IADSA NEWSFLASH

JULY 2018

The power of knowledge, experience & ideas

In June, representatives from across the membership, government and scientific bodies celebrated the 20th Anniversary of IADSA, in London. The Annual Week provided a unique opportunity for many who are deeply involved in creating and shaping regulation and policy to work together and learn together.

When IADSA was created the world was a very different place. There were very few associations in SE Asia, there were almost no associations in Latin America and far fewer in Europe than today. The network of associations across the world is now widespread and vibrant.

It is easy to forget that the power of a global network such as IADSA lies in linking people together, sharing knowledge, experience, ideas and resources. Our job at IADSA is to continually find new ways to harness this opportunity and help everyone move forward.

As the IADSA community has evolved, so has our role at IADSA. Yes, we continue to work directly with government to provide knowledge and expertise when required. But increasingly, we see our key role as providing the resources to help others achieve their goals.

In this context, the IADSA website has been redeveloped around the Resource Centre and our goal is to keep adding tools, information and scientific, technical, regulatory and policy documents that can be accessed by our members and by those in decision-making roles in government.

London 2018 IADSA week in (a few) pictures

Regulatory news

India

FSSAI gives its verdict on ingredients awaiting their inclusion in the positive supplement list

The Food Safety Standards Authority (FSSAI) has recently deemed the majority of the 33 ingredients that were put on an on-hold list earlier this year unsuitable for use in health supplements/ nutraceuticals.

These ingredients not included originally in the health supplement/nutraceutical standards were awaiting their assessment by FSSAI based on data provided by the sector.

Among the 33 ingredients, it appears that only S-acetyl glutathione (50-600mg/day Max)' and 'alpha-cyclodextrin' (already covered under 'other fiber sources') can continue to be used.

Immediate withdrawal from the market has been requested for Oaramono benzoic acid (PABA), 'Vanadium' 'Prenolit', 'Selenium dioxide', and 14 ingredients for which there was a lack of data.

Taiwan

FDA flags 'dubious' food and supplements

The Taiwan Food and Drug Administration (FDA) has recently launched a website listing "dubious" food and dietary supplements sold via e-commerce or social media platforms registered overseas.

The agency has urged consumers to read package labels carefully when purchasing food, dietary supplements, drugs, and beauty and cosmetic products, and seek professional advice when they have questions about a product's claims

Link to the list:
https://www.fda.gov.tw/TC/news.aspx?cid=5085

Thailand

Sibutramine to be classified as psychotropic substance

The Ministry of Public Health has recently upgraded sibutramine to a psychotropic substance in order to prevent use of the appetite suppressant in weight loss products.

An imprisonment of 4 to 20 years and a fine of 400,000 to 2 million baht will be given to companies selling sibutramine.

The measure will come into force with immediate effect after the announcement is signed off by the Public Health Minister in July.

Sibutramine was removed from the Thai drug registration system in 2010 and classified as potentially dangerous by the FDA.

New Zealand

New NZ supplement Bill tabled

A new Food Supplements Amendment Bill, which will bring health supplements under the framework of food regulation, was recently tabled by a New Zealand First politician.

This new bill would aim to replace the Natural Health and Supplementary Products Bill which lapsed when Parliament was dissolved at election time last November.

Health supplements according to the draft include herbal remedies, traditional medicines, homeopathic remedies and dietary supplements.

European Union

Green light for 4 novel supplement ingredients

Member States have recently agreed to authorise for use in supplements four ingredients:

Dried aerial parts of Hoodia parviflora at a maximum level of 9.4 mg/day in adult population.

1-Methylnicotinamide chloride at a maximum level of 58 mg/day in adult population excluding pregnant and lactating women.

Pyrroloquinoline quinone disodium salt at a maximum level of 20 mg/day in adult population excluding pregnant and lactating women.

Latitol powder. The novel ingredient was already authorised for use in capsules and tablets.

EFSA opinion on titanium dioxide will not be reopened

The European Food Safety Authority has closed the door to the possibility to reopen its scientific opinion on the safety of titanium dioxide E171 published in September 2016.

In that 2016 opinion, the Authority concluded that current exposure of consumers to E171 related to its use was not likely to constitute a health risk, but that it was not possible to establish an acceptable daily intake (ADI).

