

IADSA NEWSFLASH

May 2019

IADSA Week Sydney

The IADSA Annual Week was held this year in Sydney overlooking Harbour Bay. Surely one of the world's most impressive locations for any meeting. This helped contribute to what many considered one of IADSA's most rewarding Annual Weeks so far with a unique combination of discovering new approaches and skills and being brought up to speed with the latest in regulatory, policy and market developments from across the world.

What came through loud and clear from the three days is that the food supplement sector has a great story to tell, but that we need to work harder and smarter at how to tell it even better. Progress is being made in regulation, science and policy. But we still face a lack of understanding of the value that supplements can bring to consumers, particularly among policy makers.

All who participated went away with a renewed energy to contribute to building the supplement sector's shared story to help create the most appropriate regulatory and policy outcomes.

Thanks in particular to our Australian member association CMA for inviting us to Sydney and sharing some of the many great things about Australia with us.



Regulatory new



ASEAN

Almost there

Discussion continued early May in the Task Force on ASEAN Regulatory Framework for traditional medicines and health supplements to see if a solution could be found to the concerns of Thailand regarding the implementation of the GMP and Stability requirements. Thailand considers that the two documents would be too challenging for their small and medium sized companies.

A 'deferment' clause was proposed to address the Thai issue. Three options are now considered for reflection: *Option 1 Deleting the deadline for notification of deferral of implementation of the two Annexes; Option 2 (proposed by Indonesia) New text with cut-off date implementation of the two Annexes; Option 3 Maintain the original text of the Agreement.*

Member States are requested to provide their feedback by 15 June. Should agreement be reached, the agreement would be ready for signing in September 2020.

China

Notification: 5 functional ingredients under consideration

China State Administration for Market Regulation (SAMR) is considering to add five new health food ingredients to its food raw materials directory:

1. Coenzyme Q10
30-50mg
Function: Enhance immunity
2. Melatonin
Amount 1-3mg
Function: Sleep improvement
3. Fish oil
No more than 4.0g (among them, the usage amount of EPA+DHA should be no less than 1.0g)
Function: Assist to reduce serum triglycerides
4. Reishi shell-broken spore powder
1-4g
Function: Enhance immunity

5. Spirulina
3-4g
Function: Enhance immunity

Ingredients included in food raw materials directory are eligible for health food filing (notification).

Claims Regulation: Change in the air

China State Administration for Market Regulation (SAMR) is consulting on adjustments to health food functions. The authorities are considering to re-phrase 18 health functions by adding "help/aid" or similar terms to the current wordings. 3 out of the current 27 functional permitted claims could also be proposed for deletion. These include: 1. *Beautify/balance skin lipid*, 2. *Facilitate growth/improve growth* 3. *Stimulate lactation*.

Further investigation on the appropriateness of six borderline claims are also being considered: 1. *Assisting blood lipid reduction* 2. *Assisting blood sugar reduction* 3. *Assisting blood pressure reduction* 4. *Assisting protection against chemical injury of liver* 5. *Protection against radiation hazards* 6. *Alleviating lead excretion*

Companies had until end of April to submit their comments.

State Council passes draft rules on implementing Food Safety Law

China's State Council has passed a draft regulation on the implementation of the Food Safety Law, detailing the responsibilities of production operators and governments as well as accountability measures. Under the draft rules, companies involved in illegal activities will be subject to more severe punishment. The draft also optimizes food safety standards and risk monitoring systems so as to ensure food safety and better protect the health of the people, according to the State Council.

Proposed changes to probiotics

The SAMR has recently issued draft Provisions for Declaration and Review of Probiotic Health Food. At the moment, the declaration and review of probiotic health food is based on an earlier draft named Provision for Declaration and Review of Probiotic Health Food (Trial), which was implemented in 2005. The new draft requires minimum levels of active probiotics, raw material inspection reports, research reports, scientific literature and other evidence related to probiotic functions based on specific strains. Under the proposed

provisions, probiotics refer to living microorganisms which are beneficial to human health when ingested in sufficient quantities. (As such) probiotics are required to be living microorganisms.

