IADSA NEWSFLASH

June 2021

Regulatory news

China

New measures for imported and exported foods

China has recently updated the Administrative Provisions on Registration of Overseas Manufacturers of Imported Foods and measures for the Safety Administration of Imported and Exported Foods.

India

FSSAI license code on bills

The Food Authority's order of 8 June 2021 requires food businesses to provide their 14-digit FSSAI license code on transaction documents such as invoices, bills, cash memo and receipts. Though this is a mandatory declaration on every pre-packaged food label, the move is to discourage unlicensed sale by businesses. The measure does not require any additional documentation except for its inclusion in existing commercial documents. It is expected to strengthen the track and trace mechanism and will be implemented from 1 October 2021.

Korea

Amendments to the health functional food code

The Ministry of Food and Drug Safety (MFDS) is consulting on its Health Functional Food Code with two announcements: No. 2021-252 and No. 2021-253.

These announcements cover amendments on new precautions for intake of 8 functional ingredients: Ginseng / Red Ginseng : People with an allergy to the ingredient should be cautious; If any adverse reactions occur, please stop the intake of this product and consult experts immediately.

Chlorella: If any adverse reactions occur, please stop the intake of this product and consult experts immediately.

Milk Thistle (Cardus marianus) Extract: Children, pregnant and lactating women should avoid this product; If any adverse reactions occur, please stop the intake of this product and consult experts immediately.

Marigold Extract: Children, pregnant and lactating women should avoid this product; Smokers should consult experts before taking this product; If any adverse reactions occur, please stop the intake of this product and consult experts immediately.

Nondigestible Maltodextrin: If any adverse reactions occur, please stop the intake of this product and consult experts immediately.

Aloe Gel: Children, pregnant and lactating women should avoid this product; Please consult experts before taking this product if you have kidney or liver disease, or if you are taking diabetes drug; If any adverse reactions occur, please stop the intake of this product and consult experts immediately.

MSM (Methyl sulfonylmethane/ dimethyl sulfone) Newly added: Please consult experts before taking this product if you have kidney disease; If any adverse reactions occur, please stop the intake of this product and consult experts immediately.
The consultation also include Vitamin K2 Menaquinone-7, MK-7) as a new raw material for manufacturing Vitamin K.

New mineral sources, new limits for EPA DHA

South Korea has recently updated its health function food code as follows:

Authorisation of new chemical compounds as sources of Calcium and Magnesium: Calcium: Calcium Stearate, Calcium L-Ascorbate and Magnesium: Magnesium Stearate

Increase of maximum daily intake for EPA and DHA Oil: The maximum daily intake of oil containing EPA and DHA is increased from 0.6-1g o to 0.6 - 2.24g for dry eye symptoms improvement.

The test methods of (-)-Hydroxycitric acid, Ginkgolic acid, and (αS1-casein) (f91-100) have also been modified. The amino acid score for converting protein is changed.

Europe

Vitamin D overdosage

The EFSA Discussion Group on Emerging Risks has recently discussed the potential risk of vitamin D overdosage. The issue was raised by the French Food Safety Agency ANSES. Recently France has published an article recommending the use of vitamin D medicines rather than food supplements to prevent the risk of overdose in children due to several cases of overdosages that were reported via the national nutrivigilence system, the poison centres and individual paediatricians. Similar concerns were reported by other Member States as part of the EFSA Emerging Risks Exchange Network (EREN).

While it is not clear what EFSA will do next, these concerns will likely return in other discussions impacting supplements such as maximum levels for vitamin D or food additives for infants and young children where no progress has been made for many years due to the absence of a consensus on the legality of food supplements for under 3 y.o.

Risk of overdose of vitamin D intake during preconception, pregnancy and lactation were also recently addressed by the UK Committee on Toxicity on 4 May.

Alpha lipoic acid in question

The European Food Safety Authority (EFSA) has recently concluded that the riskss associated with the development of insulin autoimmune syndrome (IAS) following the consumption of alpha-lipoic acid (ALA) cannot be quantified precisely. While the incidence of this syndrome in Europe is low and likely lower than in Japan, individuals at risk cannot be identified without genetic testing.