However, concerns were raised by the French Authorities who wanted to ban the use of the additive by the end of 2018. EFSA was therefore asked by the European Commission to look at the findings of four new studies that reported possible harmful effects on the immune system and the development of pre-neoplastic colonic lesions associated with intake of titanium dioxide (E 171).

Whilst acknowledging that more research exploring the possible effects observed in three of the four studies would be required, the Authority concluded at the end of June that the outcome of the four studies altogether did not merit re-opening the existing opinion related to the safety of TiO2(E 171) as a food additive.

EU to set maximum levels for pyrrolizidine alkaloids in supplements

The Commission is contemplating to set maximum levels for pryrrolizidine alkaloids (PAs) for all botanical food supplements. The maximum levels could be established for 21 PAs.

EU to change its policy relating to data protection

Published data are today not eligible for data protection in the European Union. The EU is currently considering aligning its rule with the US model where data needs to be published for the FDA to accept a GRAS notification.

The change of policy would avoid the situation where companies have to delay US GRAS submission and commercialisation until the data protection authorisation had been granted in the EU.

Member States asked to to reflect on EGCG level for green tea

The European Commission and Member States are currently reflecting on the setting of maximum level for ECCG for green tea.

This discussion followed the publication of the EFSA advice on the safety of green tea catechins. Whilst catechins from green tea infusions and similar drinks are generally safe according to the European Food Safety Authority, catechin doses at or above 800 mg/day may pose health concerns when taken as food supplements.

This work on the safety of green tea was initiated by the European Commission on behalf of Norway, Sweden and Denmark. These three national food administrations have raised concerns related to possible harmful effects associated with the use of green tea extracts and infusions and intakes of green tea catechins.

Belgium

The Superior Health Council (SHC) recommends to keep the limit of CoQ10 to 200 mg/day

"Currently there is no evidence of a need to complement CoQ10 (ubiquinone) in apparently healthy individuals and no convincing evidence has been gathered supporting supplementation as a preventive or curative role in certain pathologies or situations, the SHC therefore sees no benefit in consuming additional quantities of CoQ10 at levels exceeding usual food intake" the Superior Health Council (SHC) has said.

The SHC opinion was sought by the Ministry of Health following a request made by the national sector to increase the daily dose to 300 mg/day.

Other substances used in food supplements are regulated by the Belgian Royal Decree of 12 February 2009. Ubiquinone is currently included in this Decree at a minimum level of 4 mg/day and maximum of 200 mg/day.

Belgium extends its list of recommended methods of analysis for certain plants

Belgium has recently updated its recommended list of methods of analysis for certain plants increasing the number of methods from 22 to 119.

The intention of this list is to assist companies by providing recommended analysis methods for those plants for which maximum levels per daily recommended dose are set.

https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/2018_6_analysis_methods_version_1_0.pdf

Croatia

Croatia aligns its rules on edible oils and fats with Codex Standards

The proposed rules notified to the European Commission on edible oils and fats repeal the currently applicable national provisions on edible oils and fats (Narodne Novine [Official Gazette of the Republic of Croatia] Nos 41/12, 70/13 and 141/13).

According to the authorities the new regulation was necessary to bring the requirements for the quality of edible oils and fats in line with the appropriate Codex Alimentarius standards and the latest scientific, research and analytical knowledge. The proposed requirements apply to edible vegetable oils, vegetable and animal fats, including those placed on the market in the form of food supplements.

Czech Republic

Czech Republic revises its supplement regulation

Czech Republic has recently published a revision of its food supplement legislation to align its national rules with EU texts. This include the inclusion of all the sources and forms of vitamin and minerals set in the EU Directive, and the alignment of terminology with the labelling Regulation, also known as FIC (Food information to consumers).

The new provisions also see Gamma amino butyric acid (GABA), Coleus forskohlii, Hedera helix and Vitex agnnus-castus deleted from the negative list.

Maximum permitted levels for monacolin K from Monascus purpureus and Coenzyme Q10 (ubiquinol and ubiquinone) have also been introduced.

The new provisions enter into force on 1 November 2018. Foods placed on the market or labelled before the date of entry into force of this Decree may be marketed until stocks are exhausted.