India

The Standard question

FSSAI is in the process of reviewing and developing Microbiological Standards for various food commodities. In this regard, Microbiological Standards for nutraceutical products are currently under consideration by the Scientific Panel on Biological Hazards.

Japan

GMO free: Japan to strengthen labelling requirements

From 2023 more stringent requirements for food products using "free from GMO" labelling claims will be implemented. The use of "free from GMO" labelling claims will be restricted to foods which do not contain GMO materials. New labelling requirements will be imposed in cases where there is the possibility of cross contamination.



European Union

Additives: 2019 plan revealed

Under EU legislation dating from 2008, the safety of all food additives authorised for use in the EU prior to 20 January 2009 must be re-evaluated. The deadline for completion of the re-evaluation of all food additives is 2020. Having this deadline in mind, EFSA has recently published its 2019 tentative work programme which will include a review of number of additives permitted for use in food supplements. These include:

- Hydrochloric acid and chlorides E 507-509; E 511
- Phosphoric acid, phosphates and polyphosphates E 338-341; E 343; E 450-452
- Sulphuric acid and sulphates E 513 - E 517
- Tartaric acid and tartrates E 334 - 337, 354

- Esters of mono and diglycerides of fatty acids E 472 a-f
- Polyvinylpyrrolidone, polyvinylpolypyrrolidone E 1201-1202
- Polydextrose E 1200
- Dimethyl polysiloxane E 900

Further breaking down trade barriers

The EU has recently strengthened its principle of mutual recognition. A faster problem-solving procedure was introduced in March for disputes between companies and national authorities to prove lawful marketing in an EU Member State.

The Mutual recognition procedure aims to ensure market access for products that are not subject to EU harmonisation. It helps guarantee that any product lawfully sold in one EU country can be sold in another.

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0515&from=EN>

Rethinking support to SMEs

EFSA has launched new support initiatives dedicated to small and medium-sized enterprises (SMEs). SMEs will now be able to access support from EFSA when preparing, submitting and monitoring their applications.

EFSA will use the experience gained in providing these new forms of support to decide whether to include them in its catalogue of support initiatives.

<https://www.efsa.europa.eu/en/press/news/190402>

Contaminants under EFSA microscope

EFSA is to collect all available data on the occurrence of chemical contaminants in food and feed. National food authorities, research institutions, academia, food business operators and other stakeholders are invited to submit data by 1 October. More information at: www.efsa.europa.eu/en/consultations/call/190410

“No” to Yohimbe

The EU decision to prohibit the use of Yohimbe is now official. Yohimbe and its preparations had been placed under Union scrutiny due to scientific uncertainty on its harmful effects on health. The European Commission had four years to decide whether to ban it or remove it from scrutiny. However,

since no data was submitted during these four years to demonstrate the safety of the substance, its prohibition was inevitable.

E200/ E202: ADI up!

EFSA has confirmed the exchange of the temporary group ADI of 3 mg sorbic acid/kg bw per day for sorbic acid (E 200) and its potassium salt (E 202) to a new group ADI of 11 mg sorbic acid/kg bw per day. This increase is based on the findings of an extended one-generation reproductive toxicity study (EOGRTS) provided as a follow-up to the conclusions and recommendations of the 2015 EFSA Panel opinion.

#EUandMyFood campaign

EFSA is raising awareness of how the EU food safety system enhances the lives of citizens. The campaign #EUandMyFood will run from 24 April to 26 May 2019 to capitalise on the increased attention on the EU due to the upcoming European Parliament elections in May.

<https://www.youtube.com/watch?v=5H6h2gwPgbo&feature=youtu.be>

Glutamates: Call for help

EFSA is seeking additional data to complete its risk assessment on six glutamate additives (glutamic acid (E 620), monosodium glutamate (E 621), monopotassium glutamate (E 622), calcium diglutamate (E 623), monoammonium glutamate (E 624) and magnesium diglutamate (E 625)). Companies are requested to supply EFSA with information on use levels, function and technological need of the food additives and data on the lowest achievable limits for the impurities of toxic elements.

https://ec.europa.eu/food/sites/food/files/safety/docs/fs_food-improvement-e620-625_glutamates_201904113_e422_data.pdf

