IADSA NEWSFLASH

April 2020

Regulatory news

China

Advertising: a risky link

Eleven departments, including SAMR, NHC, NRTA (National Radio and Television Administration), and MPS (Ministry of Public Security) have recently unveiled a plan to tackle false and illegal advertising, including those related to Covid 19 prevention. Health food will be one of the sectors to be subject to more stringent control.
The March "Report of Consumer Product Complaints during COVID-19 Control Period" highlighted that 37% of the complaints about health foods related to false advertising.

http://gkml.samr.gov.cn/nsjg/ggjgs/202003/t20200318_313133.html

Open approach

Shanghai SAMR has issued Guidelines permitting manufacturing of health food and ordinary food in the same production line in Shanghai.

In the absence of national rules, requirements regarding the manufacture of a health food and an ordinary food vary across Chinese *provinces*.

http://scjgj.sh.gov.cn/shaic/html/govpub/2020-02-28-0000009a202002260001.html

India

New FSSAI CEO of FSSAI

After many months of expectation, the CEO of the Food Safety Standards Authority of India is moving to become Secretary in the Department of Consumer Affairs in the Ministry of Consumer Affairs, Food and Public Distribution.

He has now been replaced by Shri G S G Ayyangar who was previously the Senior Deputy Director General in the Indian Council of Medical Research (ICMR) under the Department of Health Research. At the request of FSSAI, ICM established in 2018 Tolerable Upper Limits (TUL) for some vitamins and minerals in order to allow a possible review of the current maximum levels in fortified foods and supplements.

European Union

Claims: How close should it be?

The Court of Justice of the European Union (ECJ) was recently requested to clarify the term "accompanied" by a specific authorised claim.

Under the European Claims Regulation, general health claims may only be made if they are accompanied by an appropriate specific authorised health claim.

The Court of Justice was asked whether the general wording could be displayed on the front of the packaging and the specific health claim at the back, without an apparent link between the two.

The ECJ indicated that the concept of "accompanying" should include both a substantive and a visual dimension and that it was for the national court to decide.

Regarding the visual dimension, the ECJ stated that both type of claim had to be located on the packaging in such a way as to enable an average consumer to understand the link between the two.

The ECJ acknowledged that exceptionally it may be possible for a general, non-specific and the "accompanying" specific health claim not to appear on the same side of the packaging, provided that an explicit reference, such as an asterisk allows the consumer to make the connection between the two.

http://curia.europa.eu/juris/document/document.jsf?text=&docid=222888&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=7840722

HAD: Drawing a safety line

The European Commission is consulting through the so-called feedback mechanism on directions to regulate plants containing hydroxyanthracene derivatives HAD.

This follows concerns raised by Member States during discussions on the health claim under consideration in 2013 about the possible harmful effects associated with the consumption of foods containing hydroxyanthracene derivatives and preparations.

The measure has also been notified to the WTO: G/TBT/N/EU/702

Pragmatic sampling

At a recent meeting of the Contaminants Working Group, Member states discussed best practices to reduce the high costs related to the sampling of supplements and/or herbal preparations. Two Member States indicated that sampling 1 kg was not always possible but prefer to sample these types of products in retail per package as per Table 4 of Regulation 333/2007. This issue should be further discussed in a future meeting.

Correction in the list of novel foods

The upper limit for the cadaverine content in the novel food spermidine rich wheat germ extract has been increased from 0.1µg/g to 16µg/g. The novel ingredient is currently authorised for use in food supplements intended for the adult population, excluding pregnant and lactating women at an equivalent max level of 6 mg/day spermidine.

Voting rules after Brexit

The relative power of each Member State in EU decisions has increased since the UK left the EU earlier this year. At the February meeting of the Standing Committee on Novel Food and Toxicological Safety of the Food Chain where future EU measures are discussed with Member States, the European Commission clarified that a 'qualified majority' still needs to account for 65% of the population. Clarity on this was requested by a Member State.

New novel food summary

The European Commission has published on its website two new summaries of novel food applications for supplements.

