IADSA NEWSFLASH

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Regulatory news

China

New Guidelines on Health Food Testing and Assessment

The China State Administration for Market Regulation (SAMR) has released three health food related technical guidelines:

Technical guideline for toxicological testing and assessment of health foods and their raw materials. This new document aims to replace the 2003 version that was abolished in 2018. Its contents include reference, scope, testing substances, main items of toxicological testing, selection of toxicological tests among others.

Technical Guideline for Safety Testing and Assessment of Bacterial Strains Used in Health Food Raw Materials. This publication is applicable to pathogenicity testing and assessment of bacterial strains used in health food raw materials. Notably, it covers the documentation required for the assessment of microorganism strains and testing methods.

Technical Guideline for Physicochemical and Hygienic Examination and Assessment of Health Food. This version replaces the content of functional ingredient evaluation in the 2003 technical standards. It is applicable to health food registration and filing. It lists test methods for 51 functional ingredients against 35 in the 2003 technical standards.

India

Amending supplement regulation

In a welcome development the Food Authority's draft amendment of November 2020 clarified that combinations of vitamins sold in dosage forms - capsules and tablets - are covered by food regulations, ending speculation these were under drug oversight. It further clarified that health supplements must contain vitamins and minerals (Schedule I), or amino acids (Schedule II) or both, with options to include plants, botanicals and other permitted ingredients listed under schedules. While nutraceuticals must contain ingredients from Schedule VI with options to use any other ingredients or nutrients. Health supplements and nutraceuticals continue to be compositionally different without a forthright distinction. Positive list entries have increased to 439 plants and botanicals and ingredients for nutraceuticals with specified range up to 40, those without a specified range to 194; several changes are also made for permitted additives The limit of vitamins and minerals in supplements and nutraceuticals (tablets, capsule forms) continue at not more than RDA. However for certain foods for special dietary uses (FSDU) levels up to 50% of TUL's are permitted. Products formulated for young children 6-24 months are required to obtain prior approval and supplements for children below age 5 years should be given only on advice of a physician or a certified dietician/nutritionist. The draft is open from 29th October 2020 up to sixty days to receive public comments, before it is finalized.

India to amend its food Act

The ministry of health and family welfare (MOHFW) is inviting suggestions and comments to its proposed draft bill to amend the Food Safety and Standards Act, 2006. Sections seeking more powers to the Authority (FSSAI), raising penalties, simplifying administrative procedures and extending its jurisdiction to animal feed, are some of the more than 60 amendments being sought. Apart from amending existing sections, such as substituting the term 'withdraw or withdrawal' with 'recall' in the section on food recall, changes introduced include defining "materials in contact with food". While no amendments are proposed for health supplements under Section 22, businesses may offer suggestions; the comment period is open for 30 days from publication (23rd September 2020). However, requests have been made for an extension.

New RDAs, levels up

The Expert Group (EG) of the Indian Council of Medical Research-National Institute of Nutrition (ICMR-NIN) has revised upwards the RDA for Indians. Its 2020 report for the first time includes the Estimated Average Requirement (EAR) and the Tolerable Upper Limits (TUL), which along with the Recommended Dietary Allowance (RDA) provides an important framework for policymakers advising on health and nutrient intakes from all foods including fortified foods and food supplements. Upward revisions are made for vitamin A (600 to 1000 µg); vitamin D (10 to 15 µg) and vitamin C (40 to 80mg). Several water soluble vitamins, thiamine (1.2 to 1.4 mg); riboflavin (1.4 – 2.0 mg); vitamin B12 (1.0 – 2.5 µg) and dietary folate (200 to 300 µg) have also been revised. While

RDA's of some minerals are retained, the following have been revised: calcium (600 to 1000mg); copper (1.7 to 2 mg); iron (17 to 19mg); magnesium (340 to 385mg); phosphorus (600 – 1000mg) and zinc (12 – 17 mg). The report also provides the Acceptable Macronutrient Distribution Ranges (AMDR) intakes , expressed as a percentage of energy with lower and upper limits. Food businesses may use the revised RDA's once these are notified by the FSSAI.