France

Titanium Dioxide: ANSES in doubt once again

Following the expert appraisal work it conducted in 2017, the French Food Agency, ANSES, was asked in February 2019 to review the most recent studies on the oral toxicology of titanium dioxide (E171) and to update its recommendations. The Agency concluded in April that it had not obtained any new information to resolve the uncertainties regarding the safety of the additive. ANSES reiterated the need to limit the

exposure of workers, consumers and the environment to the additive. The food additive is used in many different food products for its colouring and opacifying properties.

https://www.anses.fr/en/system/files/ERC_A2019SA0036.pdf

France/ EU: An unavoidable clash - or not - over titanium dioxide

The French authorities have decided to go ahead with the ban of the use of titanium dioxide in foods including food supplements. This ban, to start from 1 January 2020, is based on the precautionary principle after the French food safety agency, ANSES, recently indicated that uncertainties remain as to the safety of the additive.

The French decision will be addressed with the European Commission and Member States mid-May. Nine consumer groups have recently written a letter to the European Commission requesting it not to raise any objections or initiate any legal proceedings against the French measure.

Will the European Commission follow the demands of these consumer groups? This remains to be seen. The impact of the French decision on the supplement sector range from €20,000 for the smaller companies to €148,000,000 for the bigger one.

Swelling concerns over joint health substances

Following the recently published opinion on the risks associated with consumption of food supplements containing glucosamine and/or chondroitin sulphate, the French food safety agency ANSES has called for measures be taken to better inform consumers about the risks associated with the consumption of these products. Diabetic and pre-diabetic individuals, pregnant and breastfeeding women should not consume such food supplements, said the Agency.

ANSES also considers it necessary that the maximum authorised daily doses of glucosamine and chondroitin sulphate in food supplements be harmonised at the European Union level.

<https://www.anses.fr/en/content/certain-food-supplements-joint-pain-should-be-avoided-risk-populations>

Ireland

Ireland taps new DNA technology for food fraud

The Food Safety Authority of Ireland (FSAI) has disclosed that it now has a new scanning tool that can identify the entire DNA content of a food. The way the tool works is that it compares actual ingredients in a food ingredient identified by their DNA profile against the ingredients that are displayed on the label.

"It is now possible to scan the entire DNA content of a food without any prior knowledge or suspicion of what may or may not be present in that food," said FSAI. The tool has recently been used on 45 plant-based foods and food supplements from Irish health food shops and supermarkets.

https://www.fsai.ie/news_centre/press_releases/DNA_based_food_scanning_tool_18022019.html

Norway

Fluoride: Find the limits

The Norwegian Food Safety Authority has requested its Scientific Committee for Food Safety to evaluate the maximum level of fluoride for use in food supplements. This assessment should particularly consider the safety of fluoride from fluoride tablets / dental care products at daily levels of 0.5, 1, 5 and 7 mg/day.

In 2017 Norway published an amendment that has led to the deletion of most of the maximum levels for vitamins and minerals including the limits of fluoride at 0.5 mg per day. The reason for these deletions was that those levels were not established based on the criteria defined in the EU food supplement directive.

Italy

Notification register: time to tidy up

The Italian Ministry of Health has recently requested that 'all food supplement products notified up to 2014 in Italy, must be re-notified with the new online procedure "NSIS Foods subject to notification" by 30 June 2019.' The Ministry of Health has currently published 2 separate registers on its website of notified food supplements: The first, Register of Food Supplements, includes food supplement products notified from 1

January 2015 and will become the only reference register in future as it will be updated monthly with all new notifications. The second, Transitional Register of Food Supplements, includes food supplement products that were notified from 2008 to 31 December 2014 via the previous notification system. This register will no longer be updated and will expire after 30 June 2019.

Switzerland

Balancing the risk for VMs supplements

Switzerland aims to no longer allow in food supplements nutrients (such as vitamin A) that may have health consequences in cases of over-dosages. Conversely, maximum amounts will be removed for non-problematic substances such as vitamin B1.