Tetrahydrocurcuminoids from turmeric. The novel ingredient is intended to be used as food supplement at a maximum daily dose of 300 mg (corresponding to 4.3 mg/kg for a 70 kg person) intended for the adult population and excluding children (<18-year-old) and pregnant or lactating women.

Dried Tetraselmis chuii microalgae. The request related to the changes in the specifications namely:
- protein: proposed 15-40% versus the authorised 35-40%
- ash: 14-20% versus 14-16%
- carbohydrates: 25-32% versus 30-32%
- fibre: 2-20% versus 2-3%, and
- fat: 5-15% versus 5-8%.

Belgium

Tracing botanicals

The Advisory Committee on Plant Preparations has recently published recommendation on methods of analysis for 4 new plants:

- Baptisia tinctoria
- Cordia myxa L.
- Coscinium fenestratum (Goetgh.) Colebr.
- Sorbus domestica

https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/aanbevolen_analysemethoden_4.pdf

France

Preparing to not add more to the crises

The French Agency for Food, Environmental and Occupational Health & Safety, ANSES, has announced a modification to its organisation due to the Covid-19 outbreak. Laboratories will continue to carry out their activities, while its activities around vigilance, expertise and authorisation and alert will be carried out remotely.

With the objective of not adding crises to the crisis, continuity of activities around major pathogens will remain fully ensured in order to respond to health alerts concerning food, animal health and plant health.

Germany

Iodine intake in decline

The iodine intake of the population is still not optimal and declining again, according to the the German Federal Institute for Risk Assessment (BfR)

In its recent updated FAQs document on iodine intake, BfR has emphasised the need for continual long-term measures to ensure that the German population has a sufficient iodine supply, and to prevent iodine deficiency.

However, BfR notes that such recommendations may not be appropriate for people that may demonstrate higher sensitivity to iodine. This is particularly true for elderly. BfR highlighted that Germany has experienced a prolonged iodine deficiency in the past which lasted until the 1980s, and that functional autonomy of the thyroid gland is still to be expected in the elderly in particular. In order to protect sensitive consumers, the German Nutrition Society therefore has recommended limiting the total iodine intake from food and food supplements for adults to 500 µg per day.

https://www.bfr.bund.de/en/iodine_intake_in_germany_on_the_decline_again___tips_for_a_good_iodine_supply-128779.html

Ireland

CBD: A catalogue of fraud

A national survey of CBD products by the Food Safety Authority of Ireland (FSAI) has found that the majority of products analysed were in breach of various articles of food law and some posed potential safety risks for consumers.

The survey reveals that 37% of the products tested had a THC delta-9-tetrahydrocannabinol content that could result in safety limits set by the European Food Safety Authority (EFSA) being significantly exceeded and the implicated batches of these products are currently being recalled.

The survey also highlighted that the analytically determined CBD content in over 40% of samples varied significantly (>50%) from the declared CBD content, putting consumers at risk by the ingestion of relatively high levels of THC.

36% of samples classed as food supplements had also not been notified to the FSAI before being placed on the market, as required by the law.

34% of the samples were classified as novel foods and thus had to be authorised before being placed on the EU market.

Finally, 50% of the 38 samples tested made misleading claims including unauthorised health claims including claims considered medicinal.

https://www.fsai.ie/news_centre/food_alerts/CBD_recall.html

https://www.fsai.ie/news_centre/press_releases/cbd_food_supplement_survey_130220.html

Norway

Cafeine, how much is too much

The Norwegian Scientific Committee for Food and Environment (VKM) has self-initiated a risk assessment of caffeine including caffeine exposure estimates from multiple sources including food, food supplements and personal care products.

This aim would be to examine whether the total caffeine exposure from multiple sources constitutes a health risk to the Norwegian population. The assessment is scheduled for publication March 2021.

https://vkm.no/download/18.21473d40170b088c20e3726b/1583755764083/Protokoll_samlet%20eksponering%20for%20koffein%20fra%20mat%20og%20kosmetikk_final.pdf

Poland

Vitamins complete, minerals a work in progress

The Food Supplements Team of the Chief Sanitary Inspector in Poland has completed its work regarding the setting of maximum daily levels for vitamins in supplements with the publication of its last resolution on vitamins E and K.