Denmark

Danish authorities publish changes to their 'other ingredient' list

The latest amendment to the list of bioactive substances permitted for use in food supplements include the inclusion of quercetin from pagoda tree at 28 mg per day and the increase of the maximum daily limit for Curcumin from 60 to 210 mg.

IADSA
International Alliance of Dietary/ Food Supplement Associations

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France

French Authorities report a nutrivigilance' case for flax supplement

The opinion of the French Agency for Food, Environmental and Occupational Health & Safety concerns a case of allergic reaction suspected to be linked to the consumption of the supplement containing a flax seed extract.
Given that the severity of the undesirable effect was rated 3 out of 4, ANSES felt the need to publish this case to alert the public and health professionals, with the aim of improving the safety of consumers.

ANSES recalls in its opinion consumers must report to a healthcare professional any adverse reaction that occurs as a result of consumption of a food supplement; consumers must respect the conditions of use fixed by the manufacturer (RDD); consumers should avoid multiple, extended or repeated consumption of food supplements during the period of years without taking advice from a health professional; consumers should be very vigilant with abusive claims or products sold outside of traditional circuits, especially via the internet.

Italy

Mandatory electronic system for food supplements notification

The Italian Ministry of Health has introduced a new web-based electronic notification system for food supplements and other foods that are required to be notified in Italy, which is applicable as of 2 July 2018.

This system is now exclusively based on the electronic submission of notification files via a specific web-platform system, entitled 'Food subject to notification' ('Alimenti soggetti a notifica'). Notifications made using the previously followed methods (i.e. via post-mailing or email) will now no longer be taken into consideration

Foods that need to be notified in Italy via the web-system before or at the moment of first marketing include food supplements, foods with added vitamins and minerals, foods intended for specific groups, gluten-free foods and foods specifically formulated for coeliacs.

Ireland

Ireland sets guidance for the setting of maximum levels in vitamin and mineral supplements

The Food Safety Authority of Ireland (FSAI) has published recommendations on the UL to be used when carrying out risk assessments on food supplements.

Currently and in the absence of EU maximum levels, vitamins and minerals can be used in the manufacture of food supplements in Ireland with maximum levels established by the manufacturer while ensuring that only safe products are placed on the market.

"Many food supplement products provide vitamins and minerals in excess of NRV, with some approaching or exceeding the UL. These food supplements require risk assessment by the FSAI" 'indicates the FSAI report.

The authorities recall that the daily amount from the food supplement should be based on the measured amount in the product as purchased, not the amount declared on the label. When consumed according to manufacturer's instructions, this measured daily amount of a micronutrient added to the usual daily intake from food sources (excluding food supplements) of the highest consumers (95th percentile), should not exceed the UL for the population group(s) for whom the food supplement is intended.

Norway

Norway to establish list of amino acids permitted for use in food supplements

Mattilsynet has published a draft law for consultation regarding the addition of other substances to food supplements. This list was developed in co-operation with the Norwegian Scientific Committee for Food and Environment (scientific advisor to the authorities) who published a series of scientific opinions for the products and substances found on the Norwegian market. The draft Regulation only applies to the addition of "other substances" to foods, including food supplements, that have a purity of at least 50% or are concentrated 40 times or more and are not normally consumed as a food in themselves and not normally used as an ingredient in foods.

Brazil

Brazil finalises its draft framework for food supplements

The Brazilian authorities met early June the supplement sector to discuss the revised draft provisions of the new legal framework for supplements: Some specific progress has been made on additives with key substances for supplements now included in the draft regulation. No prohibition of umbrella brand use as it was originally announced is now foreseen. However, no consideration was given yet at that meeting to increase the proposed vitamin B levels. ANVISA is also working on a draft paper for probiotics that is aligned with WHO guidelines. A draft guide on the aspects that should be considered for establishing food shelf life is also under development. This document is based on international references, including those published by IADSA, the International Conference on Harmonization (ICH) and the Australian and New Zealand government authorities.

Ecuador

Restriction on food supplements' manufacture were repealed

The sanitary authority has published a new regulation update for food supplements. This latest modification has repealed the restriction that companies are not permitted to manufacture food supplements in the same facilities where medicines are manufactured.