EFSA was asked to provide a scientific opinion on alpha-lipoic acid at the request of the European Commission that initiated the Article 8 procedure due to safety concerns raised by Denmark.

The EFSA conclusions will be addressed with the EU Members States. However in the absence of a limit set by EFSA, defining conditions to restrict the use of ALA may be difficult at this stage.

Monocolin K: Managing risk

The European Commission is proposing to place Monacolin K, which has an authorised health claim, on the EU scrutiny list for the next 4 years. Following safety concerns raised by several Member States including Belgium, France and Germany, the European Food Safety Authority (EFSA) was consulted in 2017 by the Commission through the Article 8 procedure. This procedure was established to allow the EU to address problematic substances by putting them under scrutiny or prohibiting their use.

In 2018, EFSA released its safety opinion highlighting that the substance could pose "a significant health concern". At even 3g a day, there were reports of severe adverse reactions on the musculoskeletal system and the liver, according to the EFSA. Following this publication and given the level of scientific uncertainty persisting around the safety of the substance, the European Commission has now proposed to place under European Union scrutiny the use of monacolin from red yeast for a period of four years, during which time the industry will be invited to submit data to demonstrate the safety of the ingredient. A new law requiring this could be adopted early in 2022.

Belgium

Botanicals: Revised opinions

The Belgian Advisory Commission for Plant Preparations has recently published 4 new opinions:

Advice concerning the use of the gum resin of Boswellia serrata Roxb. ex Colebr.: The oleo gum resin of Boswellia serrata Roxb. ex Colebr. may be used in food supplements.

Advice concerning the use of the underground parts of Hieracium pilosella L.: All parts of Hieracium pilosella L. may be used in food supplements, but that the use by pregnant or lactating women is not recommended. So far only the use of arial parts was permitted.

Advice concerning the use of the underground parts of Valeriana officinalis L.: In addition to the use of the root, the use of the rhizome of this botanical could be used in supplements provided that the recommended daily amount should not lead to an intake higher than the amount equivalent of 3.6 g dried underground parts.
Monography/ Review of essential oils in capsules Mentha x piperita L.. The use of the essential oil in food supplements should be limited to a maximum of 14 days; medical advice is warranted if prolonged use is considered.

It remains to be seen when the authorities will update the legislation to reflect these opinions. It is however understood that these published opinions can in general be considered the latest views of the authorities receiving food supplement notifications.

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Bulgaria

Updating FS provisions

Bulgaria has notified the European Commission and the Member States on their new draft Ordinance on Food Supplements. This draft introduces a number of amendments and additions which include:

Update of maximum levels for vitamins and minerals. For many vitamins, the levels have been increased. Where maximum level were not necessary, the levels have been deleted. Only the level of vitamin A has decreased from 1500 to 1000 µg RE and for manganese from 4 to 2 mg. A level for potassium (1500 mg) and boron (3,6 mg) has been introduced.

The new Ordinance also clarifies that botanicals used in food supplements should be prohibited if they are not in the positive list established in the Annex of the Ordinance.

Finally, mutual recognition provisions have been introduced for food supplements lawfully marketed in another Member State.

Denmark

Tyrosine up!

The Danish Veterinary and Food Administration has published a new amendment of their national law related to the addition of certain substances other than vitamins and minerals to food, including food supplements. The new amendment introduces a higher level for tyrosine in food supplements. The level has been raised from 50 mg to 300 mg per day. The executive order enters into force on 1 July 2021.

Probiotics a mandatory category

The Ministry of Food in Denmark has recently announced with immediate effect, that the term “probiotics” should be regarded as a mandatory category designation that can be applied to supplements. This means that food supplements can be labelled with the term "probiotics" when they contain live lactic acid bacteria and / or bifidobacteria. It is assumed that the term "probiotics" is used in such a way that it does not appear as a claim for the product.

France

Coumarin: Danger

The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) has recently revealed that essential oil of cinnamon used in particular in food supplements is at the origin of the majority of the undesirable effects (16 cases out of 28 analysable) identified by the French Nutrivigilance system, such as hepatic and gastroenterological symptoms.

In order to avoid exceeding the tolerable daily intake (TDI) set by EFSA, ANSES recommends that the intake of coumarin from food supplements be less than 4.8 mg per day for a 60 kg adult.