The following maximum daily levels were adopted for the two minerals.
vitamin E: 250 mg (Resolution No. 1/2020)
vitamin K: 200 µg with the warning statement: "The product should not be consumed by persons taking anticoagulants containing vitamin K antagonists (e.g. warfarin and acenocoumarol)
Maximum daily levels of the following minerals for use in food supplements intended to adults have also been established:

boron: 3 mg (Resolution No. 3/2020);
chromium: 200 µg (Resolution No. 4/2020);
fluoride: 3,5 mg (Resolution No. 5/2020);
phosphorus: 450 mg (Resolution No. 6/2020).

As for botanicals, a daily limit of 3g was set for Withania somnifera (L) with the restrictions that the maximum content of vitanolids may not exceed 10 mg in the recommended daily portion of the product. Companies placing a food supplement on the market containing *Withania somnifera* should attach a quantitative specification confirming the content of vitanolids per the recommended daily portion of the product.

The team also recommended to use the following warning statement on the labelling of food supplements containing the botanical:"*The product should not be consumed when using sedative, hypnotic, anti-epileptic drugs, not to be used by children, pregnant and lactating women.*"

United Kingdom

CBD: Bringing order

The UK Food Standards Agency (FSA) has set a deadline of 31 March 2021 for companies to submit their novel food authorisation applications for products containing CBD extract. After 31 March 2021, only products which have a fully validated application will be allowed to remain on the market. All other novel CBD products will be removed from sale. The authorisation process will ensure these novel foods meet legal standards, including safety and content.

The FSA statement and updated business guidance clarifying the national position on CBD can be found at these links:

https://www.food.gov.uk/business-guidance/cannabidiol-cbd

https://www.food.gov.uk/news-alerts/news/food-standards-agency-sets-deadline-for-the-cbd-industry-and-provides-safety-advice-to-consumers

Tumeric: Warning signs

The UK Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) has been investigating the safety of turmeric and curcumin in their various forms.

This work was motivated by the increased consumption of curcumin/turmeric supplements and the number of reports of hepatotoxicity linked to the consumption of curcumin supplements that have been monitored by the Food Standards Agency.

In its March statement, COT recommended 'that there would be value in commissioning a chemical analysis of turmeric supplements and raw/powdered turmeric available on the UK market'.

The Netherlands

ERRATUM Title in the previous edition should read: Phytoestrogens: Consumer protection V Consumer choice

South Africa

Market access clarified and simplified

The South African Health Products Regulatory Authority, SAPHRA, has announced the launch of an online licencing system. The new system will allow applications for licence to manufacture, import or export Complementary Medicines (Category D) - Manufacturers only), licence to import or export Complementary Medicines(Category D) – Holders of certificate of registration, and licence to act as a wholesaler of or distribute Complementary Medicines (Category D) – wholesalers or distributors.

https://www.sahpra.org.za/wp-content/uploads/2020/02/Notice-online-portal.pdf

USA

New Supplement Facts Labels: Extending deadline

The U.S. Food and Drug Administration FDA will work with manufacturers regarding using updated Nutrition and Supplement Facts labels and will not focus on enforcement actions through the end of 2020. This update follows a previous announcement from FDA indicating the agency would exercise enforcement discretion for six months following the 1 Jan. 2020, compliance date.

Last Installment of the Draft Guidance for the Intentional Adulteration Rule

The U.S. Food and Drug Administration has released a supplemental draft guidance designed to support compliance with the Intentional Adulteration (IA) Rule under the FDA Food Safety Modernization Act (FSMA). This is the last installment of the draft guidance for the IA rule.

This installment covers notably topics focusing on food defence corrective actions, food defence verification, reanalysis, and record keeping. The installment also includes appendices on FDA's online Mitigation Strategies Database and how businesses can determine their status as a small or very small businesses under the rule.

Food facilities covered by the rule are required to develop and implement a food defence plan that identifies vulnerabilities and mitigation strategies for those vulnerabilities. These facilities are also required to ensure that the mitigation strategies are working by implementing mitigation strategy management components. Compliance requirements for large facilities began in July 2019; inspections will begin in March 2020.