Uruguay

Authorities review their draft Regulation for supplements

The Ministry of Health is reviewing its draft regulation on food supplements where there is currently no specific regulatory framework. The proposal includes a definition and permitted list of ingredients. Safety studies would not be required for ingredients

approved as new/novel ingredients by the Brazilian ANVISA or the European Union.

United Sates

FDA warns supplement companies promising sun protection claims

“When the FDA sees companies taking advantage of people's desire to protect themselves from the harmful effects of the sun — we'll step in," FDA said in a statement published in May. "There's no pill or capsule that can replace your sunscreen."

The Food and Drug Administration sent warning letters to five companies marketing products that make unproven claims they protect consumers from the sun.

https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm608499.htm

FDA Proposes new sources of dietary fiber

The U.S. Food and Drug Administration (FDA) has issued guidance and a science review identifying eight additional non-digestible carbohydrates (NDCs). The new sources are intended to be added to the list of non-digestible carbohydrates that meet the definition of “dietary fiber” established in the Nutrition Facts label final rule. These include mixed plant cell wall fibers (a broad category that includes fibers like sugar cane fiber and apple fiber, among many others), arabinoxylan, alginate, inulin and inulin-type fructans, high amylose starch (resistant starch 2), galactooligosaccharide, polydextrose, and resistant maltodextrin/dextrin.

https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm610111.htm

FDA releases draft guidance for intentional adulteration rule

FDA has released the first of three instalments of a draft guidance document designed to support compliance with the Intentional Adulteration (IA) Rule under the FDA Food Safety Modernization Act (FSMA). The remaining two instalments are expected to come out later this year.

The FSMA final rule on intentional adulteration is designed to address hazards that may be intentionally introduced to foods, including by acts of terrorism, with the intent to cause widespread harm to public health. Unlike the other FSMA rules that address specific foods or hazards, the IA rule requires the food industry to implement risk-reducing strategies for processes in food facilities that are significantly vulnerable to intentional adulteration.

This first part of the draft guidance includes chapters on: the components of the food defence plan; how to conduct vulnerability assessments using the key activity type method; how to identify and implement mitigation strategies; and food defence monitoring requirements.

The second instalment will focus more specifically on vulnerability assessments and training requirements, with the third including greater detail on corrective action, verification, re-analysis, and record keeping requirements.

http://s2027422842.t.en25.com/e/es?s=2027422842&e=101471&elqTrackId=B1F0B909CCF90C71B9C490C37BFE6647&elq=d58dc30c8698442d83b327d75efa8ff9&elqaid=3967&elqat=1

Russia

New concept proposed for developing functional foods market in Russia

The meeting of the committee on commerce in health care and the medical industry under the Russian Chamber of Commerce and Industry in April have discussed ways to stimulate production of functional foods in Russia. The meeting considered a draft concept of the interdepartmental innovative programme “Functional foods for healthy lifestyles and active ageing”.

Despite the fact that the term “functional foods” is not used in the existing legislative acts pertaining to foods, the trend towards developing the market for functional foods is in line with the action plan for the strategy to improve the quality of foods in Russia through to 2030. The action plan calls for the development of criteria, methods and procedures for validating the efficacy of functional foods.

Seeing as functional foods are mentioned in parallel with foods for special use, fortified foods and dietary supplements, it is not entirely clear what foods fall into the category of functional foods.The proposed concept contains the following definition of functional foods:
“Functional foods are foods intended for regular use as part of diets for all groups of the population. Functional foods preserve and improve health and reduce the risk of different non-communicable diseases. Because they contain functional ingredients, functional foods can have a favourable effect on one or several physiological functions and metabolic reactions in humans.”

The concept calls for setting up a self-regulating organisation of functional food manufacturers.

Belarus

Belarusian manufacturers to disclose information on substances banned from use in sport

The Belarusian president's Decree “On counteraction to doping in sport” of 24 May 2018 mandates that Belarusian manufacturers of dietary supplements and foods for special use intended for athletes are to amend the instructions for use to include information about the presence of any substances which are contained in the nationwide list of substances banned from use in sport. The list contains substances and methods which are capable of improving athletic performance, endanger athletes’ health and conceal the use of said substances and methods. The nationwide list is based on the World Anti-Doping Agency’s list of banned substances and methods, and on the recommendations of the National Anti-Doping Agency.
The provisions of the decree to come into force six months after its official publication.