Saudi Arabia

Requirements for Herbal & Health Products Submission discussed

The Saudi Food and Drug Authority (SFDA) has published draft "Requirements for Herbal & Health Product Submissions". The guideline provides recommendations on the documentation requirements for the registration of herbal & health products. The SFDA has divided natural herbal and health products into two classes:

- Class A: refers to health supplements where the marketing authorisation holder (MAH) is required to submit a partial application in order to meet certain requirements of quality and safety (e.g. multi-vitamin products).
- Class B: refers to herbal and health products where the MAH is required to submit a complete application in order to meet the requirements quality, safety and efficacy.

[https://www.sfda.gov.sa/ar/drug/resource/s/DocLib2/Requirements-herbal-health-submission\(draft\).pdf](https://www.sfda.gov.sa/ar/drug/resource/s/DocLib2/Requirements-herbal-health-submission(draft).pdf)

Product Classification Guidance: where responsibility lies

SFDA has recently published the Saudi FDA Products Classification Guidance,

Version 3". The objective of this guideline is to present the SFDA's current view on specific products or a category of products (including supplements) and whether they should be under the responsibility of Saudi Food and Drug Authority and particularly where the regulation could fall on the borderline between two SFDA sectors.

<https://www.sfda.gov.sa/ar/oper/Documents/SFDA-products-classification-guidance.pdf>



USA

Compliance with Intentional Adulteration Rules: The clock is ticking

Routine inspections to verify compliance with the Intentional Adulteration (IA) rules will begin in March 2020 has announced by the FDA. The IA rule, issued under FDA's Food Safety Modernization Act (FSMA) authority, 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. Food facilities covered by the rule will be required to develop and implement a food defense plan that identifies vulnerabilities and mitigation strategies for those vulnerabilities.

FDA unveils new tool for unlawful ingredients

The FDA is launching a new tool to quickly alert the public when they become aware of ingredients that appear to be unlawfully marketed in dietary supplements.

This Dietary Supplement Ingredient Advisory List is housed on the FDA website. The FDA emphasised that the List is not exhaustive and it will always be a work in progress. Ingredients will be added to the list following an initial FDA assessment indicating the ingredient may not lawfully be sold in dietary supplements.

<https://www.fda.gov/food/dietary-supplement-products-ingredients/dietary-supplement-ingredient-advisory-list>

Food (supplements) for thought

The Food and Drug Administration (FDA) is having a public meeting mid May entitled "Responsible Innovation in Dietary Supplements". On February, the FDA announced new efforts to strengthen the regulation of dietary supplements by modernizing and reforming its oversight. The purpose of the public meeting is to give interested parties an opportunity to present ideas for facilitating responsible innovation in the dietary supplement industry.



Argentina

New look at supplement rules

Argentina resumed its work to update the rules for the food supplement category. In April, the National Commission of Foods opened for comments a new draft regulation for food supplements. It is worth recalling that during 2015 a draft was issued but it was put on hold. The main changes to current rules cover the revision of the maximum limits for vitamins and minerals. Minimum level for vitamins and minerals would be increased from 20 to 30%. The permitted botanical list could also be cut from 35 to 27 species.

Brazil

Contaminants: Under the spotlight

From April to January 2020, ANVISA will be collecting data on the concentration of contaminants in foods marketed in Brazil, in order to help define or update maximum limits of 31 food contaminants. The list of contaminants was determined after considering the following international regulatory references: Codex Alimentarius, European Union, United States, Canada, Japan, Australia and New Zealand.

Specifications for supplement ingredients: how to fill the gaps

ANVISA is discussing criteria for defining specifications of food supplement ingredients not covered by the 10 the international references recognized by the Agency. Where no standardized and validated specifications exist, specifications will

need to be developed following calls for data. ANVISA has stressed that the fact that an ingredient is specified in some recognized reference does not mean that is safe. ANVISA will publish the draft document that will then be available for comments for 60 days.

