# IADSA NEWSFLASH

DECEMBER 2018

# 2018: Another good year to build the future

The central role of IADSA is to help put in place the building blocks of good regulation and good policy for the food supplement sector. As associations and companies, it is our responsibility to show leadership for the sector as a whole. Our job is to work with government decision-makers, scientific bodies and many others to shape the future.

2018 was, in general, another good year along this path. While quick fixes are always great to achieve in regulation and policy, they are also rare. Most initiatives come about due to long-term, step by step, communication and partnership. In two of the world's largest countries, Brazil and India, there is clear forward momentum. New ground-breaking regulation in Brazil and the implementation of new regulation in India are significant in global terms but have not come about overnight. in China, the creation of the new government body SAMR potentially opens up opportunities for a new essential stage of regulatory change, but it will take time.

However, it is not just in the area of regulation that we see change. Government policy towards supplementation is key. While very few IADSA member associations would say they are happy with the policy of their government regarding the supplements, the building blocks of change are being developed.

It is becoming clear that time is on our side, that things will change. This can be seen most clearly with the potential crisis of the growing ageing population. It goes to the centre of most societies, most of which are totally ill-equipped to deal with it. How are we going to keep people living in the community and out of expensive nursing homes the state and individual cannot afford? How are we going to keep people working productively until their increasingly distant retirement age, so that they can afford retirement and there are sufficient people to pay for those who are already retired?

Food supplements can of course not answer the above questions, but 2018 has been a year when the seeds of fresh thinking have continued to grow among at least some policy makers that supplements could and should form part of the armoury of initiatives that can help. As national health budgets hit crunch points, it is inevitable that governments will have no choice but to consider employing some of these to keep people healthier for longer.

Thank you to all the members for your support in 2018 and we look forward to fresh energy to working with you all to continue to build a strong supplement sector that is respected by government and the scientific community in 2019.

## IADSA Annual Week 2019

**10 Apr - 12 Apr 2019, Sydney Australia**

Members can register by **28 February 2019** via
*http://events.iadsa.org/event/7*

## IADSA latest publications

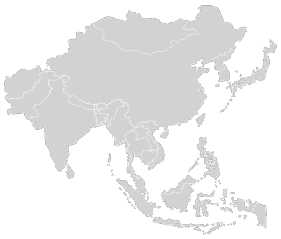
Tolerances for food supplements: An introductory guide
https://www.iadsa.org/resources/39

Codex Alimentarius: The International Reference for Food Supplements
https://www.iadsa.org/resources/34


**International Alliance of Dietary/Food Supplement Associations**
*International Non-Profit Organisation*
Gridiron Building, One Pancras Square, London, N1C 4AG, United Kingdom
Website: www.iadsa.org

IADSA
International Alliance of Dietary/ Food Supplement Associations

# Regulatory news



## ASEAN

### ASEAN reflects on options for differing implementation of its two annexes on manufacturing

The ASEAN Traditional Medicines Health Supplements Product Working Group met in October with the goal of overcoming the concerns of Thailand regarding the annexes on manufacturing (GMP and Stability) and moving to finalisation of the ASEAN Agreement. Thailand considers that the two documents are too challenging for their small and medium sized companies.

A new option was put on the table by the ASEAN Secretariat legal officer that would allow Member States to defer implementation of the two annexes as long as they inform the ASEAN Secretary General, who will then inform the other Member States. However, resolution was not achieved, and discussion will now be continued next year.

## India

### Claims rules to enter into force

The Food Safety and Standards Authority of India (FSSAI) has released its final notification on the standards for claims and advertisements in the packaged food industry. The Regulation aims to enter into force from 1 July 2019.

Business operators not complying with the regulations, would be “penalised with a fine of up to Rs 10 lakh, as per Section 53 of the Food Safety and Standards Act 2006” according to the press statement published by FSSAI.

## Japan

### Food Contact Materials: From negative to positive list

Japan is to introduce a positive list of food contact materials instead of the negative list currently in use

The new list is expected to be in place by June 2020.

## Tawain

### FDA issues Guidelines for stability testing

Taiwan FDA has recently issued Guidance for Health Food Stability Testing covering verification of product shelf life and stability.

The guidelines specify that tested items should be based on indicators that may affect product quality and safety.