Malaysia

New Halal requirements

Malaysia has recently released its second circular confirming the implementation on 1 January 2021 of the Malaysian Halal Certification Procedure Manual (Domestic) 2020, Malaysian Halal Management System 2020, and Malaysian Standard 2019. The documents apply to both domestic and international companies.

South Korea

Revision of Health Functional Food Code

Korea has recently introduced some changes to its health functional Food Code:

Inclusion of a new benefit for chromium "helps to break down carbohydrates, fats, proteins"
Inclusion of new warning statements for 9 nutrients: beta-carotene, vitamin K, vitamin B1, vitamin B2, pantothenic acid, vitamin B12, biotin, potassium, and chromium (See below).
Optimisation of the test methods of Vitamin D, Vitamin B2, Vitamin B6, Vitamin B12, and biotin.
The amendments to the Health Functional Food Code came into force on 23 September. The provisions related to the new warning statements will come into effect in 2021.

Warning statements:

Beta-carotene
Smokers shall consult a health professional before taking the supplement

Stop taking the supplement and consult a health professional if you experience side effects.

Vitamin K
Consult a health professional before taking the supplement if you are taking an anticoagulant.

Potassium
Consult a health professional before taking the supplement if you have kidney diseases or gastrointestinal disease. Stop taking the supplement and consult a health professional if you experience side effects.

Chromium
Consult a health professional before taking the supplement if you have diabetes. Stop taking the supplement and consult a health professional if you experience side effects.

Vitamin B1, B2, Pantothenic acid, B12 or Biotin
Stop taking the supplement and consult a health professional if you experience side effects.

USA

Labelling: Additional flexibility

The U.S. Food and Drug Administration (FDA) has announced additional flexibility for manufacturers who need to comply with updated Nutrition and Supplement Facts label requirements by 1 January 2021. This upcoming compliance date applies to manufacturers with less than $10 million in annual food sales. Although the compliance date will remain in place, the FDA has also indicated that it will not focus on enforcement actions during 2021 for these smaller food manufacturers.

Australia

Sports supplements are therapeutic goods

Sport supplements are now classified therapeutic goods. The Australian Therapeutic Goods Administration (TGA) has now confirmed in its recent declaration under the Therapeutical Goods Act 1989 (F2020L01204) that certain sports supplements - those that include higher-risk ingredients or are in the form of a tablet, pill or capsule - should be regulated as medicines.
The declaration will come into effect on:

• 30 November 2020 for sports supplements containing ingredients identified in the declaration.

• 30 November 2023 for sports supplements presented in the dosage form of pills, tablets or capsules (providing they do not contain ingredients identified in the declaration).

European Union

Max Levels: The second time around

It is now official, the European Commission has re-initiated its attempt to harmonise the use of maximum amount of vitamins and minerals that may be added to food supplements and foods fortified with vitamins and minerals. With a proposed adoption of the Regulation in Q1 2024, the Commission timing remains ambitious.

Since the creation of the Food Supplement Directive, many EU Member States have established their own limits or develop their own risk assessment/ management model with often little convergence on approach taken. Will this new attempt at harmonisation lead to harmony or more discord? Time will tell.

Titanium dioxide hits EU obstacle

The European Parliament Environment, Public Health and Food Safety Committee has recently voted to block the revision of the titanium dioxide specifications proposed by the European Commission. The revision was aimed to include the characterisation of particle size distribution, required for the identification of potential nanoparticles. In objecting to the revision of the TiO2 specs, MEPs have backed the French authorities in their decision to suspend the use of the food additive in France. This veto should also be seen as a warning sign for the Commission and EFSA on future decisions to be taken regarding the use of the additive on the European market. In the absence of a decision,

the current specifications remain unchanged. The European Commission will likely wait until EFSA publishes its opinion on the safety assessment of the additive in March next year before reinitiating its work.

On hold claims still valid

The European Court of Justice has recently clarified the status of claims 'on hold'

The Court confirms that the on-hold health claims are to be made ‘under the responsibility of food business operators’ and, ‘a food business operator making a nutrition or health claim shall justify the use of the claim’. This evidence can be as contained in a file prepared in support of the application for entry in the list provided for in legislation or come from other sources provided that the evidence is of sufficient scientific value.

The Court judgment is in response to the Swedish Consumer Agency that was of the view that a company should not be allowed to use a claim on hold.

