IADSA NEWSFLASH

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Regulatory news

Malaysia

QBI method introduced

Malaysia has introduced the QBI method for supplements when the assay of active ingredients cannot be achieved in the finished product.

The QBI is taken from the Australian Therapeutic Goods Administration (TGA) and is defined as the content of an active ingredient which is estimated from the amount dispensed during the manufacture of the product.

QBI is allowed when:

There is no assay method for active ingredients in the monograph/compendial (pharmacopoeia)

There is a justification that can be supported with scientific references and a test report showing the test results of the material cannot be achieved due to the quantity of active ingredients.

Indonesia

New registration requirements

The Indonesia Food and Drug Administration (BPOM) has recently published its revised Criteria for Health Supplement Registration. The new version replaced the 2020 version. A two-year transition period is introduced to comply with the changes.

Product registration is required for companies to obtain a licence that is valid for a 5-year period. The licence can be prolonged through the re-registration of the health supplement

Korea

Defining vegan products

The Korean Ministry of Food and Drug Safety has released a proposed vegan guideline for food, food additives and health functional foods in Korea. According to the guideline, a vegan product does not use any animal or animal-derived ingredient and has not been tested on animals except when a safety test is required on raw materials by law and regulations. Vegan products can use microorganisms (bacteria, enzyme, fungi, etc.) as raw materials. However, if the microorganism was isolated from animal sources, then it should be disclosed.

Vegan products need process control to avoid contamination with animal or animal-derived ingredients.

Taiwan

Flavoured Eucalyptus Globulus

Taiwan has decided to prohibit the use of Eucalyptus globulus and its extracts as food raw materials. The restrictions will take effect on 1 January 2024.

The reassessment of the safety of Eucalyptus globulus and its extracts concluded that the use of the plant was not acceptable for purposes other than flavouring in food. Fines up to NT $3 million are foreseen for non compliant products.

EU

Harmonisation of maximum levels: Delay?

The recent minutes of the European Food Safety Authority (EFSA) seem to foreshadow a delay in the setting of maximum amounts of vitamins and minerals in fortified foods and food supplements.

The deadline of March 2023 set by the European Commission for EFSA to revise its opinions on Tolerable Upper Intake Levels (ULs) for 8 nutrients vitamin A , folic acid / folate, vitamin D , vitamin E , Vitamin B6, iron, manganese and ßcarotene could be delayed to June 2024 based on the report of the EFSA Working Group that met on 15 November.

Upper safe levels (ULs) of vitamins and minerals are part on the criteria to be taken into account when establishing maximum limits for

vitamins and minerals in fortified foods and food supplements.

Article 8: The list goes on

Fennel, beberine, hydroxycitric acid are the three new substances that the European Commission has requested EFSA to assess under the so-called article 8 procedure, allowing the Commission to possibly restrict or prohibit the use of a substance on the EU market.

These requests have been triggered respectively by Germany, France and Spain who raised concerns on the potential risk for consumers to consume these substances. These concerns include:

Genotoxic and carcinogenic effect linked to the consumption by infants and young children of fruit preparations from bitter and sweet fennel, mainly due to the presence of estragole in these preparations - according to the German Federal Office of Consumer Protection and Food Safety and the German Federal Risk Institute for Risk Assessment (BfR).

Gastrointestinal disorders, hypoglycemia and hypotension linked to the consumption of food supplements made with plants or plant preparations containing berberine - according to the French Agency for Food, Environmental and Occupational Health & Safety (ANSES)

Liver injury linked to the consumption of the pericarp of the fruit of *Garcinia gummigutta (L.) Roxb.* containing HCA - according to the Spanish Agency for Food Safety and Nutrition (AESAN).

The EFSA conclusions are expected by May 2025.

EU unveils plan to cut packaging waste

A draft EU regulation has been published setting mandatory targets for the amount of recycled materials used in plastic packaging.

The proposal is part of the European Commission's circular economy package, which aims to put the packaging sector on track for climate neutrality by 2050.

The new rules, which will have to be approved by EU Member States and the European parliament, are intended to tackle the surge in plastic and other packaging waste. EU officials estimate that 40% of new plastics and 50% of paper are used in packaging. Without action, the EU would see a further 19% increase in packaging waste by 2030, and for plastic packaging waste a 46% increase.

One of the key objectives of the initiative is to make all packaging recyclable by 2030. To increase recyclability, the measure sets criteria that all packaging will have to comply with to make sure it is recyclable.

