

IADSA Newsflash

FEBRUARY 2018

5 Learnings from the past 12 months

Countries are seeing supplements as a strategic sector

Many governments have traditionally tolerated the supplement sector: the emotion has often been far from affection. Their goal has been just to keep control. It is today clear that this is starting to change. From the Pacific Alliance signing an agreement on supplements last year, to China looking at integrating health foods in their Nutrition Plan, to the Food Safety Authority of India encouraging the creation of the Resource Centre on Health Supplements, we see supplements starting to occupy a different space. This is where governments start to appreciate their economic importance and, even more importantly, start to understand that they may have a role to play in helping to address a range of challenges society is facing, cost effectively.

The quest for safety can easily get out of balance

The European Food Safety Authority has quietly become the world's preeminent scientific body in the food area. With cooperation agreements with countries across the globe, an increasingly far reaching communications programme, and with scientific opinions being generated on an epic scale, EFSA could soon find itself becoming the de facto scientific body for many governments who do not have the technical experts or financial strength to do this work. In principle this is of course fine - we believe strongly in science underpinning our sector. However, we are also aware from Europe and other regions that

this quest for ever more safety can one day can become almost obsessive and any safety issue can become - sometimes quite unnecessarily - a reason to restrict products or push companies to invest in procedures which could make products uneconomic. There is a balance and explaining this balance is going to be something that everyone in the supplement sector who talks to government is going to be doing more of in future.

Agreement on a connection between the science and supplements as a delivery form is still elusive for many in the scientific community

It is clearly important for scientists to remain separate from business. But sometimes this can lead to frustration. To witness so many scientists in the International Congress on Nutrition talking about their scientific conclusions with passion and excitement, but to see that the supplement channel does not seem to cross their minds as the most logical route for them to deliver these results was frustrating. Clearly, there is much more work to be done so that one day these scientists are aware and supportive of supplementation.

Keeping things moving

The ASEAN Agreement on Health Supplements has still not been signed. It probably could have been signed two years ago but, as with many international agreements, politics and new issues emerge which cause delays. What has been so impressive is that

this has not held back the process. With both government and industry working together, the programme of building the tools and the training to help its application and compliance across the 10-member countries continue to move forward. Momentum, even at a slower pace, is maintained.

Investment in policy, regulation broadly on track

In the survey of IADSA member associations, 71% said that regulation was broadly on the right track in their country, but only 54% considered this to be also true of policy. We know that one issue that has historically held our sector back is the lack of government recognition about our role in society. It is clear that a priority for the sector is to continue to invest in studies which evaluate and establish this value.

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Regulatory news



China

Guidance on Research and Development of Additional Food Testing Methods

CFDA has published its guidance on Research and Development of Additional Food Testing Methods to encourage organisations (including food manufacturers and marketers) to research and develop additional food testing methods (means the testing methods which are not included China National Standard yet), including testing methods for active ingredients, nutrients and other ingredients which are not allowed to be added in food.

<http://www.cfda.gov.cn/WS01/CL0050/218823.html>

Draft Implementation Regulation on Spot Inspection for Registration of Special Food

CFDA published its draft Implementation Regulation on Spot Inspection for Registration of Special Food. The regulation, which is a supporting regulation for the registration of special food, covering health food, infant formula and medical food in China, aims to verify the consistency between the dossiers submitted for product registration and the real situation on the spot.

<http://www.cfda.gov.cn/WS01/CL0782/217238.html>

India

Health Supplements/ Nutraceuticals: FSSAI extends transition period

Companies have been given another few weeks to comply with the provisions of the new Standards for health supplements and nutraceuticals. The extension of the transition measures applies specifically to

a) ingredients and additives approved by the scientific panel and b) ingredients not yet approved by the panel due to inadequate data as long information to support the substance was submitted before the end of January.