Source: https://www.fda.gov/food/cfsan-constituent-updates/fda-releases-third-installment-draft-guidance-intentional-adulteration-rule

Post marketing Adverse Event Reporting during a pandemic

FDA has updated their guidance on post market adverse event reporting for medical products and dietary supplements during a pandemic. FDA highlighted that the latest updates in this guidance are applicable to any pandemic, including COVID-19. This revised version will replace the 2012 final guidance.

Source: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-adverse-event-reporting-medical-products-and-dietary-supplements-during-pandemic

Accreditation: Towards a single approach

The ANSI National Accreditation Board (ANAB), a subsidiary of the American National Standards Institute (ANSI), has launched a new pilot accreditation programme for the Global Retail and Manufacturer Alliance (GRMA) certification scheme. The scheme focuses on a wide range of non-food product categories, including dietary supplements.

ANAB's accreditation programme will operate in accordance with ISO/IEC 17065, General requirements for bodies operating product certification systems, and the GRMA's certification scheme, which incorporates the following American National Standards (ANS) for Dietary Supplements: NSF/ANSI 455-2-2018, Good Manufacturing Practices for Dietary Supplements.

The auditing standards are intended to:

- Protect consumer health and safety
- Provide better risk-management programs and protect store brand integrity
- Improve the efficiency of retailer-to-manufacturer interactions
- Create a single audit report accepted by all participating retailers
- Create consistency through auditor qualification, training, and calibration requirements
- Reduce the number of audits required by retailers
- Reduce manufacturer audit costs in terms of time and money
- Give manufacturers time to address continuous improvement

Source: https://anab.ansi.org/latest-news/anab-launches-accreditation-program-for-grma-certification

Brazil

Building up ingredient list

On 18 March ANVISA opened for public consultation a proposal to include 28 new permitted substances and new permitted claims in the food supplement regulation. It seeks to update the Administrative Order 28/2018 that establishes the permitted ingredients, maximum levels and permitted claims for food supplements. The proposal seeks to include:

- 9 new vegetal protein sources, for example proteins and isolated proteins from pea, bean, sunflower, lentil and chickpea.
- 19 new substances including microalgae oil from Prototheca moriformis, sources of vitamins such as folic acid and vitamin K, sources of hyaluronic acid, silicon, collagen, among other, the enzyme lactase, and a list of probiotics which includes several strains of Lactobacillus rhamnosus, Bifidobacterium animals, Lactobacillus helveticas, among others.
- New permitted claims for undenatured type II collagen linked to the keeping of the joint function, and for probiotics, for example, "Lactobacillus acidophilus NCFM can contribute to gastrointestinal health".
- Specific mandatory warning statements for new substances such as probiotics: "This product should not be consumed by pregnant women, nursing mothers, children, immunocompromised people (either due to illness or the use of immunosuppressive drugs) or people with a severe debilitating health condition".

The proposal is open for comments until 4 May 2020.

Guide for microbiological criteria

ANVISA has published a Guide for new Microbiological Criteria to provide greater clarity on the implementation of regulations related to microbiological criteria in food and food supplements, as foreseen in Resolution RDC 331/2019 and its Normative Instruction 60/2019. The Guide includes clarifications on the microbiological criteria adopted, limits, scope, methods of analysis, samples, and the interpretation of results and actions in case of non-compliance, among other points.

http://portal.anvisa.gov.br/documents/33916/2810640/Padrões+microbiológicos/e0206465-1392-4333-a2dc-9feef2dbf462?fbclid=IwAR2ndF8jOtMDTO-tKyiM3iueoxa3HkCjLzR80UFd3svyfggsYnZ_9lejWpQ

Uruguay

Green light for cannabis supplements

In January and February, the Ministry of Health issued two decrees approving the use of non-psychoactive cannabis

derivatives as ingredients in food and food supplements:

- Decree 19/2020 approves the use of cannabis seed protein from the variety Cannabis sativa L. and sets the physicochemical requirements this ingredient must meet.

- Decree 42/2020 approves the use of cannabis seed oil from the variety Cannabis sativa L. and sets its physicochemical requirements and the fatty acid profile.