People who have had a history of liver disease or who are taking medicines that may cause undesirable hepatic effects are also requested to not consume supplements containing coumarin or foods rich in cinnamon (a natural source of coumarin).

Keeping to the wording

The General Directorate for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF) has recently published the results of a study carried out in 2019 according to which 44% of foodstuffs are not compliant with the law because they use therapeutic or health claims that are illegal.

Only positive lists of claims authorised by the European Commission can appear on products. However, For example, the claim " Vitamin C enhances the immune system " is often preferred over the authorised claim " Vitamin C contributes to the normal functioning of the immune system” according to the DGCCRF.

It should also be noted that non-compliant products have been found much more frequently over the internet. The rate of non-compliance increases to 69% in the case of products sold online against 38% for products sold in stores.

Germany

Vitamin D for nursing home residents

The Federal Institute for Risk Assessment (BfR) has recently acknowledged that the use of food supplements can especially be useful for people who belong to a risk group for an inadequate vitamin D supply. Risk groups include people who are hardly or not at all outdoors, who for cultural or religious reasons only go outside with their bodies completely covered, people with dark skin and the elderly. BfR has therefore recommended a general vitamin daily D intake of up to 20 µg for nursing home residents. The Federal Institute is also advising consumers who would like to supplement their diet with vitamin D, to take food supplements with a daily dose of up to 20 µg (800 IU).

TiO2: Pressure to remove it

The German Agricultural Minister Julia Klöckner has called for the EU approval of titanium dioxide to be withdrawn, after the European Food Safety Authority (EFSA) published a statement saying the substance could no longer be considered safe as a food additive.

The chemical is often used as a colouring agent. “It cannot be ruled out that this food additive causes genetic damage,” Klöckner explained, and announced that she had already asked the European Commission to take action on the issue. The future of the additive will be addressed by the Commission and Member States.

Norway

MSM: safety threshold

The Norwegian Scientific Committee for Food and Environment (VKM) has recently concluded that a daily dose of 3g of methylsulfonylmethan (MSM) from food supplements may represent a risk of adverse health effects in adults 18 years and older, whereas it is unlikely that a daily dose of 0.2g causes adverse health effects in the same age group. Since the data available was limited, VKM cannot conclude on a daily safe dose of MSM for children and adolescents.
This risk assessment is part of the VKM's new assignment on "other substances" from the Norwegian Food Safety Authority. The use of MSM is currently not authorised in Norway.

Safety of melatonin in children

While melatonin is permitted for use in supplements at a level up to 1 mg/ day for adults, the Norwegian Scientific Committee for Food and Environment (VKM) has stated that it is not able to demonstrate the safety of its use in children and adolescent at the following doses

0.2 mg melatonin for 3-6-years-olds,
0.3 mg melatonin for 7-10-years-olds, and
0.5 mg melatonin for 11-18-year-olds
Importantly VKM cannot conclude either on the safety of continuous use of 1 mg/day of melatonin for three months for adults. Current conditions of use could therefore be reconsidered.

Coffee before bed: Bad idea!

The Norwegian Scientific Committee for Food Safety (VKM) has recently examined whether the total caffeine exposure from diet (incl. food supplements) alone and in combination with personal care products (e.g. cosmetics) constitutes a health risk to the Norwegian population.

VKM concluded that in adults, coffee was the main source of caffeine and may represent a risk for sleep disturbances while cosmetics and personal care products accounted for less than five percent of the total caffeine exposure. It was also identified that caffeine exposure can lead to parts of the population having sleep disorders. For adults with extra high caffeine intake, it can represent a risk for cardiovascular effects.

Omega 3 in children

The Norwegian Food Safety Authority (NFSA) has requested the Norwegian Scientific Committee for Food and Environment (VKM) to examine whether the exposure to EPA and DHA from food supplements in children and adolescents might constitute a health risk for Norwegian children and adolescents (both sexes) in the age group from 3 to 18 years. The following daily intakes should specifically be reviewed:
Daily intake of a food supplement containing 1100 mg DHA for ages from 3 to 18 years (both sexes).
Daily intake of a food supplement containing 1550 mg EPA for the ages from 3 to 18 years (both sexes).
Daily intake of a food supplement containing both 1550 mg EPA and 1100 mg DHA for the ages from 3 to 18 years (both sexes)
Looking back at 2015, the VKM reported that a daily dose of 1290 mg DHA in food supplements would unlikely cause negative health effects in the age group 10-18 years.