There are currently more than 2000 claims on hold in the EU. These claims are primarily those for plant and herbal substances. In 2010 the Commission decided that it was not possible to continue with the assessment of these health claims due to a difference in legal requirements between health claims and Traditional Herbal Medicinal Products. As a consequence, the European Food Safety Authority (EFSA) was asked to discontinue its assessment. All these claims were put on hold until the Commission decides how to address this issue.

Novel Food status

Mumijo when used in food supplements should not be considered as Novel according to the European Commission. This follows the confirmation of the Czech Authorities that the ingredient has been used in food supplements before 15 May 1997.

In the absence of evidence that the seeds had been used for human consumption to a significant degree before 15 May 1997, *Dipteryx alata* seeds (roasted) are considered as novel and have therefore been added to the Novel Food Catalogue.

Warning statements for green tea & red rice

In addition to the decision to set maximum levels for green tea catechins (800 mg/daily supplement dose) and monacolin K for red yeast rice (3 mg/ daily dose), the European Commission is also discussing the inclusion of warning statements for both ingredients. It is to be noted that the authorised monacolin K health claim on maintenance of normal blood cholesterol levels requiring a minimum amount of 10 mg of the substance, will no longer be permitted once the decision is adopted

Garcinia Cambodia in jeopardy

The European Commission (EC) will be requesting under the so-called Article 8 procedure, the European Food Safety Authority (EFSA) to evaluate the safety on *Garcina Cambodia* due to hepatic failure observed after consumption of this plant.

The Article 8 procedure (regulation 1925/2006/ EC) allows the possibility to prohibit, restrict or put under EU scrutiny the use of substances that could represent a potential risk to consumers.

France

Nutriviligance case reported for *Bauhinia variegata*

ANSES, the French Agency for Food, Environmental and Occupational Health & Safety, has recently reported a case of acute hepatitis related to the intake of a food supplement containing powdered bark of *Bauhinia variegata*.

While ANSES considers that the food supplement in question was very likely responsible in the occurrence of the acute hepatitis, they view the current data as insufficient to formally conclude on the hepatotoxic character of the plant. In view of the various identified issues and the growing appeal of the population for these botanical supplements, the Agency has requested that particular attention should be paid to the undesirable effects likely to occur following the consumption of this plant.

EFSA kicks off work on alpha lipoic acid

The European Food Safety Authority (EFSA) has set up a new Working Group on alpha lipoic acid (ALA) to deal with the Scientific opinion on the safety of the substance. Following a request by Denmark, the Commission has initiated the procedure under the article 8 procedure to evaluate the safety of alpha lipoid acid in food supplements. This decision was based on an assessment from the Danish National Food Institute that has raised safety concerns associated with the intake of the substance at a daily dose of 150 to 200 mg. Potential risks for Insulin Autoimmune Syndrome (IAS) and several advert effects were reported.

Norway

D-Ribose: A change of mind

The Norwegian Scientific Committee for Food and Environment (VKM) has revised its conclusion on the safety of of D-ribose (VKM, 2016). While VKM stated in 2016 that it was unlikely that a daily dose of 3100 mg or 6200 mg D-ribose in food supplements causes adverse effects in children (10 to <14 years), adolescents (14 to <18 years) and adults (≥18 years), the Scientific Committee has recently come to the conclusion that a single daily dose of 6200 mg D-ribose in a food supplement may represent a risk of adverse health effects to children, adolescents and adults and that a daily single dose of 3100 mg D-ribose in a food supplement may represent a risk of adverse health effects for children. VKM recalled that D-ribose is synthesized in all living cells and is available in small amounts in the diet via ripe fruit and vegetables. Excessive intake of D-ribose may increase the risk of hypoglycaemia, i.e. low blood sugar.

Spain

Probiotics: a U-turn

Aware of the increase in food supplements with the term ‘probiotics' on their labels in some European markets, the Spanish authorities have decided to change their mind about their national labelling rules for probiotics.

While the approach, in line with 2007 EU guidelines, was to prohibit the use of the term ‘probiotics' in the absence of related permitted health claims, the Spanish Agency for Food Safety and Nutrition (AESAN) have revised their position: "It could be accepted that the term ‘probiotic(s)’ appears on the label of nationally manufactured food products or products from other EU countries”. The use of this term cannot however be accompanied by any health

claim, unless this has been specifically authorised.

