IADSA NEWSFLASH

October 2019

Regulatory news

China

Magnifying effect

The Chinese State Administration for Market Regulation (SAMR) has issued "Guideline on Warning Statements for Health Food Labeling" which will come into force on 1 January 2020. According to the Guideline, the disclaimer 'health foods are not medicines and cannot replace medicine to treat diseases' shall now appear on health food labels and should not be less than 20% of its surface. The complaint service phone number and service hours shall now also be showed on the label of the health food, and manufacturers shall ensure they could handle calls during the hours specified.

http://gkml.samr.gov.cn/nsjg/tssps/201908/t20190820_306116.html?gs_ws=weixin_637018980805791087&from=timeline&tdsourcetag=s_pcqq_aiomsg&gs_ws=weixin_637019014358559090&from=timeline&isappinstalled=0

Unlocking opportunities

It is now possible to propose the inclusion of new ingredients in the health food raw materials directory and also expand the permitted functional claims for filing.

In China, health foods are subject to registration or filing (notification) depending om the product's composition and claims made. Products containing ingredients not in the Directory of Health Food Raw Materials and List of Auxiliary Materials for Health Food Filing are subject to registration. Systematic evaluation (clinical, toxicological, physiochemical) are required to substantiate the functional claims used on these products.

Risky game

Local government in more than 20 Chinese cities have banned the sale of health foods and health related products in Medicare pharmacies, accounting for 70% of pharmacies in China.

Over the past years, it has been revealed that some pharmacies have been caught up helping consumers getting their health foods reimbursed by insurance companies or local authorities. The ban comes as part of a coordinated action taken by local medical insurance departments in collaboration with local authorities.

Here today, gone tomorrow

Shanghai Administration had given Temporary Permit for imported unregistered infant formula and health food available to companies that wish to display unregistered products in the China International Import Expo.

The permit is valid only during the event and within the exhibition.

India

Procedure for risk reduction claims

The Food Safety and Standards Authority of India (FSSAI) has announced that food business operators who wish to seek prior approval of claims on their food products including health supplements and nutraceuticals shall submit an application with a fee of Rs. 50,000. Such claim applications shall be for a product/ingredient in a product and a maximum of 3 claim statements shall be assessed against a single application.

Adequate published scientific literature/studies should form part of Claim Support Dossiers to be submitted by the applicants. Such dossiers should provide a succinct summary of published scientific data comprising in-vitro, in-vivo and human studies data.

Applicants should also clarify if the ingredient/ product on which the claim is intended to be made is protected under Intellectual Property Rights /patented. Information on the validated method of analysis of the ingredient or substance for which the claim is to be made is also requested.

Following the publication for the Food Safety and Standards (Advertising and Claims) Regulations in 2018, FSSAI has constituted an Expert Committee on Claims with the mandate to assess health claims, specifically disease risk reduction claims and other claims made in advertisements.

Framing partnership with private sector

The Food Safety and Standards Authority of India (FSSAI) is planning to frame its engagements with the private sector via official guidelines.

The draft guidelines cover all areas of public-private collaboration including selection of private industry representatives to scientific panels and standards review groups, collaboration with private food laboratories for quality testing, training and capacity building, third party accreditation and outreach and awareness creation.

FSSAI has invited public comments on the draft until 25 October.

https://www.fssai.gov.in/upload/uploadfiles/files/Notice_Draft_Guidelines_Private_Sector_04_10_2019.pdf

Japan

Voluntary labelling

Japan's Consumer Affairs Agency announced the revision of the "Food Labelling Standard". The presence of almonds will now be subject to voluntary labelling bringing to 21 the number of ingredients subject to non mandatory labelling (Apple, Banana, Orange, Kiwi Fruit, Peach, Yam, Matsutake mushrooms, Cashew nut, Walnut, Sesame, Soybean, Abalone, Cuttlefish, Salmon Roe, Trout, Mackerel, Beef, Chicken, Pork,Gelatine).

https://www.caa.go.jp/policies/policy/food_labeling/food_labeling_act/pdf/food_labeling_act_190919_0004.pdf

South Korea

Amendment of Health Functional Food Code

The Korean Ministry of Food and drug safety has revised its Health Functional Food Code.

A rancidity management standard and testing method for products containing EPA and DHA have been introduced. The heavy metal specification for glucosamine has also been revised. Due to uncertainty related its benefit, the fructo-oligosaccharide functional claim "helps inhibit bacterial growth and contributes to calcium absorption" has been removed.

These revisions will enter into force in July next year.

More information:
https://www.mfds.go.kr/brd/m_207/view.do?seq=14415&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=

New claim for probiotic strain

MFDS has recently approved a new Probiotic related to menopausal symptoms.