FSSAI to set provisions for the use of claims

The FSSAI has issued a notification on 8 November 2017 calling for comments on its draft Food Safety and Standards (Advertisements and Claims) Regulations, 2017. The regulation has laid down detailed definitions for each claim. It also clarifies that the provisions should apply to trade marks, brand names or fancy names appearing in the labelling when they may imply a nutrition or health claim. An approval process is also proposed for new claims following a review of data provided to substantiate the proposed claimed effect.



New Zealand

Pilot phase for new health claims to be launched in 2018

The long-awaited bill designed to regulate Natural Health and Supplementary Products has been withdrawn from Parliament before its third reading. The Natural Health and Supplementary Products Bill was introduced in 2011 and was intended to establish a new regulatory regime for natural health products separate from those in place for food and medicines.

The Natural Health Products Bill has not been reinstated by the new Government in place who has not yet indicated its intentions in respect to the regulation of these products.



European Union

EFSA raises health concerns for hydroxyanthracene derivatives

Hydroxyanthracene derivatives used in food supplements should be considered genotoxic and carcinogenic unless there are specific data to the contrary, the European Food Safety Authority has concluded. In 2013, EFSA found that hydroxyanthracene derivatives in food can improve bowel function, but advised against long-term use and consumption at high doses due to potential safety concerns. The EFSA panel said that a safe level of hydroxyanthracene derivatives could not be set due to a possible link between the intake of hydroxyanthracene derivatives and colon cancer.

Member States will now be consulted to decide what measures should be taken regarding the sale of plants containing these substances.

EFSA releases final guidance on antioxidants, cardiovascular health

The European Food Safety Authority (EFSA) has published its revised guidance on scientific requirements for health claims relating to antioxidants, oxidative damage and cardiovascular health. This update takes into account the experience and information gained so far. It is intended to assist applicants in preparing applications for such claims.

EU list of novel food published

As of 1 January 2018, the new Regulation (EU) 2015/2283 on novel foods is applicable. One of the main features of the regulation includes the establishment of a European Union list of authorised Novel Foods. For the first time more than 100 food ingredients in the EU list can be marketed provided the conditions of use are met and this without demonstrating a substantial equivalence (as requested with the old law).

Companies can also obtain a five-year protection period for authorisations based on newly developed scientific evidence and proprietary data.

E-submission system for Novel Food applications now up and running

With this EU online system, an applicant will be able to follow-up the status of an application, from submission until an outcome. This applies to novel foods authorisations and/or for notifications of traditional foods from third countries.

More information can be found at the following link:
e-submission system:
https://ec.europa.eu/food/safety/novel_food/e-submission_en
e-submission user guide:
https://ec.europa.eu/food/sites/food/files/safety/docs/fs_novelfood_e-submission-system_user-guide.pdf

Green light for low-dose L-HPC

EFSA has given a positive verdict on low-substituted hydroxypropyl cellulose (L-HPC). L-HPC is a low-substituted poly(hydroxypropyl) ether of cellulose proposed for use as a food additive in food supplements in solid form (tablet), with a maximum use level of 20,000 mg/kg and a typical use level of 10,000 mg/kg. Exposure estimates to L-HPC from its proposed use were calculated for both typical and maximum use levels. The Panel concluded that there was no safety concern from the proposed use and use levels of L-HPC.

EFSA reviews safety of unmodified and modified celluloses

There is no need for a numerical Acceptable Daily Intake (ADI) for unmodified and modified celluloses and current reported exposure levels for these food additives pose no safety concern.

This is the conclusion of the European Food Safety Authority's re-evaluation of E 460(i); E 460(ii); E 461-466; E 468 and E 469 in which it is considered an indicative total exposure of around 660-900 mg/kg bw per day for microcrystalline, powdered and modified celluloses. E 460-466 and E 469 are currently authorised in food supplements at *Quantum satis*. Cross-linked sodium carboxymethylcellulose (E 468) is an authorised food additive in the EU at levels of 30,000 mg/kg in food supplements supplied in solid forms.

Commission consults on the possible revision of the General Food Law

Whilst EFSA's work in the area of risk assessment has not been subject to significant criticism, consumer groups have put into question risk assessments based on studies provided by the industry, in particular where the industry seeks an authorisation (e.g. pesticides, GMOs).