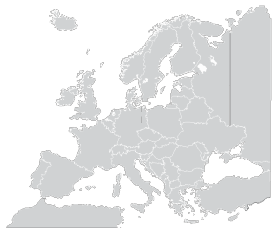
*More information at this link: https://www.fda.gov.tw/TC/newsContent.aspx?cid=3&id=24496*

## New Zealand

### New hope for the Natural Health Product (NHP) Bill

The challenging Private Member’s Bill for supplements that was put into the ballot earlier this year in New Zealand has been withdrawn.

The Ministry has now been tasked to provide a report to the Minister by Christmas to recommend a way forward which could possibly bring back the Natural Health Product (NHP) Bill with some amendments. The Bill was unexpectedly withdrawn from Parliament before its third reading in November 2017.



## European Union

### EU to limit the use of Trans Fatty Acids

Member States endorsed early December, the Commission’s proposal to limit the level of trans fatty acids (TFA) in foods including supplements via the so-called Article 8. This Article allows the Commission to prohibit or restrict the use of substances associated with a potential risk to consumers.

The maximum level proposed corresponds to 2 grams per 100 g of fat in the food intended for the final consumer. The EU provisions would apply to all foods and food supplements, with a transition period for non-compliant products until 1 April 2021.

The European Parliament has now two months to examine the draft proposal.

This text is in response to the WHO recommendation of May 2018 calling for the elimination of industrially-produced trans fatty acids from the global food supply. Similar recommendations were made by the European Food Safety Authority last June where it was concluded that "*based on review of available scientific evidence that according to the latest national and international recommendations, dietary intakes of trans fatty acids should be as low as possible.*”

The topic of trans fat was also debated in Codex Nutrition in November where Canada was tasked to develop a discussion paper on different risk management possibilities for the reduction of TFAs within the mandate of Codex Nutrition.

### EU discusses new claim on monacolin K

The European Commission has notified to WTO a proposal for the authorisation of a health claim for a product containing monacolin K. This concerns a reduction of disease risk

claim on the maintenance of normal blood-LDL cholesterol concentrations. The claimed effect is proposed for a daily amount of monacolin K of 2 mg, which is below the 3 mg that, according to EFSA, would lead to serious adverse effects.

It is however not clear whether the Commission will proceed with the adoption of the opinion before the safety of monacolin K is addressed.

## EFSA calls for data on Glycerol and polyglycerol esters of fatty acids

The European Food Safety Authority has called for data on Glycerol (E 422) & polyglycerol esters of fatty acids (E 475) both authorised for use in food supplements.

Technical data is specifically required, notably as to to presence/levels of heavy metals and other substances such as glycidol, 3 MCPDs, trans fats etc.

Detailed information can be found for each additive respectively at:

*https://ec.europa.eu/food/sites/food/files/safety/docs/fs_improv-additive_call_20181123_datae422.pdf*
*https://ec.europa.eu/food/sites/food/files/safety/docs/fs_improv-additive_call_20181123_datae475.pdf*

Industry has until 30 June to respond to this call.

## European Court dismissed pleas to annul maximum levels of polycyclic aromatic hydrocarbons (PAHs) for food supplements

The European Commission has been challenged over the benzo(a)pyrene limit of 10 micrograms in food supplements if used alone or to 50 micrograms if mixed with other substances.

The seven supplement companies who lodged the action notably alleged that the Commission failed to consult the European Food Safety Authority (EFSA) before adopting its implementation measures setting PAH limits.

The arguments from the supplement companies against the Commission was recently rejected by the European Court of Justice that highlighted that failure to consult EFSA did not constitute a breach of the procedural rules.

*https://publications.europa.eu/en/publication-detail/-/publication/ff3a244f-e438-11e5-8a50-01aa75ed71a1/language-en*

## EFSA to extend its Botanical Compendium

EFSA has launched a tender with a view to expand its Botanical Compendium.

The objective of this procurement is to update and further develop EFSA's Compendium of Botanicals as an open source tool for EFSA, stakeholders and the risk assessment community as a whole.

This requires data on chemical composition and toxicity for around 900 plants to be collated, and to characterise the toxicity of 2500 chemical substances.