According to the European Commission, consumers will also get clear labels. Every piece of packaging will have to carry a label showing what the packaging is made of and in which waste stream it should go. Waste collection containers will carry the same labels.

Importantly the measure will apply equally to domestic and imported products. European and non-European producers would face the same requirements.

B6 UL: Cut by half

The European Food Safety Authority is recommending lowering the tolerable upper intake level in adults for vitamin B6 from 25 mg to 12 mg/day.

In a draft scientific opinion, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) noted that food supplements were found to contribute up to about 40% of total vitamin B6 intake in children in Denmark. In adults, vitamin B6 supplements contributed more than 50% to total vitamin B6 intake, and up to about 80% of total vitamin B6 intake in adults in Germany (NVS II) and Finland (FINDIET 2017).

EFSA also highlighted the high variability in the maximum amounts set by national authorities for addition of vitamin B6 to food supplements.

Undoubtedly, if agreed, the new ULs will have a significant impact on the limits for vitamin B6 in supplements that the European Commission aims to harmonise across Member States.

Belgium

Nutriviligance: spreading to Belgium

Belgium is considering introducing a nutrivigilance system for food supplements, novel foods, foods for special groups and fortified foods. Such a system already exists in France.

Suspected adverse effects will have to be notified within 5 working days by the food business operator through a national web portal that will be available on the website of the FPS Public Health, Food Chain Safety and Environment or through other methods that remain to be established.

To address these notifications, a Nutrivigilance Commission will also be created. Additional assessments from the Higher Health Council or the Federal Agency for Medicines and Health Products can also be foreseen.

France

6 in 10 influencers fail to comply with advertising and consumer rights regulations

The French Authority DGCCRF has recently published a report on influencer practices. Among the influencers "targeted" by the fight against fraud since 2021, 60% do not comply with the rules on advertising. This is the result of a survey by DGCCRF, which "targeted" more than sixty agencies and influencers active in the promotion of cosmetics, food supplements, "slimming" programs or online trading and betting services.

DGCCRF have initiated several procedures so that the offenders are sanctioned. Deceptive commercial practices can be punished by two years' imprisonment and a fine of up to €300,000. These can also be accompanied by publicity measures informing the general public of the fraud.

Good new year start for probiotics

The French Authority DGCCRF has recently permitted the use of the term "probiotics" in supplements, joining a growing number of EU Member States who have approved the term probiotics on supplement labels. The use of the term probiotic, authorised in France as a category to designate the ingredients in food supplements rather than a heath claims, is allowed under a set of conditions:

Food supplements bearing the probiotic name have to contain at

least from 10^7 to 10^9 UFC of a strain per day so that a significant level of live microorganisms can reach the gastrointestinal tract.

The term probiotics may also be used with the wording "Contributes to the balance of the intestinal flora". It however remains to be seen whether this would be allowed by the European Commission who have recently requested Italy to remove the indication "It promotes the intestinal flora balance" from its probiotics guidelines. This followed a Commission audit on the application of the Health Claims Regulation.

Poland

Supplements under the spotlight

Poland has recently issued a draft act amending the act on food safety and nutrition providing for more detailed requirements on the presentation and advertising of food supplements.

The draft included the following proposed changes, among others:

A general commitment to ensure that the presentation and advertising of food supplements represents the food supplement fairly, is not misleading, and complies with the requirements of EU Regulations on food information and claims.

The obligation to include the following message in the presentation and advertising of a food supplement: *A food supplement is a foodstuff intended to supplement a normal diet. The food supplement does not have medicinal properties. (PL: Suplement diety jest środkiem spożywczym, którego celem jest uzupełnienie normalnej diety. Suplement diety nie ma właściwości leczniczych.)*

The proposal is targeting advertising to children under the age of 12. It is also recalled that it is prohibited to use images of authorities and experts in the field of medical and health sciences, objects that may evoke associations with professions applicable to health care presentations or activities that may evoke associations with these professions.

As for distribution channels, it will remain possible to advertise supplements in pharmacies, pharmacy outlets, and pharmaceutical wholesale stores providing that the presentation of food supplements is made in separate areas placed in the buyer's field of vision, which must not be in the immediate vicinity of the customer service point.

The draft also introduces the possibility to use a voluntary mark confirming the quality and safety of the product based on an analysis of its composition. This should be permitted after laboratory tests and after obtaining an opinion of a scientific unit confirming the compliance of the composition of the food supplement with the requirements for food safety and food supplements.

Violation of the proposed provisions would lead to fines between PLN 10 000 and PLN 1 000 000.

