (RIVM) has published a template for performing, in a consistent way, safety assessments for dietary supplements, particularly plant food supplements. The template has been developed using the principles described in the 2009 EFSA guidance document on how to perform safety assessments of botanicals and botanicals. The template aims to provide an overview of the information that is required. Depending on the extent and quality of this information, it also provides guidance on how this can be used to assess safety.


St. John’s wort in trouble

The Dutch Food and Consumer Product Safety Authority (NVWA) has instructed a number of companies to withdraw certain herbal preparations containing St. John’s wort and to warn consumers not to use these products anymore.

Among the 47 herbal preparations of St John’s wort tested from October 2018 to February 2019, 9 preparations containing harmful levels of pyrrolizidine alkaloids (PAs) have been identified (between 1600 μg/kg and almost 5000 μg/kg).

This inspection was carried out following the outcome of an investigation conducted by the UK Medicines & Healthcare products Regulatory Agency and the European Food Safety Authority (EFSA) that found high PA values in St John’s wort preparations. The toxins do not naturally occur in St John’s wort but research has shown that these substances may end up in St John’s wort preparation where, for example, the plant has been co-harvested with botanicals containing this toxins.

https://www.nvwa.nl/documenten/waarschuwingen/2019/03/01/belangrijke-veiligheidswaarschuwing-sint-janskruid-diverse

Phytoestrogens: Consumer protection V Consumer choice

The Pharmacovigilance Centre - Lareb - in the Netherlands has recently published a report regarding herbal preparations with phytoestrogens sold as food supplements. Lareb highlights that although phytoestrogens have benefits, such as a lowered risk of menopausal symptoms like hot flushes and osteoporosis, consumers should be aware of the (anti)estrogenic properties of phytoestrogens, since they might act as endocrine disruptors, indicating a potential to cause adverse health effects.

From September 1999 until November 2019 Lareb received 51 reports of the use of phytoestrogen containing preparations. Lareb highlighted that all these preparations were sold as food supplements. Better information about the possible undesired side effects is recommended to help women make a well-considered decision about the use of this type of supplements.


The UK

31 January: The day when nothing changed, while everything changed

On 31 January 2020, the UK formally left the European Union, after 45 years of membership. A transition period, set to end on 31 December 2020 has now commenced. During the transition period few changes are expected regarding food supplement regulation.


South Africa

Cannabis demystified

The South African authorities SAHPHRA have recently released a Frequently Asked Questions (FAQ) on Cannabis and related substances. In this, the authorities clarify that a processed product containing the naturally occurring trace amounts of THC (≤ 0,001 %) and CBD (≤ 0,0075 %) is specifically excluded from the regulation when the product does not contain whole cannabis seeds and does not make any medicinal claim. If such substances align with the definition and annexures identifying health supplements, they may also be considered as health supplements.

The FAQ also specifies that only certain CBD preparations have been excluded from the operation of the Schedules by the Minister of Health for a time-limited period (12 months from the date of publication of the exclusion notice, 23 May 2019). Exemptions were made for those preparations that: (a) contain a maximum daily dose of 20 mg CBD with an accepted low risk claim or health claim; or (b) consist of processed products made from cannabis raw plant material, where only the naturally occurring quantity of cannabinoids found in the source material are contained in the product, and which contain not more than 0,001 % of tetrahydrocannabinol (THC) and not more than 0,0075 % total cannabidiol (CBD).

https://sahpra.org.za/
Alert Concerning Dietary Supplements Containing cesium Salts

The US Food and Drug Administration (FDA) is warning consumers to avoid using dietary supplements containing cesium chloride or any other cesium salt due to significant safety risks, including heart toxicity and potential death. According to FDA, multiple clinical case reports and non-clinical studies showed significant safety concerns related to the use of such products, including potentially fatal cardiac arrhythmias, hypokalemia (low potassium), seizures, syncope (fainting, unresponsiveness), and death. While it appears that few dietary supplements containing cesium salts are currently on the market, the US authorities request consumers to be aware of the risks associated with them and avoid purchasing and using such products.

Nutrition Facts labelling regulations: Compliance help

The U.S. Food and Drug Administration has issued a final guidance to help manufacturers of conventional food and dietary supplements to comply with the FDA’s updated Nutrition Facts labelling regulations.

The new guidelines include an update on “Nutrition and Supplement Facts Labels: Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals”

http://www.fda.gov/media/133699/download

Interim final rule on Hemp

The US Department of Agriculture (USDA) published an interim final rule to produce hemp. The program includes provisions for maintaining information on the land where hemp is produced, testing the levels of delta-9 tetrahydrocannabinol, disposing of plants not meeting necessary requirements and licensing requirements.

Brazil

Updated microbiological criteria for food supplements

At the end of December, ANVISA issued Resolution RDC No. 331/2019 that establishes the general microbiological criteria for foodstuffs and its corresponding Normative Instruction IN No. 60/2019 which foresees the maximum and minimum limits for microorganisms, toxins and metabolites in 24 food categories, including food supplements. This rule introduces new microbiological requirements for food supplements which has resulted in, for example, Bacillus cereus being removed and moulds and yeasts being included. Also, food supplements have been regrouped based on their form of presentation: powder, liquids and gels (non-sterile), and pills, capsules and tablets. These requirements do not apply to ingredients intended exclusively for industrial use, including additives. Both regulations will take effect on December 26, 2020.

Link RDC No. 331/2019


Link IN No. 60/2019:

http://portal.anvisa.gov.br/documents/10181/4660474/IN_60_2019_COMP.pdf/05a7df36-5ac8-450c-be2b-46c796b12683

Updated rules on residues of veterinary medicines

At the end of December, ANVISA launched two regulations that update the rules for risk assessment and maximum limits for residues of veterinary medicines, which may impact some ingredients used in food supplements. Resolution RDC No. 328/2019 foresees the evaluation of human health risk of veterinary medicines and the methods of analysis for conformity assessment purposes; while the Normative Instruction IN No. 51/2019 establishes the maximum residue limits, the acceptable daily intake (ADI) and the acute reference dose (ARfD).