The EFSA compendium of Botanicals is a database of botanicals that are reported to contain naturally-occurring substances of possible concern for human health when present in food. It is intended to help with the safety assessment of botanicals and botanical preparations that may be used in food, including supplements, by facilitating hazard identification. The compendium has no legal or regulatory force related to the classification of products or substances.

Replies to the call of tender are expected by January 31, 2019.

## EU consults on levels on 3 MCPD and Glycidyl fatty acid

The European Commission discussions continue for the possible setting of maximum levels for Glycidyl esters (GE) in fish oils placed on the market for the final consumer or for use as an ingredient in food and for the sum of free 3-monochlorpropanediol (3-MCPD) and 3-MCPD fatty acid esters, expressed as 3-MCPD. 1 µg/kg for glycidyl fatty acid esters and 2500 µg/kg for 3-MCPD are considered.

The Commission has issued a consultation. The deadline for comments and data was 2 November 2018.

## Calls for data on Glycerol and polyglycerol esters of fatty acids

Part of the on-going re-evaluation programme of additives, the European Food Safety Authority has published two calls for technical and toxicological data for the re-evaluation of two food additives, currently authorised for use in food supplements at *quantum satis*.

Mono- and di-glycerides of fatty acids (E471) for uses as a food additive in foods for all population groups including infants below 16 weeks of age
http://www.efsa.europa.eu/en/consultations/call/181129-0

Deadline for submission of data: 30/06/2019

Sucrose esters of fatty acids (E 473) for uses as a food additive in foods for all population groups including infants below 16 weeks of age
http://www.efsa.europa.eu/en/consultations/call/181129

Deadline for submission of data: 31/12/2019

The absence of data may result in withdrawal of the additives from the permitted list.

## EU corrects limits for additives in supplements requiring dilution

The EU has recently corrected a transposition error implying that the level of additives for supplements requiring dilution could no longer apply to the form ready for consumption.

The revised Regulation also re-categorises syrup- and chewable-forms as liquid and solid supplements. Syrup and chewing gums were falling up to now in a separate category which resulted in many implementation issues related to the limits of food additives applying to them.

## European Commission to restrict the use of green tea

Following the April opinion of the European Food Safety Authority opinion on the safety of green tea catechins, the European Commission is aiming to set a maximum level for catechins in green tea with the addition of a warning statement. This level - still discussed - may likely be set below the level of catechins of 800 mg identified by EFSA as the level that may cause safety concerns. The restriction may only apply to extracts not to ordinary green tea made from green tea with water or soft drinks with green tea that do not require further preparation for consumption.

This decision followed concerns raised by Norway, Sweden and Denmark on the possible harmful effects in green teas with high levels of catechins, notably with epigallocatechin-3-gallates.

## Belgium

### Belgian set ranges of authorised limits for 4 new substances

Belgium has updated its Decree on substances that can be added to supplements, bringing up to seven the number of substances for which specific conditions of use are set.

Among them *Monascus purpureus* (red rice yeast) or any other source of monacolin K, for which a limit of 10 mg per day of monacolin K is laid down. In 2016, concerns about the safety of red rice supplements were addressed by the Belgian Supreme Council of Health.

The new Decree also defines limits for caffeine, choline, Carnitine, Lutein, lycopene, *and* Ubiquinone.

*https://www.health.belgium.be/fr/arrete-ministeriel-du-19-fevrier-2009-autres-substances*

### EU to decide on the future of Monacolin K in red yeast rice

The European Commission is currently reflecting on the EFSA findings related to the safety of Moncaolin K. In August, EFSA considered that the safety of the ingredient which is allowed to carry a health claim, could pose a significant health concern with adverse effects similar to those of lovastin.

According to the EC, inclusion of the substance in the scrutiny list is not an option, considering that EFSA has already undertaken a thorough risk assessment.

While some Member States would prefer to prohibit the use of monacolin K knowing that EFSA has not been able to provide a level at which it is considered safe, others would prefer restricting its use under specific conditions of use where a maximum amount of monacolin K and warning statements could be set.

https://www.efsa.europa.eu/en/efsajournal/pub/5368

## Germany

### BfR review the safety of Chondroitin sulfate in food supplements

Food supplements containing chondroitin sulfate in isolated form cannot be recommended for pregnant or nursing women, children and adolescents according to the German Federal Institute for Risk Assessment BfR. The Institute also recommends that persons on antiplatelet medicinal products should seek medical advice before taking any product in the 800-1200 mg / day intake range. Persons allergic to fish protein may be at risk of allergies to products containing chondroitin sulfate isolated from shark tissues or other fish tissues.