Norway

Understand food supplements

Norway has issued a new guide on food supplements for those who want to develop, manufacture, import, sell, label and market supplements in Norway. The purpose is to present the regulations, how they should be understood and how they can be complied with. It covers sections such as what is a supplement, how to find out if a supplement is legal, how to find out if an ingredient is permitted etc.

Australia

Melatonin and Green tea

TGA has published a Notice of Interim Decisions in relation to green tea extract and melatonin. The consultation closes on 3 March 2023. The decisions are:

Not to amend the Poisons Standard in relation to green tea. Green tea extract will remain unscheduled;

Amend the Poisons Standard in relation to melatonin; to amend the Schedule 3 entry for melatonin to allow divided preparations containing 5 mg or less of melatonin, in packs of no more than 10 dosage units, for adults aged 18 and over to be prescribed by a pharmacist for the treatment of jetlag. This decision is to be implemented on 1 June 2023.

Proposed improvements to the recalls process

The Therapeutic Goods Administration (TGA) is seeking feedback on proposed changes to the therapeutic goods recall process. Recalling medicines, medical devices and biologicals, when they are not fit for purpose, is the responsibility of the product's 'sponsor'.

Under the Therapeutic Goods Act 1989 (the Act), this is the person or company legally responsible for the product. However, before starting any recall action, the sponsor should consult with the TGA for agreement on the type of recall and how it will occur. Recalls should be carried out in accordance with the procedures in the TGA guidance document - the Uniform Recall Procedure for Therapeutic Goods (URPTG). Given new types of products being used and the increased complexity in supply chains,

TGA is currently investigating a range of potential improvements to the way recalls are managed.

New Zealand

A significant step forward for Natural Health Products

The long awaited legislation to modernise the way medicines, medical devices and natural health products are regulated in New Zealand has been introduced in Parliament.

The Therapeutic Products Bill, when enacted, will replace the Medicines Act 1981 and Dietary Supplements Regulations 1985 with a new regulatory regime for all natural health products.

It defines natural health products as traditional and herbal medicines, and vitamin and mineral supplements and will regulate them a separate category from medicines and medical devices.

'*Natural health products are intended to support, promote or maintain health in some way, so are in the category of 'therapeutic products'. However, the rules applying to natural health products will reflect the fact that they are generally lower risk than medicines and medical devices"* Said Ministry Andrew Little.

The Bill also include a number of enforcement tools to respond more efficiently when breaches occur, including infringement fines.

Israel

Ashwagandha safety under review

A re-evaluation of the safety of the Ashwagandha plant is being carried out in light of several reports around the world of alleged liver damage following the consumption of supplements containing the plant.

The National Food Services in the Ministry of health is requesting traders who import or manufacture supplements and infusions containing the ingredient, as well as any other party, to express their opinion on the matter.

USA

Existing regulatory frameworks for supplements not appropriate for Cannabidiol

UU.S. Food and Drug Administration (FDA) denied the requests in three citizen petitions that the FDA issue a regulation that would allow cannabidiol (CBD) products to be marketed as dietary supplements. Such a regulation would be needed in order to provide a potential pathway for CBD products to be lawfully marketed as dietary supplements, because a provision in the law prohibits the marketing of certain drug ingredients as dietary supplements.

The FDA's responses explain that they do not intend to initiate such rule making, because in light of the available scientific evidence, it is not apparent how CBD products could meet the applicable safety standard for dietary supplements.

In addition, the FDA issued a statement on the broader work of the cross-agency Cannabis Product Committee to explore potential regulatory pathways for CBD products. That statement explains that the agency does not consider the existing dietary supplement and conventional food pathways to be appropriate for CBD and that the FDA is interested in working with Congress to develop a new pathway that balances consumers' desire to access CBD products with the regulatory oversight necessary to better manage the risks these products present.

Brazil

Post market surveillance review

The National Agency for Sanitary Surveillance (ANVISA) has published its post-market monitoring bulletin carried out in 2022. The document analyses the record of adverse events and complaints filed with ANVISA about products subject to sanitary surveillance.

The evaluation was carried out under the Notification System in Sanitary Surveillance (Notivisa) and automated forms for receiving notifications from consumers.

Specifically, regarding food, during 2022, nutrivigilance received 33 (77%) records of adverse effects and 10 (23%) of technical complaints, totalling 43 notifications related to foods, versus the 31 records received during 2021.

According to the data, the category of products that were most suspected of causing adverse reactions were food supplements, with 14 notifications (32%), and food for special purposes with 13 records (30%).