In 2018, the probiotics market size in South Korea reached 470 billion South Korea Won (USD 390 million), according to the Korea Health Foods Supplement Association.

European Union

Almost there

The European Food Safety authority EFSA has recently confirmed the safety of a synthetic form of nicotinamide riboside in food supplements for the healthy adult population at levels up to 300 mg/day and for pregnant and lactating women at levels up to 230 mg/kg.

The new nutrient will now have to be added to the list of niacin forms authorised for use in food supplements before it can be used in new formula.

Positive thinking

Empty gelatine capsules could be exempted from border inspections. The European Commission is about to finalise the necessary implementing acts to allow a full application of the new rules on Official Control to apply by mid-December this year.

While there is no intention for the time being to exempt supplements as low risk products from border controls,

there are indications that empty gelatine capsules could be proposed for exemption.

In the line of sight

Monacolin K from red yeast rice, green tea, hydroxy anthracene derivative, fennel, alpha lipoid acid, D-ribose, betaine, trans-resveratrol and melatonin are on the agenda of the European Commission who is discussing their prohibition or restriction of use with the European Member States.

These substances are discussed under the so-called Article 8 of Regulation 1925/2006 which can allow an EU-wide prohibition or restriction on the addition of certain ingredients to food and food supplements if they represent a potential health risk.

Ephedra and Yohimbe bark have been the two first ingredients banned through this procedure.

TiO2: No decision yet

Discussions continue on the approach that the European Commission should take on titanium dioxide (TiO2) following the announcement of the French Government earlier this year of its intention to ban the use of the additive from 1 January 20120. Four scenarios are under consideration for the European Commission: EU-wide ban; partial ban for use in products primarily consumed by children; opposition to the French ban; no action at EU level. No decision should be foreseen before the new Commissioner to takes office later this year.

DRVs: A milestone is reached

With the publication this week of dietary reference values (DRVs) for sodium and chloride, the European Food Safety Agency has hit a key milestone with the completion of the assessment of 34 DRVs for the European population.

Dietary reference values (DRVs) is an umbrella term for the complete set of nutrient reference values which include population reference intakes (PRIs), the average requirements (ARs), adequate intakes (AIs) and reference intake (RIs) ranges for

macronutrients. These values indicate the amount of a nutrient which must be consumed on a regular basis to maintain health in an otherwise healthy individual (or population).

A interactive tool, DRV Finder, is now available on EFSA's website to assist the retrieval and use of these values by the nutrition community. The tool is currently available in English, German, French, Italian, Spanish and Czech.
https://www.efsa.europa.eu/en/interactive-pages/drvs

Define nano in TiO2

EFSA has recently presented its opinion on changing the specifications for TiO2 where the particle size distribution is recorded in the specifications.

Based on the data provided, the EFSA Panel has proposed the following specifications for the particle size of the additives : The minimum Feret diameter of the TiO2 particles must be determined by electron microscopy, and the median thereof must be greater than 100 nm (hence is less than 50% of the number of particles <100 nm). In terms of properties, E 171 may still consist of anatase and / or rutile. Coated forms of TiO2 should be excluded, from the definition, as well as the platelet form using mica. Anatase may also consist of a maximum of 2% rutile and vice versa, and may contain <0.5% residues of certain excipients as a result of the production process"

The opinion also highlights that ongoing toxicological studies will reduce the existing uncertainties about the safety of E 171, but also mentions that until the results of those studies are known, the conclusions of EFSA's previous opinions and the uncertainties identified regarding E 171 still remain the same.

In 2016, EFSA concluded that on the basis of the available evidence, titanium dioxide used as a food additive did not raise concern with respect to genotoxicity; was not carcinogenic after oral administration; and its exposure from the reported use/analytical levels would not be of concern. However, some recommendations were made to address data gaps.

Italy

Curcumin: Warning!

Italy has released the outcome of its investigations related to the recently reported cholestatic hepatitis cases following the consumption of food supplements containing turmeric.

It was reported that the analysis carried out on the samples of the products related to the cases of hepatitis have excluded the presence of contaminants or voluntarily added substances as possible causes of liver damage.

In view of this finding, Italy had decided to adopt a specific warning for the labelling of food supplements containing turmeric preparations/extracts from Curcuma longa L. (rhizoma, aetheroleum) Curcuma xanthorizza Roxb. (rhizoma), Curcuma zedoaria (Christm.) Roscoe (rhizoma).

Companies have until end of December to comply with the new labelling provisions.

http://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?anno=2019&codLeg=70165&parte=2&serie=

In pursuit of pure

While purity criteria have only been set for vitamin and minerals listed in the annex of the European Food Supplements Directive, Italy and Denmark have issued guidance for the purity of amino acids and other substances, mirroring the provisions of Regulation on foods intended for specific groups (Regulation (EU) 609/2013).