The BfR recalls "*that food supplements are not intended to cure or relieve illness. Persons suffering from osteoarthritis / joint complaints should take medical advice to clarify the actual disorder and the therapeutic procedure. The efficacy of chondroitin / chondroitin sulfate in maintaining normal joint function in the general population (ie persons not suffering from osteoarthritis / joint complaints) is currently lacking scientific evidence, according to an assessment by the European Food Safety Authority (EFSA, 2009)*"

## Ireland

### FSAI clarifies CBD and hemp oil status

Following recent discussions of the European Commission and Member States regarding the novel food status of certain Cannabidiol (CBD) enriched ingredients/extracts, the Irish Food Safety Authority (FSAI) has recently published their FAQ on CBD and Hemp Oils. This Q&A notably focuses on which forms are considered novel, or not.
'*At present there are no authorised medicines in Ireland that contain CBD as the only active ingredient. Accordingly, CBD products currently being sold for consumer use are not approved for the prevention or treatment of medical conditions or symptoms associated with such conditions*' said the Authority.
*https://www.fsai.ie/faq/cbd_oils_and_hemp_oils_legal_status.html*

## Sweden

### A ban on food supplements broke Swedish and EU law

In 2015 the Planning and Environmental Services Committee of the Nacka region decided that vitamin D supplements with doses higher than the proposed EFSA's UL of 100 µg could no longer be sold. The decision was motivated by the fact that the food supplement could present health risks to consumers and therefore should not be considered as safe in accordance with the EU's food rules.

The recent verdict of the Swedish Supreme administration court has however overruled the decision. The Court found that the local Committee "lacked the necessary constitutional support" for its decision to ban food supplements with a level of vitamin D higher than 100 µg which is the EFSA UL." It was also highlighted that the Food Supplements Directive contains inter alia rules on the determination of maximum and minimum levels for vitamins in food supplements, but no such values have yet to be established.

A similar case was addressed in 2016 regarding vitamin B6. In 2013, the local authorities of Gävle ordered a reduction in levels of vitamin B6 in supplements, so that they are under the EFSA upper daily limit value of 25 mg. Back then the Administrative Court in Falun indicated that "it is common ground that there are no statutory upper limits for vitamins and minerals in either Swedish or EU law". The Administrative Court ruled that, in such a case, it is up to the food producer to take responsibility for ensuring that its products meet all safety requirements.

Sweden has so far not established legal levels for the use of vitamins and minerals in food supplements. It is up to the food business operators to ensure the safety of their final products.



## USA

### Arizona Board of Pharmacy considers dietary supplements to be non - prescription medicines

The Arizona State Board of Pharmacy is requesting every manufacturer and marketer of dietary supplements in the state to be registered as a non-prescription drug facility.

### Tianeptine is unsafe said FDA

The Food and Drug Administration has recently issued warning letters to two companies whose products marketed as dietary supplements were labelled as containing tianeptine. The letters explain that, even if the labelling for these products did not contain disease claims, and assuming the products meet the definition of a "dietary supplement" under the Act, the products would be considered adulterated because tianeptine is a substance that does not meet the statutory definition of a dietary ingredient and is an unsafe food additive.

Tianeptine is used as a prescription drug in some European, Asian, and Latin American countries, but it is not approved as a drug in the U.S.

## Brazil

### ANVISA publishes guide for the determination of shelf life validity

The National Health Sanitary Surveillance Agency (ANVISA) has published a guidance document to help companies to determine the shelf life validity of food products, including food supplements. The guide brings together a range of information based on the Brazilian regulation and ANVISA's understanding of adequate procedures and methods to meet the Brazilian requirements. The guide mentions in its scope that IADSA's Global Guide to GMP for Supplements from 2011 and Stability Test for Shelf Life Determination of Supplements have been used as references. The document will be open for comments for 1 year and contributions can be submitted online.
*http://portal.anvisa.gov.br/documents/10181/5056443/Guia+16_2018+Prazo+de.pdf/e40032da-ea48-42ff-ba8c-a9f6fc7af7af*