The maximum limit of tetrahydrocannabinol (THC) for both ingredients has been set at 10 mg of THC/kg. These new ingredients have already been introduced in the section of "Complementary Ingredients" from the National Bromatological Regulation.

Decree 19/2020
https://medios.presidencia.gub.uy/legal/2020/decretos/01/msp_153.pdf
Decree 42/2020
https://medios.presidencia.gub.uy/legal/2020/decretos/02/msp_24.pdf

Eurasian Union

New review of labelling regulation

The Eurasian Economic Commission (EEC) Council's resolution of 30 January 2020 appoints Belarus to draft Amendment 4 to CU TR 022/2011 on food labelling. Information about the types of vegetable and/or animal oils and fats used will become mandatory on food labels, including food supplements. Belarus will submit the draft to the EEC in Q1 2021.

Russia

Healthy food repositioned as of national importance

In March, the President of Russia signed amendments to the Federal Law on quality and safety of foods (Federal Law №47). The amendments significantly alter a number of the articles contained in the law, including the nomenclature, the marketing, quality and safety of foods, the powers of controlling agencies and the requirements for confiscating inferior, unsafe and falsified foods. They also introduce a number of new terms, such as healthy nutrition and food quality.

The document introduces new measures to ensure the quality and safety of foods, including scientific research on nutrition and preventing non-communicable diseases; establishing identification criteria for foods; encouraging manufacturers to produce foods which meets the quality criteria and the healthy nutrition principles and educational programmes to promote a healthy nutrition culture.

The document also deals with the regulation of claims in food labelling. In particular, the use of claims will be allowed in accordance with a new procedure to be developed by the consumer authority, Rospotrebnadzor.

The document contains a separate article on children's nutrition. Importantly, the current version of the law defines baby foods as foods for children aged 14 and below. The original draft amendments expanded the age bracket up to and including 18 years of age. The final version effectively copies the definition contained in CU TR 021/2011 which sets no age cap at all. This could entail certain challenges for manufacturers of certain baby food types, including food supplements for children.

Strategy for healthy lifestyles

The Russian Health Ministry's Decree 8 of 15 January 2020 adopts the strategy to promote healthy lifestyles and prevent and control non-communicable diseases through to 2025. The strategy states that non-communicable diseases remain a leading cause of disability and mortality both globally and in Russia. The ministry also says that "obesity and arterial hypertension are primarily caused by improper diets, first and foremost by high intakes of sugar, saturated fatty acids and salt".

The strategy is aimed at reducing the incidence of non-communicable diseases and preventing associated mortality, as well as at achieving an increase of healthy life expectancy by way of promoting healthy lifestyles.

The ministry believes prevention and control of non-communicable diseases should be based on healthy lifestyles which include, inter alia, total exclusion or reduction of unhealthy dietary habits. The strategy identifies a number of ways to promote healthy lifestyles and prevent non-communicable diseases, including:

- elimination of micronutrient deficiencies, primarily iodine deficiency.
- reducing excessive consumption of salt, sugar and saturated fats in the population;
- increasing consumption of fruit and vegetables, fibre, fish and seafood;

The strategy also calls for the development of programmes to promote healthy nutrition.

Russia to crack down on falsified dietary supplements

On 25 March 2020, two bills approved by the Federation Council (upper house of the Russian Parliament) were submitted to the President:

- the bill on amending the Administrative Violations Code;
- the bill on amending Article 238-1 of the Criminal Code.

Both bills are aimed at cracking down on the marketing of falsified dietary supplements via standard or electronic media, including through the Internet.

Both bills were submitted to Parliament in October 2018 by a group of MPs and were adopted in the third and final reading on 19 March 2020.

The administrative fine for selling falsified dietary supplements stands at between 75,000 and 200,000 roubles ($952 to $2,540) for individuals and between 2 and 6 million roubles or suspension of activities for businesses.

Sales of dietary supplements to a value in excess of 100,000 roubles containing unapproved pharmaceutical ingredients will entail compulsory work for between four and five years or imprisonment of between four and six years plus a fine.

COVID-19

For national Covid-19 updates, please follow our bulletins