To address these issues, the European Commission has launched a public consultation on the revision of the General Food Law, inviting stakeholders to share their views and experiences on the following:

- the transparency and independence of the EU risk assessment system with respect to the underlying industry studies and information on which EFSA's risk assessment/scientific advice is based;
- risk communication; and,
- the governance of EFSA, in particular the involvement of the EU Member States (MS) in the EU risk assessment system.

This exercise will feed into a legislative proposal to be presented to the European Parliament and Council by May 2018.

Silicon Dioxide: EFSA requires clarification on the presence of nanoparticles

The European Food Safety (EFSA) Authority recently reviewed the safety of silicon dioxide (E551) and has concluded that a major uncertainty is the behaviour of the additive at different particle sizes.

It emphasised that it cannot be totally excluded that some aggregates of primary particles could be smaller than 100 nm in size.

EFSA has advised the Commission to revise the EU specifications to include "the characterisation of particle size distribution using appropriate statistical descriptors, ie range, median quantities as well as the percentage in number and by mass of particles in the nanoscale". Nanomaterials in food additives are currently one of the most contentious issues in the EU.

Two new authorisations for supplements

Lyophilised microalge *Tetraselmis chuii* and Chondroitin sulphate obtained by *E. coli* fermentation have both obtained the novel food status for use in supplements.

Lyophilised microalge *Tetraselmis chuii* was authorised as novel food ingredient in 2014 for use in sauces, special salts and condiments. It is now authorised for use in food supplements at a maximum level of 250 mg per day.

The chondroitin sulphate produced by fermentation with the bacterium *Escherichia coli* has granted its novel food status in supplements with a maximum level of 1,200 mg per day in adults (aged 18 years and over) with the exception of pregnant women and lactating women.

EFSA consults on nano draft guidance on labelling

EFSA has opened a public consultation on its draft guidance for the risk assessment of nanoscience and nanotechnology applications in the food and feed chain.

The guidance covers the relevant areas within EFSA's remit, such as novel foods, food contact materials, food and feed additives, and pesticides. The new document takes account of scientific developments that have taken place since publication of the previous guidance in 2011, particularly studies that offer new insights into exposure assessment and hazard characterisation of nanomaterials.

It also considers nano-specific considerations relating to in vivo/in vitro toxicological studies and outlines a tiered framework for toxicological testing, and proposes ways to carry out risk characterisation and uncertainty analysis.

France

France to publish new maximum levels for vitamins and minerals in food supplements

The French authorities (DGCCF) are considering to update their 2016 guidance for maximum levels for healthy adults for the marketing of food supplements in France without prior authorisation.

Limits should be set on the basis of the Upper Tolerable Intake Levels, intake from the diet and the reference intakes for the population. Values for each of these criteria have been specified.

The main changes foreseen include an increase in the acceptable levels for Vitamins D, E, C and for magnesium in adults, and an increased level for iodine for pregnant and lactating women and the setting of a maximum level for beta-carotene. Warning statements may be introduced for a number of nutrients. Maximum levels for children (1-10 and > 10 years of age) could also be introduced.

European Commission clarifies framework applicable to food for special medical purposes

The European Commission has recently published a Notice on the classification of Food for Special Medical Purposes (FSMP) reiterating that that FSMP are food and not medicinal products. The guidance also aims at preventing companies from circumventing the health claims regulation by masquerading their products as FSMP.

EFSA consults on its draft guidance on nutrient sources

EFSA has launched a public consultation on its draft document which is intended to assist applicants in the preparation of dossiers for the evaluation of new nutrient sources. It specifies what kind of information and data applicants need to include in their dossiers to allow EFSA to assess the safety of the source as well as the bioavailability of the nutrient from the source proposed.

<https://www.efsa.europa.eu/en/consultations/call/171215>

Germany

German BfR publishes maximum levels for vitamins and minerals in food supplements

The German Federal Institute of Risk Assessment (BfR) has published its proposed maximum levels for use in food supplements.