About 76% of the notifications reported symptoms related to the digestive system.

Ecuador

Reviewing standards for supplements

The Ecuadorian Standardisation Service (INEN) placed in public consultation the update of the Ecuadorean Technical Standard NTE INEN 2983 for nutritional supplements which would be the first revision after its approval in 2016.

This standard is currently voluntary. The only mandatory requirements for supplements are in Resolution ARCSA-DE-002-2018-JCGO and its 2021 update. The revision of the standard proposes a number of changes, including:

- Food complements /supplements are considered, along with nutritional supplements, as synonyms which apply to the product name applicable on the labelling.
- More comprehensive definition, which introduces that nutrients or substances must have a nutritional or physiological effect, and that they may contain botanical, nutritional or supplementary ingredients (caffeine, probiotics, bioactive substances, etc.).
- New specifications on microbiological requirements for supplements that contain probiotic bacteria or yeasts and for those that are presented in liquids
- New specifications for the calculation of the maximum level of heavy metals
- Ban of botanical species that require aristolochic acid tests I: *Akebia, Clematis, Saussurea, Stephania, Vladimira, Diploclisia, Menispermum and Sinomenium*
- Labelling requirements for supplements with caffeine and probiotics
- New minimum values for vitamins and minerals. Although it is maintained that they should be 15% of the RDA, the current regulation establishes that it should be 15% of the FAO/WHO RDA. In this

case, country-specific RDA are proposed for 4 age groups.

For certain vitamins and minerals, new test methods are established.

The proposal is open for comments until April 2023.

Belarus

Flexibility' for distance sales

Belarus' trade ministry is to allow distance sales of dietary supplements provided the retailer sells from a fixed location.

On 24 January 2023, the Ministry of Antimonopoly Regulation and Trade of Belarus published for comments a draft decree that will lift current restrictions on distance sales of certain consumer goods.

The decree stressed that dietary supplements used to support the body's functional activity within its physiological range may be sold through distance selling channels (including e-commerce) provided that the seller has a pharmacy where such products are offered for sale. Supplements with other functions, including probiotics, will have to be sold from pharmacies only. Currently, the Rules for Distance Sales ban such sales of all dietary supplements.

EAEU

Registration: 5-year validity

The validity period of state registration certificates should be limited to five years (now no time limit exists) according to new draft amendments to CU TR 021/2011. The provision covers dietary supplements and foods for special dietary use.

New draft amendments to CU TR 021/2011.

Ukraine

Aligning with EU law

Ukraine's parliament is set to legalise a series of EU food laws including health claims, and a new definition for food supplements. The new bill on food and feed safety, veterinary medicines, and animal welfare has been submitted to the Ukrainian parliament for adoption. It proposes:

Harmonizing Ukrainian legislation with EU Regulation (EC) 1924/2006 on nutrition and health claims made on foods; Regulation (EC) 1169/2011 on the provision of food information to consumers;

Reviewing definitions of a "food", "food additive" and "novel food", introducing definitions of "food flavour", "disease risk claim", "health claim", "nutrition claim", "largest side of the packaging".

Introducing EU procedure for registration of food additives, enzymes and flavours, and an EU-type database of health claims.

The bill also introduces a new definition for a "dietary supplement" (as compared to the one drafted in October 2022 for the law On key principles and requirements to safety and quality of food).

The definition aligned with the EU reads:
Dietary supplement is a food which: is a concentrated source of nutrients (including proteins, fats, carbohydrates, vitamins, minerals) or other substances with a nutritional or physiological effect; is manufactured in the form of capsules, strips, tablets and sachets, ampoules with liquids, dosage bottles or other forms of liquids and/or powders; is intended for consumption in small amounts; is consumed in addition to the usual food diet on a standalone basis or in combination with other foods.

Global

Rhodiola: Step against threat of extinction

A proposal submitted by China, the EU, Ukraine and the UK to regulate *Rhodiola spp.* was agreed at the Conference of the Parties to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CoP19, CITES) in November 22.

"All parts and derivatives except a) seeds and pollen; and b) finished products packaged and ready for retail trade." were included in CITES Appendix II addressing species not necessarily now threatened with extinction but that may become so unless trade is closely controlled.

Trade of Rhodiola will now be brought under more effective control. Like any Appendix-II species, trade could be authorised by the granting of an export permit or re-export certificate.

According to CITES, estimates suggest that trade volumes are considerable. Uncontrolled harvest leading to a decline in wild populations of *R. rosea*and *R. crenulata* was also reported.

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