Romania

Getting harder

New legislation governing food supplements has recently been published in Romania (attached). This law has been hotly debated since 2012 and was recently confirmed by a Romanian Constitutional Court ruling in April.

More detailed implementation rules on manufacturing, sale and use of food supplements are expected to be issued by the Ministry of Health beginning of July 2021.

The law aims to transpose into Romanian legislation the relevant EU framework for food supplements, addressing specific requirements for the category, the regulatory body in charge, provisions around market placement, advertising and consumer protection against misleading and counterfeit products. No advertising materials will be able to be placed on the market without the approval by the Ministry of Health.

One of the main challenges relates to supplements containing a combination of ingredients. A positive safety opinion would need to be obtained by a Technical Committee before the product is notified and placed on the market. This technical Committee at present meets once a year.

UK

An eye on lutein claim

The Nutrition and Health Claims Committee (UKNHCC) will be addressing shortly their first health claim focussing on lutein, zeaxanthin and meso-zeaxanthin and visual performance Such a claim has not yet been authorised in the EU.

UK Post Brexit, Regulatory Reform Proposals

With the UK no longer an EU member, there is considerable pressure in government to change existing regulation to allow for more flexibility and innovation. Three senior Members of the UK Parliament were therefore requested to put together proposals for regulatory reform within the framework of a Taskforce on Innovation, Growth and Regulatory Reform and their recommendations have now been released. This report positions the supplement sector as of strategic importance.

Turkey

Health claims discrimination

The Turkish Ministry of Heath (MoH) has not given up on its efforts to treat supplement claims differently from food claims.

In its recent revision of its draft claims Regulation (first released in September 2020), MoH has revived the threat of a two-speed approach, proposing a pre-authorisation procedure for food supplement claims while claims on food would be exempt from pre-authorisation.

USA

“Healthy" symbol

The U.S. Food and Drug Administration (FDA) has published a procedural notice in the Federal Register announcing preliminary quantitative consumer research on symbols that could be used to convey the nutrient content claim “healthy”. The FDA currently regulates the use of the term “health” (and related terms, such “health,” “healthful,” “healthfully,” “healthfulness,” “healthier,” “healthiest,” “healthily,” and “healthiness”) as an implied nutrient content claim when used in food labeling.

This regulation establishes specific criteria for nutrient content claims related to the nutrients present in a food subject to the “healthy” claim, irrespective of the food ingredients from which the nutrients are derived.

The agency is currently testing a set of voluntary front-of-package symbols, some of which will include an

accompanying URL. The notice does not provide images of the symbols under consideration, and does not suggest the agency is considering changes to the criteria currently used to regulate “healthy” claim.

Brazil

Use of probiotics clarified

The National Agency for Sanitary Surveillance (ANVISA) issued its second version on the "procedural instructions to request the assessment of probiotics for use in food products", including food supplements. The updated paper provides further details for the correct interpretation of the regulation (RDC 241/201) addressing more specifically proof of the identity, safety and beneficial effect on health.

Ecuador

Update

The National Agency for Regulation, Control and Sanitary Surveillance (ARCSA) has issued a proposal to update the food supplement regulation foreseen in Resolution ARCSA-DE-028-2016-YMIH. The proposed changes include:

• To update the definition of Daily Reference Intake

• To update the definition of nutrient, in order to include antioxidants, trace elements, probiotics and polyphenols

• To update the definition of food supplements, in order to include a special paragraph relating to non-permitted substances

• To include a definition for probiotics

•For permitted food additives, in addition to those foreseen in Codex Standard 192, it is proposed to include those additives approved by the European Union and US FDA for the category of food supplements.

Montserrat

Tax incentive for health foods

Montserrat has decided to reduce the tariff rate for the importation of food supplements, to "encourage people to consume healthy foods”. The consumption tax has been reduced from 15% to 10%.