With this Spanish U- turn, the question of the status of probiotics claims may resurface on the EU table

Switzerland

Support for supplements during pregnancy

Pregnant women who seek to lead a healthy pregnancy know that they should eat a balanced diet. To guide future mothers, the Federal Office for Food Safety and Veterinary Affairs of Switzerland has issued its nutritional recommendations promoting the use of supplements during pregnancy and breastfeeding. Supplementation of iodine, vitamin D, omega 3, folic acid, iron, B12 for vegan and vegetarian) is notably suggested if the diet does not permit adequate intake.

United Kingdom

CBD: Need for toxicological studies

CBD novel foods applications must include toxicological data. In response to the concerns expressed by the government's Committee on Toxicity (COT), the UK Food Standards Agency has recently updated its CBD guidance document with a new section clarifying the need for toxicological information to be included in novel food application. Products containing CBD extract for which the FSA has a valid application by 31 March 2021 will be allowed to remain on the market. Until this date, businesses can continue to sell their existing CBD products, provided they are not incorrectly labelled, are not unsafe and do not contain substances that fall under drugs legislation.

EU, GB or NI?

The UK Government has recently updated their Guidance on Food and drink labelling changes from 1 January 2021.

The recent update concerns the addition of more detail to country of origin labels and food business operator (FBO) address sections.

- Use of an EU, GB or NI address for the FBO on pre-packaged food sold in GB can continue until 30 September 2022.
- From 1 October 2022, pre-packaged food sold in GB (Great Britain) must include a UK address for the FBO.
- Pre-packaged food sold in NI (Northern Ireland) must include a NI or EU FBO address from 1 January 2021

It is clarified that Great Britain (GB) means England, Scotland and Wales, whereas UK means United Kingdom of GB & Northern Ireland (NI).

Brazil

"New Formula" Guide ready

Following the decision to label new products as "New formula" (Resolution RDC No. 421/2020), ANVISA has now published a Guide for companies on how to use the statements "New formula", "New composition" or "New recipe" on the label of foods and food supplements.

Recommendations for food ingredient specifications

The National Agency for Sanitary Surveillance (ANVISA) has recently published its draft Guide on Food Ingredient Specifications addressing the establishment of specifications where there is no recognized reference. This guide covers ingredients, compounds of nutrient sources, bioactive substances, food additives to be used in food and food supplements. The new document notably aims to help companies understand ANVISA's approach to the evaluation and assessment of food ingredients, including information on how to characterize them

Supplements exempt from FOP labelling

In its recent resolution introducing changes to the nutrition labelling rules, the Brazilian authorities have clarified that food supplements are exempt from front-of-pack labelling.

The new law reconfirms rules already enforced that the nutrient declaration for supplements remains per serving as recommended by the manufacturer. Claims for food supplements must also follow the rules foreseen on Resolution RDC 243/2020.

Food supplements will have however to comply with the new provisions introduced, which include:

- More visibility of the nutritional information table: black font with white background Inclusion of the linear model as a format for the declaration of nutritional information
- Total and added sugars (if applicable) must be declared
- Number of servings per package must appear on the nutritional labelling Updated rules for individual containers
- Updated sentence on what the % Daily Value means Changes in the way of declaring non-significant amounts
- Updated Recommended Daily Values for nutrients.

The new regulation will take effect on 9 October 2022. However, Brazil indicated that the new rules could be revised before the enforcement date as a result of the current discussion at Mercosur level to update the harmonised nutrition labelling rules.

Accuracy

The National Agency for Sanitary Surveillance (ANVISA) has published an Amendment to Annex I from Administrative Instruction 28/2018, which foresees the list of permitted ingredients in food supplements. Changes relate to the permitted forms or specific terminology of certain substances, and mainly amino acids. For example, the list previously mentioned "cysteine", now it states "L-cysteine"; in the case of "calcium glutamate", now the permitted ingredient is "calcium L-glutamate". Importantly, no new substances have been listed. However, the Board of ANVISA plans to review Administrative Instruction 28/2018 to include new substances. This discussion is expected in November.

