IADSA NEWSFLASH

December 2019

Regulatory news

ASEAN

Finalisation postponed to 2020

The ASEAN Health Supplement Agreement will not be finalised this year.

At the last Regulatory Framework Task Force meeting held in November, further discussion took place regarding the text permitting Thailand to defer from implementation of Annex V (stability requirements) and VIII (GMP).Indonesia objected to the lack of a cut-off date by which Thailand would need to have implemented the provisions. A compromise was eventually reached whereby this would be reviewed 5 or 7 years from the date of entry into force. This change means that the Member States agreed to take the new text back to their national capitals for review. Finalisation is now foreseen in June 2020 with signing in July 2021.

China

Health food naming: complex!

The State Administration for Market Regulation (SAMR) has announced the publication of its "Health Food Naming Guidelines 2019", which applies to all health food subject to registration or filing (notification). This regulation specifies that all product names must be accurate and cannot refer or imply a disease prevention or treatment function.

It also stipulates that health food names should be composed of the 1.brand name, 2.generic name and 3.attributed name.

The brand name refers to a trademark name registered in accordance with the law for use on health foods or an unregistered trademark name.

The generic name refers to the name describing the characteristics of the main raw materials of the product. If the product is made from a single active ingredient, the health food generic name should be named after this active ingredient's name or its abbreviation. For multiple active ingredients, the active ingredient with the highest concentration shall be used as the product's generic name. The generic name of a registered medicine cannot be used except when the active ingredient is approved for use as both a medicinal product and a health food.

As for the attributed name, it should refer to the product's dosage form or food classification. It should correspond to the national food safety standard, industry standard or local standard where applicable.

Smart move

The State Administration for Market Regulation (SAMR) is consulting on its updated directory of raw materials and claims of health food nutrient supplements. According to these drafts, health food nutrient supplements may be allowed to use the nutrient function claims specified in the National Food Safety Standard for the nutrition labelling of prepackaged foods, namely:

Supplement Calcium
Calcium is the major component of human bone and teeth; many physiological functions require calcium.
Calcium is the major component of bone and teeth, and it maintains bone density.
Calcium helps the development of bone and teeth.
Calcium makes the bone and teeth firmer.

Supplement Iron
Vitamin A helps maintain visual acuity in darkness
Vitamin A helps maintain the health of skin and mucosa

Supplement Vitamin D
Vitamin D facilitates the absorption of calcium.
Vitamin D is good for bone and teeth health.
Vitamin D helps the formation of bones.

Supplement Vitamin B2
Vitamin B2 helps maintain the health of the skin and mucosa.
Vitamin B2 is an indispensable component of energy metabolism.

The proposals also suggest the authorisation of the following ingredients: Calcium citrate malate (from 4 y.o), Magnesium gluconate, Ferric pyrophosphate, Ferric citrate, Zinc acetate, Choline chloride.

Beta carotene is proposed for inclusion for adults together with the newly added claim: "*Supplement Β-carotene*"

Korea

Competitive advantage

A 3-year protection period will be given to companies that have received newly approved functions for already approved active ingredients. Newly approved functions will only be added to the list of active ingredients with associated approved functional claims after the 3 year-period. Competitors seeking to use the claims will have to submit their own data or wait for the new claims to be added to the list.

https://www.mfds.go.kr/brd/m_207/view.do?seq=14443&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=1

Optimising resources

The Minisrty of Food and Drug Safety MFSD has revealed its new mechanism for health functional food approval. The new approach should aim to help save time and resources for both the applicant and authorities by providing advice to companies on data required for their application.

In South Korea, approximately 120 days is required today to assess functional food ingredients.

https://www.mfds.go.kr/brd/m_210/view.do?seq=14409&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=1

Taiwan

Labelling: What's new

Taiwan FDA has recently announced the amendment to "Regulations on Nutrition Labelling for Pre-packaged Vitamin and Mineral Tablets and Capsules". Under the new provisions, the label should include: the title of "Nutrition labelling", the number of servings per pack, vitamin and mineral content expressed as a percentage of the Daily Reference Value in Arabic numerals. Note that vitamin A, vitamin D and vitamin E should be marked with International Units (IU). Other ingredients should be distinguished from vitamin and minerals, with a clear heading, such as Other ingredients.

https://www.fda.gov.tw/tc/includes/GetFile.ashx?id=f637090858541493422
https://www.fda.gov.tw/tc/includes/GetFile.ashx?id=f637085665371641240

European Union

Heat-killed *Mycobacterium setense manresensis*

The novel food, Heat-killed Mycobacterium setense manresensis, is an encapsulated ingredient composed of 200 mg mannitol and ≤ 105 heat-killed, freeze-dried M. *setense manresensis*. It is intended to be marketed exclusively in food supplements (gelatin capsules) for the general adult population excluding, children, pregnant and lactating women. The European Food Safety Agency (EFSA) has recently reached conclusions on the safety of this new ingredient under the following conditions: the novel food should not be consumed longer than for 14 consecutive days. Between two fourteen-day periods of intakes, there should be a minimum of six months with no consumption of the novel food.