Holiday workbook for active IADSA members!

PART I

IADSA
International Alliance of Dietary/ Food Supplement Associations

A

Which countries host and chair the following Codex Committees?

Codex Additives (CCFA)

Codex Nutrition (CCNFSDU)

Codex Contaminants (CCCF)

Codex Fats and Oils (CCFO)


China


Netherlands


Germany


Malaysia

B

Three ASEAN Member States are missing below, which ones?

Thailand, Indonesia, Vietnam, Malaysia, Singapore, Philippines, Laos and…. +….+…. !

C

Match the name of the category or categories to the country

Food supplement (FS)	India
Health supplement (HS)	European Union
Dietary supplement (DS)	ASEAN
Nutraceutical (N)	Russia
Biologically Active Supplement (BAS)	USA

Answers: (A) CCFA China, CCFO Malaysia, CCNFSDU Germany,CCCF Netherlands (B) Myanmar, Cambodia, Brunei (C) EU: FS, ASEAN: HS, USA: DS, India: HS + N, Russia: BAS (D) Chile, Colombia, Mexico, Peru (E) 2) India ReCHaN with FSSAI and the Confederation of Indian Industry CII (F) Pink : EAR /Grey: RDA /Black: UL - See newsflash May 2016 (G) Australia (Sydney)

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PART II

D

Hidden words: Find the 4 countries forming the Pacific Alliance?

C O L O M B I A U

E L I H C I C R R

M Q M E X I C O E

I Q W E R F G H P

F

Which goes where?

EAR Estimated Average Requirement
UL Tolerable Upper Intake Level
RDA Recommended Daily Allowance

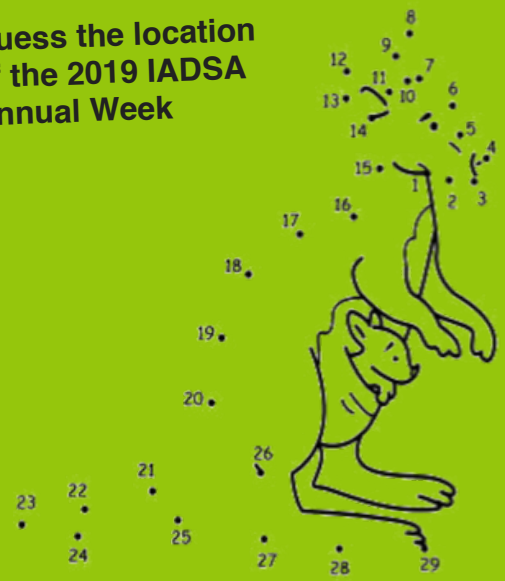
E

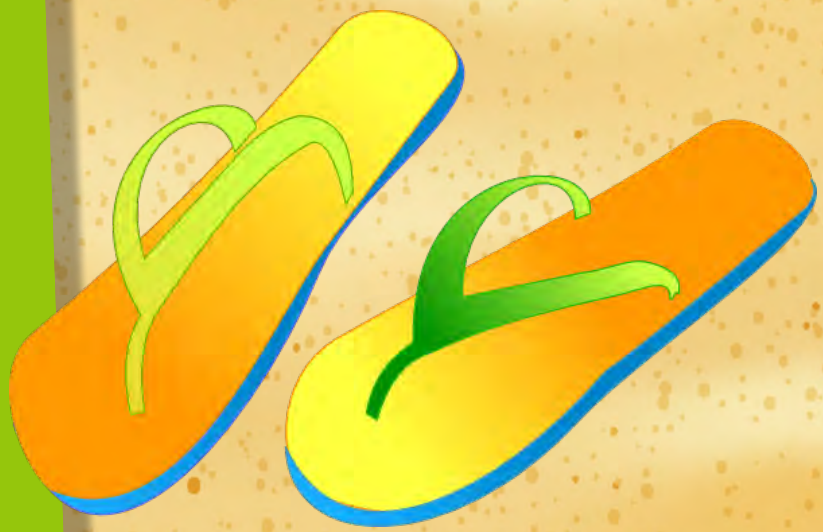
Where has IADSA created a Resource Centre in partnership with the Food Safety Authority?

1) China
2) India
3) Turkey

G

Guess the location of the 2019 IADSA Annual Week





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