Italy recalls that it is necessary to use quality raw materials to guarantee a high level of consumer protection, a goal set by the food supplement directive.

For substances for which purity criteria have not yet been established at EU level, generally accepted purity criteria recommended by international bodies shall apply. It includes recommendations from the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the European Pharmacopoeia (Ph. Eur.) and the Food Chemical Codex (FCC).

Norway

High or low risk substances

The Norwegian Food Safety Authority (NFSA) requested the Norwegian Scientific Committee for Food and Environment (VKM) to provide a ranking of 79 substances in foods, drinks and dietary supplements that may constitute a potential health risk for humans, based on the VKM members' expert judgements.

The substances requested to be included were food additives and flavourings, substances used in food contact materials, environmental contaminants, process-induced substances and natural toxins.

The ranking of the substances was based on inherent toxicity (hazard) and level of exposure (both occurrence and intake). In addition, vulnerable groups, adequacy of toxicity data and lack of exposure data were considered.

High scores (>8/10) were given to Mycotoxins, Furans, Pyrrolizidine alkaloids (PAs), Dioxins and Dioxin-like PCBs, Acrylamide among other ingredients while Sucralose (E955), Coenzyme Q10 (CoQ10), D-Glucurono-γ-lactone, Taurine, EPA/DPA and Chromium were given a low score (<3/10)

Excluded from this work were:
- Titanium dioxide - it was not clear to the project group how to rank titanium dioxide, due to the variation in particle size and toxicity of different particles),
- Microplastics - due to on-going assessment by VKM and
- Nanoparticles – It was not possible for VKM to rank such a large group of different substances due to the limited time available.

Based on the results of the VKM Report, the Norwegian Food Safety Authority will now draw its monitoring priorities targeting substances with high ranking as first and specific food categories.

https://www.mattilsynet.no/mat_og_vann/uonskede_stofferimaten/miljogifter/ranking_of_substances_for_monitoring_in_foods_drinks_and_dietary_supplements__based_on_risk_and_knowledge_gaps.36240/binary/Ranking%20of%20substances%20for%20monitoring%20in%20foods,%20drinks%20and%20dietary%20supplements%20-%20based%20on%20risk%20and%20knowledge%20gaps

United Kindgom

Get ready for no deal Brexit - helpful links

UK

Link to nutrition legislation guidance for industry and organisations involved in health and care about plans for a no-deal Brexit: https://www.gov.uk/government/collections/planning-for-a-possible-no-deal-eu-exit-information-for-the-health-and-care-sector#nutrition-legislation:-guidance

EU

Link to the EU Brexit preparedness website: https://ec.europa.eu/info/brexit/brexit-preparedness_en

Link to latest preparedness Communication, including check-list : https://ec.europa.eu/info/publications/communication-4-september-2019-finalising-preparations-withdrawal-united-kingdom-european-union-1-november-2019_en

Link to Brexit preparedness notices: https://ec.europa.eu/info/brexit/brexit-preparedness/preparedness-notices_en#sante

France

Link for goods imported or transiting through France from the UK (80% of the good entering in France are destined to the EU market): https://brexit.gouv.fr/sites/brexit/accueil/vous-etes-une-entreprise.html

South Africa

New Guidelines published

SAHPRA has recently released two new documents impacting supplements that fall under the cAMs Regulation in South Africa:

Roadmap and transitional process for the regulation of complementary medicines. This roadmap is intended to provide guidance on the intended future regulatory pathway, including licensing of activities associated with the supply as well as the registration of complementary medicines in order to best harmonise activities of the industry and regulator.

Naming and labelling conventions for active ingredients in complementary medicines. This document seeks to standardise the presentation of the naming of active ingredients used in complementary medicines.

https://www.sahpra.org.za/documents/cba8ad2e7.02_Roadmap_for_CMs_Sep19_v2.pdf

https://www.sahpra.org.za/documents/b424d31f7.05_CMs_Quality_Annex_BLabelling_AIs_Sep19_v1.pdf

Australia

Made in Australia

The Australian government has announced the use of stopgap regulation to reinstate Australia's complementary medicines industry's right to access the 'Made in Australia' logo.

The change to Country of Origin laws inadvertently created a contradiction to the sector where a product is deemed to be manufactured in Australia under one law (regulated by the TGA), but not Australian Made under consumer law.

The announcement means that complementary medicines manufactured in Australian facilities regulated by the Therapeutic Goods Administration, can once again qualify to use the Made in Australia logo.