<http://portal.anvisa.gov.br/documents/219201/4340788/Documento+Orientador.pdf/85dd1d7d-5687-43c3-b960-e6f8ff6c925f>

Honduras

Confusion over supplement categorisation

The Sanitary Regulation Agency (ARSA) has opened for comments two draft Regulations: one for food products and the other for pharmaceutical products, both covering food supplements known as nutritional supplements in Honduras. It is unclear how the supplements will be regulated in future: whether under the food law or pharmaceutical law, or under both legislations depending on the composition of the supplement.

Mexico

COFEPRIS revokes guidelines for the use of cannabis in food products

The sanitary authorities from the Federal Commission for the Protection Against Sanitary Risks (COFEPRIS) has revoked the guidelines and criteria for assessing the use of cannabis, including in food supplements, issued in October 2018. COFEPRIS has stressed that the use of cannabis is only approved with medical and scientific purposes.

MERCOSUR

Alignment with Codex GSFA

Work to revise and update the Mercosur harmonised list (based on Codex) – including additives used in supplements - has now been finalised. Suggestions made by Brazil to include additives evaluated by JECFA but not yet included in the GSFA was not followed by the other Member States. Mercosur is a trade bloc composed of Argentina, Brazil, Paraguay, Uruguay and recently Bolivia. Venezuela's membership is currently suspended for political reasons.

Peru

Food supplements to become foods

The Health Commission of the Peruvian Parliament approved in March a Bill

(No. 1717-2016) proposing that food supplements, known as 'dietetic products' in Peru, fall under food jurisdiction. Once the Bill is approved and signed, responsibility for food supplements will be transferred from the General Directorate of Medicines, Supplies and Drugs (DIGEMID) to the General Directorate of Environmental Health (DIGESA).



Eurasian Economic Union (EAEU)

Gelatine fish oil capsules get exempt from veterinary control

The Eurasian Economic Commission (EEC) has recently excluded gelatine-coated fish oil capsules from the veterinary control when imported into the EAEU territory.

New classification is up for preparations containing probiotic microorganisms

By the EEC Board's Resolution 56 of 16 April 2019, preparations based on living lactic acid bacteria that are used for maintaining and managing the human gastrointestinal microbiota, shall be classed under EAEU FEACN Subheading 3002 90 500 0 (cultures of microorganisms) The resolution enters into effect on 19 May 2019.

Ukraine

New labelling law to come into force

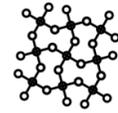
The Ukrainian Law on Food Information to Consumers of December 2018 (officially published in February) will come into force in August 2019. The new law, aimed at harmonising Ukraine's food labelling requirements with EU standards, introduces requirements for the labelling of foods including dietary supplements. In particular, the law introduces general food labelling provisions. A three-year grace period is foreseen during which products conforming to the previous laws may continue to be manufactured and/or put on the market until August 2022. Such foods may remain on the market until their shelf life expires.

Focus on Titanium Dioxide

Steps towards the decision to ban the use of the additive in foods (including supplements) in France



Titanium dioxide (TiO₂), also known as E171, is the most widely used white pigment because of its brightness and opacity. The additive is permitted for use in supplements and other foods at quantum satis.



While EFSA stated in its 2016 opinion that TiO₂ poses no health concerns, a 2017 French scientific study from the French National Institute for Agricultural Research (INRA) highlighted potential carcinogen risks of nanoparticles of TiO₂. This led the French National Assembly to pass an amendment to the Farm and Food Bill signed in October 2018 (so called EGALIM Law) aiming to ban the use, import and marketing of TiO₂ and any food containing it. This ban requires a ministerial implementing order before it can be applied.



The legal basis proposed by France to ban TiO₂ is included in Articles L521-17 of the French Consumer Law and 54 of the EU General Food Law that are both based on the presence of grave or immediate danger to be justified. Article L521-17

- In case of grave or immediate danger, the ministers in charge can suspend for a maximum of one year the production, import, export, marketing (incl. free samples) of a product and can proceed to the recall or destruction when this is the only means to cease the danger.
- Products can be marketed again when they are compliant to the law in force.
- Possibility to extend the suspension for an additional 1 year period.