Citrinin: Safety first

The European Commission has recently lowered the level of citrinin in food supplements based on rice fermented with red yeast *Monascus purpureus* to 100 µg/kg.

The maximum level of citrinin in food supplements based on rice fermented with red yeast *Monascus purpureus* was set in 2006 at 2000 mg/kg. However, given the gaps in knowledge as regards the presence of citrinin in red yeast rice preparations and the uncertainties as regards the carcinogenicity and genotoxicity of citrinin, the European Commission decided to review the maximum level of this contaminant. These new occurrence data indicated that while there was no need to regulate for the time being citrinin in food, limits in red yeast rice supplements needed to be cut.

The new limit shall apply from 1 April 2020.

https://eur-lex.europa.eu/eli/reg/2019/1901/oj

Exemption to lower erucic acid limits

Camelina oil, mustard oil and borage oil have recently been exempted from the new lower level for erucic acid.

Evidence has demonstrated that it is not possible to achieve lower levels by applying good practices for these three ingredients.

Given that these oils are also of less significance for human exposure than other vegetable oils, the European Commission decided to maintain the current limit of Erucic acid at 50g/kg. Limits for other vegetable oils and fats placed on the market for the final consumer or for use as an ingredient in food including food supplements is reduced to 20 g/kg.

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R1870&from=EN

Belgium

Curcumin: warning!

As other European Member States, Belgium has also recently reviewed the safety of curcumin. Conclusions are summarised below:

The intake of curcuminoids with their natural bioavailability (original bioavailability, present by nature/not reinforced by using other substances such as piperin/quercetin) must be limited to 500 mg of curcuminoids per day.

In the case of addition of substances, modification of the natural composition of curcuminoids or the use of preparation techniques in order to increase the bioavailability of curcuminoids, it is necessary to demonstrate that the systemic values obtained as a result of ingestion of these curcuminoids do not exceed the systemic values obtained following ingestion of 500 mg of curcuminoids with natural bioavailability. The combined use of addition of substances, modification of the natural composition of curcuminoids and / or specific preparation techniques to increase bioavailability are not recommended.

In addition to the statement "Consult your doctor or pharmacist if you use concomitant anticoagulants" the label must also indicate: "It is appropriate to obtain the opinion of a doctor in cases

of liver or gall bladder disease or concomitant use of medicines."

Finally, "Not to be used by pregnant or breastfeeding women or by children under 18 years of age." Should also appear on the label.

https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/2019_curcuma_fr.pdf

France

Berberine: Cautious use

The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) has recently questioned the safety of supplements containing berberine. Berberine is an isoquinoline alkaloid present in various plants used in food supplements and is mainly used to regulate blood glucose and cholesterol levels.

From April 2016, the French Authorities have been recording 229 products of this type in the market, among which very high levels of berberine were found.

ANSES noted that pharmacological effects were proven from 400 mg/day of berberine in adults but did not exclude that such effects may exist at lower doses. Adverse effects were seen from 600 mg/day orally in adults including gastrointestinal disorders, hypoglycemia, hypotension, maternal and embryofetal toxicity.

Deploring the insufficiency of data on the composition of the food supplements concerned and taking into account the toxicology data and the concentrations observed in the products studied, ANSES noted that product safety "cannot be guaranteed to date."

In addition, ANSES pointed out pharmacokinetic interactions of berberine with a number of medicinal products. Given these interactions, ANSES recommended avoiding the cumulative use of food supplements containing berberine and medicines, and cumulative use of several food supplements or supplements including many ingredients.

Poland

Max levels: Work continues

The Polish Chief Sanitary Inspectorate continues its work on establishing maximum levels in food supplements.

The focus has primarily been on Pantothenic acid (10 mg/ day of pantethine, 200 mg/day of other chemical forms) Thiamin (100 mg/ day), Riboflavin (40 mg/ day), Cobalamin (100 µg/ day), Iodine (150 µg, for pregnant and lactating woman 200 µg).

Limits for caffeine and Morus alba L (mulberry) have also been set.

Cafeine: 400 mg/day provided that the product does not contain other ingredients with synergistic effect. The serving has to be divided in more daily portions where one potion must not exceed 200 mg. Caffeine products should bear "Contains caffeine. Not to be used by children and pregnant women. Not to be used with other products that are source of caffeine or substances with similar effects."

Morus alba L (mulberry): The content of the enzyme inhibitor 1-deoxynojirmycin (DNJ) must not exceed 10mg/day and must be accompanied with the following warning: "People on insulin therapy or oral hypoglycaemic drugs have to consult a doctor before use".

https://gis.gov.pl/zywnosc-i-woda/zespol-do-spraw-suplementow-diety/

Saoudi Arabia

Novel food: inform, consult

The Saudi Food and Drug Authority (DSFA) has recently published a draft Standard on Novel food General Requirements for Novel Foods together with a proposal on "Implementing Rules for Applications in the Context of Technical Regulation "General Requirements for Novel Foods.