Both regulations replace the previous texts already in force.

Link RDC No. 328/2019:


Link IN No. 51/2019:


Central America

Food additive rules impacting food supplements

In December 2019 the Central American System of Economic Integration (SIECA) approved the update of the harmonized regulation for food additives, RTCA 67.04.54:18 Food Additives, which also applies to food supplements. This update adopts the Codex General Standard for Food Additives. Importantly, where a level of an additive not included in Codex is required or a level which is different from Codex is necessary, it will be possible to request put forward a request for the revision of the list.

The permitted additives and the limits are those established in Codex General Standard for Food Additives (Codex Stan 192-1995 latest version) and those mentioned in Annex A and B of the text. Food additives listed on the annexes of the RTCA will be reviewed by the Central American Commission on Food Additives yearly, while the use of additives listed in Codex will be updated automatically every time the Codex Standard 192-1995 GSFA is updated.

The RTCA will come into force on June 5, 2020 and SIECA Member States will publish the corresponding resolutions for its adoption at national level. SIECA is composed of Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and Panama.

Link: Searching Resolution No. 419-2019 at:

https://www.sieca.int/index.php/integracion-economica/instrumentos-juridicos/actos-administrativos/consejo-de-ministros-de-integracion-economicas/resoluciones/
**Mexico**

**Food additives updated again**

On 16 December, the sanitary authorities from the Federal Commission for the Protection Against Sanitary Risks (COFEPRIS) published the latest updates to Annex X on processing aids linked to the regulation for food additives, which impacts all food categories including food supplements. The use of sodium ascorbate and trehalose has been approved as a bio-protector of bacterial strains. This update is already in force.


**Belarus**

**The end for polymer packaging**

The Belarusian Cabinet’s Resolution of 13 January 2020 adopts the action plan to gradually reduce the use of polymer packaging and replace it with environmentally safe materials. The plan primarily concerns the consumer packaging of groceries (cereals, sugar, salt and other bulk and dry products), water, beverages and beer up to 1 l, plastic bags sold at tills, volumetric plastic containers (egg trays and food containers, mainly made of polystyrene) and disposable plastic tableware.

The action plan calls for economic stimulation of replacing polymer packaging with environmentally safe (including biodegradable) packaging, and for the adoption of new packaging standards based on EU standards. Thus, this change will eventually address dietary supplements packed in polymer packaging. The draft document envisages amendments to the EAEU regulation on packaging safety in 2020-22.

**Eurasian Economic Union (EAEU)**

**Botanical negative list extended**

Early January the European Economic Community Council’s Resolution on amending CU TR 021/2011 on food safety of 8 August 2019 was published on the EAEU legal portal. Amendment 1 had been under development since 2013 and adopted in July 2019.

The amendments harmonise the list of plants whose use in dietary supplements is prohibited (Addendum 7) with the latest version of the Uniform Sanitary Requirements (Addendum 6). The document expands the list of plants banned from use in dietary supplements to include 16 new entries.

The document will come into force on 17 July 2020.

**Many proposals on food additive regulation turned down**

The working group drafting Amendment 2 to TR TS 029/2012 on safety of food additives, flavouring agents and processing aids compiled a feedback summary based on the results of the public discussion (December 2018 - March 2019). Only some of the comments related to the amendments’ terminology (processing aid, medium, traditional food manufacturing methods, flavouring substance, natural source of flavouring substances, etc.) were accepted by the WG.

The version adopted by the WG rules reject the possibility of using food additives extracted from raw materials or other components in dietetic therapeutic and dietetic prophylactic foods, foods for pregnant and lactating women and foods for babies under 3 years of age.

For foods containing both added sugar, natural sugar and sweetener(s), the product name must be accompanied by the phrase ‘with sugar and sweetener(s)’, or the phrase ‘contains sugar and sweetener(s)’ must immediately follow the ingredient statement. In its current wording, this requirement is also applicable to the labelling of products with added sweeteners and non-added, naturally present sugar.

For foods containing added polyols, the qualitative criterion (10 mg per 100 g/ml) as applied to the accompanying label statement “Excessive consumption may produce laxative effects” was not adopted; the criterion of the weight fraction of polyols (containing more than 10% added polyols) remained.

The amendments will not change the current wording of CU TR 029/2012 as applied to the use of sodium aluminium silicate (E554) and amorphous silica (E551) as anti-caking agents in dietary supplements and to the maximum level of talcum (E553ii) in colourants (the current level of 5 g per 100 g shall apply).

The draft document is to be submitted to the EAEU member governments for consideration and to undergo an EEC regulatory impact assessment.

**Russia**

**Country’s food security strategy**

Russia’s food doctrine targets food quality and health nutrition. The presidential decree adopted Russia’s food security doctrine, a strategic document aimed at ensuring the country’s food security. The doctrine reads that food security guarantees the affordability and availability, to every citizen, of foods meeting the mandatory requirements and in amounts not less than the nutritional requirements for a healthy population.

As distinct from the 2010 doctrine, the new document envisages providing the population not just with safe foods but also with quality foods. To ensure the quality and safety of foods, the document provides for: harmonisation of national food standards with international food quality and safety requirements, characteristics and parameters; an advanced technological and methodological framework aimed at improving food quality and safety monitoring; measures to encourage manufacturers to produce healthy foods; harsher administrative punishments for failing to meet the requirements of national and EAEU regulations.

IADSA 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](http://www.iadsa.org)