### ANVISA issues a new version of the guide for the Allergen Control Program

ANVISA has published the second edition of the Guide for the Allergen Control Program, which aims to provide best practices for the management and control of food allergens in establishments that manufacture and/or store food products, including food supplements. This program is required by Resolution 26 of 2 July 2015 which established the mandatory rules for the declaration of allergens on food labels. This edition of the Guide replaces the first edition issued in 2016.
*http://portal.anvisa.gov.br/documents/10181/2779039/%281%29Guia+Programa+Controle+de+Alergenicos+versao+2.pdf/69af35f5-cc11-412e-ade5-4d47fef14f5e*

## Mexico

### COFEPRIS introduces regulatory changes on the use of botanicals in food supplements

The sanitary authorities from the Federal Commission for the Protection Against Sanitary Risks (COFEPRIS) have announced that 18 new botanical species will be allowed for use in food supplements, in addition to the current 9 species permitted. In addition, they have introduced guidelines and criteria for assessing the use of cannabis, including in food supplements. This limits the tetrahydrocannabinol (THC) content of raw material to 1%.

### Regulation for food additives updated

COFEPRIS has updated the regulation for food additives, including for food supplements. Changes have been introduced for anthocyanins INS163 as natural colours. The authority has included black carrot extract INS163 (vi) and red radish extract INS163 (viii), which can be used at GMP level in all food categories.

## Russia

### New bill proposes criminalising e-sales of false dietary supplements

The Federal Law amending certain legislative acts of the Russian Federation applied to the circulation of false counterfeit, substandard and unregistered medicines, medical articles and false dietary supplements of 31 December 2014 introduced criminal liability for the circulation of false dietary supplements.

A new bill introduced by politicians proposes extending the law to cover online sales by amending the Penal Code with a clause on the use of media or electronic and telecom networks, including the Internet, for the aforementioned purposes.

The bill is being supported by the Russian government and the Supreme Court.

## Belarus

### Government introduces procedure to assess validity of claims

A draft resolution of the Belarusian government introduces a procedure for validating claims (special nutritional properties, indications and contraindication for individual age groups, etc.) of raw materials and foods, including dietary supplements.

Under the new procedure, all claims are to be subject to government assessment and approval. Claims are to be validated by a committee whose composition is to be determined by the Belarusian Health Ministry. However, the new procedure makes it clear that the responsibility for providing accurate information remains with the market operators.

If adopted, the document will come into force on 29 January 2019.

### Belarus introduces stricter rules for dietary supplements

A Belarusian government resolution published in November introduces amendments to regulations of production and circulation of dietary supplements. The document amends the procedure for the manufacture and circulation of dietary supplements to harmonise it with the new version of the law on the quality of raw materials and foods and their safety for human life and health.

The resolution introduces a new requirement for all businesses engaged in the industrial manufacture and/or wholesale sales of dietary supplements. Each batch is now to be accompanied by copies of documents confirming its quality and safety. The document will come into force on 29 January 2019.

# BRAZIL

## The new regulatory landscape for supplements

JULY 2018 - The directors of the National Sanitary Surveillance Agency (ANVISA) approved a new regulatory framework for food supplements.

### 5 Resolutions & normative instruction

These texts address the requirements for †he composition, quality, safety and labelling of food supplements. it notably provides permitted lists of nutrients, bioactive substances, enzymes and probiotics with conditions of use and claims where applicable.

*Resolution RDC 239/2018 | RDC 240/2018 | RDC 241/2018 | DC 242/2018 | Resolution RDC 243/2018 | Normative Instruction 28/2018*

**383** Authorised ingredients

**249** Authorised food additives

**189** Authorised claims

*The lists will be updated periodically provided that the safety and benefits of the ingredients are demonstrated.*

Provisions to demontrate the safety and benefit of probiotics

Guide for determining the shelf-life of foods / supplements based on IADSA guidelines

### Market access

a notification procedure for supplements
*except those containing enzymes and probiotics*

### 5 Years

Transition period for products already on the market provided that they are already authorised

### Next steps

Adoption of measures to assist in the implementation of the new regulations, such as the preparation of guidance documents and the implementation of training actions of the National Health Surveillance System.