New additives in FS for infants and young children

The National Agency for Sanitary Surveillance (ANVISA) published Resolution RDC 437/2020 introducing changes to Resolution RDC 239/2020 which foresees the list of permitted

additives in food supplements. Two new additives are allowed as anti-humectants in food supplements intended for infants and young children, presented in powder form, with their respective maximum limits as follows:

- Tricalcium phosphate (INS 341iii): 0.44 g/ 100g or ml
- Silicon dioxide (INS 551) 1 g / 100g or ml

This update is already in force.

Extension of list of substances & claims

During the 20th meeting of the Board of Directors of the National Agency for Sanitary Surveillance (ANVISA), it was considered to modify the list of permitted ingredients and permitted claims in food supplements. Although there is no final text published in the Official Gazette yet, the new regulation would introduce:

- 44 ingredients, which foresees new sources of nutrients, bioactive substances, enzymes and probiotics,
- Minimum limits for 14 bioactive substances and probiotics,
- Maximum limits for 8 nutrients and bioactive substances,
- 16 new claims.

Urugay

New allergen rules

In September the Ministry of Public Health opened for public consultation a proposal to regulate allergens labelling in packaged food products, which includes food supplements. The proposal seeks to introduce a mandatory statement in case allergen substances have been added, are part of other ingredients, or cross-contamination could be possible. If approved, food supplement labels will need to bear after the list of ingredients the statement “Contains… (followed by the allergen)” or “It might contain… (followed by the allergen)”, as appropriate.

Turkey

Health Claims Regulation under development

The Ministry of Health, who has taken over the responsibility of health claims for food and supplements, has now put together a first draft on claims. The law will aim to first set new rules for food supplements specifically.

South Africa

Health supplements are not Medicines

The South African High Court has ruled that the General Regulations to the Medicines and Related Substances Act (101 of 1965, Regulations, 2017) are unlawful: “Health Supplements” are not “Medicines” or “Scheduled substances”.

"The definition of medicine is declared to apply only to substances that are used or purport to be suitable for use or are manufactured or sold for use in the diagnosis, treatment, mitigation, modification or prevention of maladies, in order to achieve a medicinal or therapeutic purpose, in human beings and animals” clarified the High Court.
In 2018 an application was launched challenging the General Regulations to regulate health supplements on the same basis as medicines.
The South African Health Products Regulatory Authority (SAHPRA) has been given 12 months to come up with better regulations.

Ukraine

Claims: Copy pasting EU

Ukraine has now completed the harmonization of its claim’s rules with the EU regulation on nutrition and health claims.
This includes the adoption of: The requirements for nutrition and health claims made on foods; The list of nutrition claims and the conditions of their use (Appendix 1); The list of health claims permitted for use in food labelling and advertising, with the exception of claims related to reduced risk of diseases and claims related to the development and health of children (Appendix 2); The list of claims related to reduced risk of diseases and claims related to the development and health of children (Appendix 3).The document's authors believe its adoption will create a more transparent operational environment for the food industry, improve its competitiveness and ensure greater access to the EU and international food markets. Products which conformed to the legislative requirements prior to 21 August 2020 but failed to meet the requirements of the current document may continue to be imported into Ukraine, manufactured and sold for the next three years. Such foods may remain on the market until their expiry date.

Russia

Rospotrebnadzor proposes criteria for substantiating claims

Russia’s consumer authority Rospotrebnadzor has published for discussion draft decree on establishing criteria for a body of evidence used in support of food claims displayed on product labels. The document was drafted in keeping with Federal Law 47-FZ of 1 March 2020 as applied to amending Federal Law 29-FZ On quality and safety of food products, under which Article 5 of the law is amended to include the following provision: “Claims voluntarily stated on food labels must be supported by a body of evidence based on the criteria established by a federal executive authority.” The decree introduces four criteria for evaluating the body of evidence. Two of the criteria, proposed by the consumer authority, are fairly clear: the existence of methods allowing for the assessment of substances mentioned in the claim stated on the label; laboratory test results proving the claim. The third criterion requires comparative analysis of claim-bearing foods with equivalent food products sold on the market. Finally, the fourth criterion requires “the availability of research results that prove the usefulness of food products’ consumer properties for human health”. However, it fails to specify what research should be deemed as being sufficient to support the claim.