Russia

Tag: next steps

The Russian Government Decree No. 673 dated 29 April 2021 approved the Procedure for a pilot project on ID tags for dietary supplements and also introduced the list of dietary supplements included in the pilot. By 1 June 2021, the project operator was required to develop information system requirements as well as requirements for the protection of data to be stored in the system. For operators of the dietary supplements market, participation in the pilot is voluntary. The process is being coordinated by the Ministry of Industry and Trade.

The pilot allows only supplements that have been registered in accordance with food safety regulation TR TS 021/2011.

The pilot project is expected to run to 31 August 2022. The results of the pilot test and respective reports to the Russian Government are to be ready by 30 November 2021, 1 February 2022, and 1 August 2022.

Defining nutrition principles

A new version of Russia’s dietary intake requirements includes definitions of added and natural sugars and healthy nutrition principles. The draft has been developed by Russia’s Federal Research Center for Nutrition provides new terminology for glycemic index (GI), mono- and disaccharides, added sugars and natural (naturally occurring) sugars. Also, the document revises the recommended dietary intakes for macronutrients to the following:

• For protein: from 63–127 g per day for men and 50–89 g per day for women to 75–114 g per day and 60–90 g per day, respectively;
• For fats: from 70–141 g per day for men and 60–99 g per day for women to 72–127 g per day and 57–100 g per day, respectively;
• For carbohydrates: from 240–614 g per day to 301–551 g per day for men and 247–435 g per day for women.

These minor changes result in an increased share of carbohydrates in diets by reducing the protein and fat components.

The recommendations for total daily intake of critical nutrients (salt, sugars, fats, including fats with saturated fatty acids and trans-isomers) have remained the same in the guidelines. These levels act as criteria to differentiate commercially produced foods as products with excessive content of salt, fats, and sugars and have them classified as such. The document also outlines the principles of healthy nutrition, which include daily intake of foods with reduced levels of saturated fats (including trans-isomers of fatty acids), simple sugars and table salt, as well as foods enriched with vitamins, minerals, food fibre and biologically active substances.

Bonded warehousing experiment could allow for importation of dietary supplements without state registration

The Finance Ministry has drafted a law on conducting an experiment to use bonded warehouses for cross-border traded goods. The experiment, to be conducted throughout 2022, will apply the customs warehousing procedure to products imported into Russia for subsequent acquisition by individuals as part of cross-border (external) e-commerce and goods shipped as international mail. The designated postal operator will be responsible for the consolidation, storage and customs clearance of goods.

As per the draft law, goods sold on cross-border trade websites will be delivered to the postal operator’s warehouses and placed under the bonded warehousing procedure. When ordered by a customer, the bonded warehousing procedure will be replaced by the procedure of release for domestic consumption and the product will then be sent to the customer.

The draft law reads that customs clearance of goods which are subject to mandatory conformity approval will not require the submission of conformity certificates or declarations. It will suffice to provide their numbers and issuance dates irrespective of who is stated as the applicant in such documents.

Mandatory conformity approval is required for a broad group of goods as per the list of products subject to mandatory conformity approval when placed under customs procedures. The list only includes several categories of foods and does not include foods which are subject to state registration (such as dietary supplements) because registration is not a conformity approval format. Evidently, dietary supplements may be processed via a bonded warehouse for subsequent domestic consumption without the need to provide a state registration certificate. Cross-border trade operators expect the experiment to significantly cut delivery times to end consumers in Russia. The bonded warehousing experiment could also allow for importation of dietary supplements without state registration

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Eurasian Union

"To take with food only" dropped

The industry proposal to drop the requirement "to take with food only" from dietary supplement definition wins Commission's support
On 21 April 2021, the Eurasian Commission's working group responsible for developing draft amendments on dietary supplements to Technical Regulations of the Customs Union On food safety (amendments No. 4 to CU TR 021/2011) and On safety of specific types of specialized foods including therapeutic and preventive dietary food (amendments No.1 to CU TR 027/2012) met to review the comments received during public discussion.

The working group supported most of the proposals received as part of the public discussion for amendments No.4 to CU TR 021/2011, in particular the proposal to exclude the mandatory provision for dietary supplements to be taken with food (submitted by the Union of Dietary Supplements Producers).