Argentina

Enzymes and additives – alignment with global practices

The National Commission of Foods (CONAL) is seeking to introduce changes to the Argentinean Food Code impacting additives and enzymes:

Food additive specifications: It proposes updating the identity and purity specifications of 18 additives included in Article 1398 of the Food Code, based on the criteria of EFSA, JECFA and Food Chemicals Codex. http://www.conal.gob.ar/Consulta/proyectos/2019/Especif_de_Identidad_y_Pureza_de_Aditivos.pdf

Enzymes: Proposes to update Article 1263 of the Food Code. Several new enzymes have been added to the list, including cellulase, glucose isomerase, malt carbohydrase, and several types of pullulanase and xylanase. It also removed some enzymes from the list, including beta glucanase (Geosmithia emersonii), lipase (Thermomyces lanuginosus expressed in Aspergillus oryzae), and maltcarbohydrase. http://www.conal.gob.ar/Consulta/proyectos/2019/PRC_Ampliacion_de_la_lista_de_enzimas.pdf

Brazil

NRVs - All in one place

The Sanitary Authority of Brazil, ANVISA, opened for comment a proposal with changes to the nutrition labelling rules. This establishes a single list of Recommended Daily Values (RDV) for food supplements. Currently these RDVs are split between Resolution RDC Nº 243 of 26th July 2018 that set outs provisions on RDVs for protein, vitamins and minerals with the rest of nutrients described in the harmonized regulation from Mercosur.

This proposal is part of the current work developed in Brazil in the Front

of Pack food labelling which does not directly impact food supplements.

http://portal.anvisa.gov.br/consultas-publicas#/visualizar/405930
http://portal.anvisa.gov.br/consultas-publicas#/visualizar/405931

Make it easy: Database for supplement ingredients

A new online tool has recently been launched by the Brazilian Health Regulatory Agency (ANVISA). This database gathers all permitted ingredients listed in Brazil's regulation for use in food supplements. The tool not only provides the permitted ingredient, but also the maximum level for each age group and, if applicable, the permitted claim.

https://app.powerbi.com/view?r=eyJrIjoiM2M3NjkzYmMtODY0ZS00YzYzLTlhNGItM2M2NGNjZjk2YjlhIiwidCI6ImI2N2FmMjNmLWMzZjMtNGQzNS04MGM3LWI3MDg1ZjVlZGQ4MSJ9

Guide for the safety assessment of ingredients

On 9 August, ANVISA issued Guide N° 23/2019 (1st version) on Safety Assessment of Foods and Ingredients. The Guide expresses ANVISA's understanding of best practices regarding the procedure to request the safety assessment of new ingredients which is a requirement for the approval of novel ingredients for use in food products, including food supplements. In the case of food supplements, when companies request to update the list of permitted ingredients and substances and their limits, a specific request for the assessment of an ingredient's safety must be made. The Guide provides recommendations regarding the approach and interpretation of regulation. The document is already in force but is open for comment until 10 August 2020, in order to improve the transparency of the process.

http://portal.anvisa.gov.br/documents/33880/461058/Guia+23+v1+Seguranca+Alimentos/b6767a41-fcdb-4a7d-9fdb-982153516d46

Chile

Not beyond nutrition policies

Chile has recently issued an amendment of its legislation for supplements and other food products. The approach is to align provisions with the Chilean public policies on nutrition and discussions held in the Food Supplement Committee of the Pacific Alliance. Only a limited number of ingredients and health claims are therefore considered for inclusion in permitted lists.

Eurasian Economic Union

Food additives on the table

The working group drafting Amendments 2 to TR TS 029/2012 On safety of food additives, flavouring agents and processing aids convened in August to discuss proposals submitted after public discussion back in December 2018.

The working group turned down the proposed omission of sodium aluminium silicate (E554, anti-caking agent) from Addendum 2 to TR TS 029/2012 and kept the current version of the provision contained therein. The working group also turned down the proposal to set a cap on the concentration of silicon dioxide (E551, anti-caking agent) in dietary supplements at 10 grams per kilo (Addendum 3). The current provision as per TR TS 029/2012 remains.

Ukraine

Cost of misleading consumers

Law on food labelling comes into force
The Ukrainian law on informing consumers about foods came into force on 6 August 2019.

Food manufacturers and importers that breach the new law will be held liable under the law on enforcing the legislation applied to foods, feeds, animal-based by-products and the health and well-being of animals.

Operators found to have provided inaccurate or doctored information about products will be fined 15 minimum wages (2,500 USD). The fine for misleading consumers as to the presence of allergens in foods stands at 30 minimum wages.

There is a three-year grace period, meaning that any foods whose labelling meets the previous requirements may still be introduced to the market until 6 August 2022 and remain on the market until their respective expiry dates.

The law covers both food labelling and any types of advertising or information about the product. For foods sold online, such information must be available prior to the purchase of the product.

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