September 2016



Re-evaluation of TiO₂ as a food additive: As part of its re-evaluation programme of all additives permitted for use in the European Union before 2009, the European Food Safety Authority (EFSA) concluded that available data on TiO₂ in food did not indicate safety concerns. EFSA recommended that new studies be carried out to fill data gaps on possible effects on the reproductive system, which could enable the Authority to set an Acceptable Daily Intake (ADI). EFSA also noted that there are no set limits for the particle size of TiO₂ in the EU specifications. Additional data would be required to update the specifications.

January 2017



The European Commission (EC) launched a call for data on TiO₂, inviting food companies to generate the additional data requested by EFSA in its opinion of 2016. In particular, data on particle size and particle size distribution were to be submitted by June 2018. A dietary Extended One-Generation Reproductive Toxicity Study with the food additive would need to be generated by August 2019. The Titanium Dioxide Manufacturers Association (TDMA) committed to carrying out this study.



The authors of a study carried out by INRA concluded that chronic exposure of rats to TiO₂ via the oral route may cause precancerous colorectal lesions. The findings do not, however, enable conclusions to be drawn on the effects of TiO₂ in humans.

April 2017



The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) released its opinion on whether the INRA findings (NANOGUT study) provided evidence to reconsider the conclusions of the 2016 EFSA re-evaluation concerning the safety of TiO₂. In its conclusions, ANSES points out that although the results presented in this publication do not currently call into question EFSA's assessment, the study does demonstrate effects that had not been identified so far, specifically potential promoting effects for carcinogenesis. As a result, ANSES highlights the need to conduct studies to fully characterise the potential health effects related to ingestion of TiO₂, with a methodology and schedule to be defined.

March 2018



The European Commission requested EFSA to carry out a scientific evaluation of four new studies relating to the potential toxicity of TiO₂ and to indicate whether they would merit reopening the existing opinion of EFSA on the safety of TiO₂ as a food additive

July 2018



EFSA organised a hearing with the scientific authors of the studies and concluded that the outcome of the studies did not merit reopening its existing opinion

October 2018



The French Parliament adopted the EGALIM Law. The law foresees the suspension of the use of TiO₂ and its use in food products

January 2019



France reaffirmed its willingness to ban TiO₂. In order to obtain the necessary legal conditions for this prohibition, the French Ministry in charge indicated that ANSES would be asked to update its opinion on nanoparticles in relation to TiO₂ by 15 April. This assessment should be based on new studies available. On the basis of this ANSES report, the Government would refer the matter to the European Commission. The Minister planned to exercise his right of safeguard by taking a unilateral decision prohibiting TiO₂.

February 2019



ANSES launched a call for information on the use of manufactured nanomaterials in food related to a number of food additives. This list includes TiO₂, magnesium salts of fatty acids (E470b), silicon dioxide (E551) and many other additives.

12 April 2019



ANSES published its new opinion on the safety of the additive based on a literature review on the oral toxicity of E171. 25 new studies published since 2017 were identified. According to ANSES, some of these studies revealed new signals, such as changes in cellular biological mechanisms in mice or developmental abnormalities in invertebrates, as well as in vitro genotoxic effects via oxidative stress (effects identified for different forms of the nanoparticle TiO₂, including E171). However, none of these new studies were able to confirm or refute the potential carcinogenesis-promoting effect of E171 reported in the NANOGUT study. The agency highlighted again the lack of scientific data able to resolve the uncertainties regarding the safety of the additive E171. It emphasised the need to obtain data for characterising the different physico-chemical forms of E171 and additional toxicological data on the potential effects associated with their ingestion.

25 April 2019



French Order suspending the use of TiO₂ in France published in the French Official Journal. The decision enters into force as of 1 January 2020 for a period of 1 year. It is based on the application of the precautionary principle in accordance with article L 521-17 of the French Consumer Code, which requires a grave and immediate danger to be demonstrated.

26 April 2019



France notifies the European Commission

3 May 2019



9 consumer groups called for an EU-wide ban of TiO₂ and for the European Commission not to oppose to the ban in France. The groups also urged the Commission not to raise any objections or initiate any legal proceedings against the French measure.

13 May 2019



EU discussion with Member States on the emergency measure regarding titanium dioxide when used as a food additive (E171)