USA

Labelling: Extra time for companies

The U.S. Food and Drug Administration (FDA) updated its "Industry Resources on the Changes to the Nutrition Facts Label" questions&answers, highlighting that the agency does not intend to take enforcement actions related to the new nutrition labelling requirements for the first six months following the 1 January 2020 compliance for conventional foods and dietary supplements.

FDA has also announced to work cooperatively with manufacturers to meet the new requirements.

CBD: GRAS not green

The U.S. Food and Drug Administration has issued warning letters to 15 companies for illegally selling products containing cannabidiol (CBD). The FDA also published a revised Consumer Update detailing safety concerns about CBD products more broadly. Based on the lack of scientific information supporting the safety of CBD in food, the FDA stated it cannot conclude that CBD is generally recognized as safe (GRAS) among qualified experts for its use in human or animal food.

https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis

Brazil

List of additives updated

On 4 December the National Health Sanitary Surveillance Agency (ANVISA) issued Resolution RDC Nº 322/2019 introducing changes on Resolution RDC Nº 239/2018, that foresee the list of

food additives and processing aids to be used in food supplements, as follows:

- Silicon dioxide (INS 551), has been included as anti-caking for powdered products containing probiotics (maximum limit of 1g / 100g)
- Sodium ascorbate (INS 301) with antioxidant function. For products intended for children between 12 and 36 months containing lyophilized probiotics, the maximum limit of 0.333 g / 100 g is applied, for powders, and 0.5 g / 100 ml for liquids.
- Mono and diglycerides of fatty acids (INS 471) have been authorised in food supplements as glazing agent at *Quantum satis*.

http://portal.anvisa.gov.br/documents/10181/5593922/RDC_322_2019_.pdf/b6671131-7258-4273-8c7f-7dde0483877e

Stability guide: Heading for extra time

ANVISA has decided to extend the consultation period for 1 more year (5 November 2020) of Guide Nº 16/2018 that would help companies to determine the shelf life validity of food products, including food supplements. This guide was initially published in October 2018.
Elements from the IADSA GMP guide and Stability guide have been considered for the establishment of this government tool.

http://portal.anvisa.gov.br/documents/10181/5056443/Guia+16_2018+Prazo+de.pdf/e40032da-ea48-42ff-ba8c-a9f6fc7af7af

Peru

In case of changes

The Ministry of Health opened for public consultation a proposal that introduces new conditions for requesting amendments to the sanitary registration of pharmaceutical products, which impacts food supplements.

In Peru, based on their composition, food supplements can be regarded either as foods or as medicines. The majority of the products on the market fall mainly in the category of medicines. Although, the current regulation foresees the requirements for this category, it does not foresee which documents need to be submitted in case the registered product has undergone changes.

The draft proposes for each type of change which additional documentation must be submitted. The draft foresees changes related to the composition, quality, methods of analysis, stability, labelling and packaging and stipulates conditions and corresponding documentation to be submitted.

http://www.digemid.minsa.gob.pe/UpLoad/UpLoaded/PDF/Normatividad/2019/RM_893-2019-MINSA.pdf

Eurasian Economic Commission (EEC)

Confusing jargon and brands at risk

The Eurasian Commission's working group on dietary supplements in October considered a number of amendments aimed at consolidating all special requirements for dietary supplements in CU TR 027/2012.

The draft amendments introduce the new notions of bioactive substances, phytonutrients, dietetic therapeutic and dietetic prophylactic vitamin (mineral, vitamin & mineral) complexes.

The meeting formulated a new notion of dietary supplements as a food for special use intended to be taken with food for the purpose of adjusting and optimising nutrition and sold in dose forms exclusively to end customers.

The working group supported the proposal to permit sugar alcohols as ingredients in dietary supplements intended for children aged over three and also to permit the use of any flavouring agents as part of dietetic therapeutic foods for special use intended for children suffering from certain diseases.

Requirements for the made-up names of dietary supplements, as proposed by the Russian consumer authority, Rospotrebnadzor, were also included into the draft amendments. In particular, Rospotrebnadzor proposed banning in made-up names the use:

- of international generic medicine names (e.g. ascorbic acid, Vitamin E, Glucosamine and camomile blossoms);
- registered trademarks if used as commercial names for medicines.

In addition, made-up names for dietary supplements must not be identical or confusingly similar to international generic names and/or commercial names of registered medicines.
The amendments also mandate that the name of the dietary supplement be supplied with the phrase "Not a medicine" in a font size of at least 2mm for lowercase letters.

The draft amendments are to be submitted to Eurasian Commission before the end of 2019.

Finally…

International Alliance of Dietary/Food Supplement Associations
International Non-Profit Organisation
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Website: www.iadsa.org

IADSA
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