BfR Chair Prof. Dr. med. Dr. Andreas Hensel states: "The special feature of the risk assessment of essential nutrients such as vitamins and minerals is that both the risks of a deficiency and overconsumption must be taken into account.

Products that comply with our recommendations and are taken according to the manufacturer's

instructions do not pose a health risk for people aged 15 and over, according to the current state of knowledge."

BfR based its maximum levels on the following three elements:

- the EFSA Tolerable Upper Intake Levels (UL)
- the intake of vitamins and minerals from the diet
- the Recommended Daily Allowance (RDA)

BfR took the difference between the UL and the nutrient intake from the usual diet and took the age group of 15-17 years to ensure that products are safe not only for adults, but also for young. An uncertainty factor of 2 was used for almost every nutrient to account for multiple exposure.

The proposed levels largely remain below the ones recently adopted by Belgium. In addition, for some of the maximum quantities, additional mandatory information is suggested.

The BfR levels have no legal value but may be an inspiration for the German authorities to develop national legislation.

The Netherlands

Vitamin B6 maximum level notified to the European Commission

The Dutch authorities have notified to the European Commission and Member States a draft Commodities Act aiming to repeal and replace their Commodities Act Order on vitamin exemptions.

This draft would maintain the current provisions of the Act on vitamin exemption but in addition introduce a maximum level of use for vitamin B6 in food supplements of 21 mg per recommended daily dose (RDD) assigned with different warning statements according to the level used. The new text is expected to apply as of 1 April 2018.

A transition period is foreseen for food supplements which are placed on the market or labelled before this date, until exhaustion of stocks.



Argentina

New allergen substances must be declared

The National Commission of Foods has issued guidelines for the correct implementation of the regulation for allergen labelling, approved in October 2017, which impacts all food segments, including food supplements.

Apart from the list of substances foreseen in the regulation, sanitary authorities stressed that the following substances must be also declared: lactose (to be declared as milk), gluten (to be declared as wheat, rye, oat, barley), sesame, lupin, molluscs, mustard celery and latex.

Proposal to modify regulation for food additives will impact food supplements

The sanitary authorities issued a proposal to update the food additive regulation which impacts all food categories, including food supplements. The proposal includes banning the use of the following additives: brominated vegetable oils, chlorotetracycline (hydrochloride), oxytetracycline (hydrochloride), whale sperma, dupnehl and potassium bromate.

Other substances are proposed to be removed from the regulation for food additives but will continue to be accepted as ingredients in food supplements, such as: L-carnitine, carnitine (hydrochloride), electrolytic iron, iron (II) fumarate, iron (III) pyrophosphate, iron (II) lactate, iron (II) sulfate and taurine.

Brazil

New draft regulation for food supplements open for comments

The Brazilian authorities have issued a public consultation on a proposal to develop a regulatory framework for food supplements.

In relation to product composition, it proposes a positive list of permitted ingredients with maximum levels for each substance, and a positive list of food additives and processing aids. It also seeks to ban the use of substances/ingredients made or derived from genetically modified organisms (GMO).

The regulation will permit a few health claims if the conditions of use are fulfilled. The introduction of a notification procedure is also foreseen. However, for food supplements containing probiotics and/or enzymes, the registration process would continue to operate.

Bolivia

Bolivia defines food supplements under a regulation for food labelling

The sanitary authorities have issued a new regulation for the labelling of foods for human consumption, which includes a definition and requirements for food supplements, bringing more clarity to the borderline between foods and medicines. The regulation defines food supplements under the food category and foresees the use of ingredients, alone or combined, such as vitamins, minerals, proteins, amino acids, carbohydrates, lipids, bioactive ingredients, extracts, probiotics and prebiotics, among others. The regulation entered into force in January.

Ecuador

Guideline for the re-classification of food supplements

The sanitary authorities drafted a proposed guideline to help companies understand how to act in the case of having a product re-classified as a food supplement under the food supplement regulation of February 2017.

It is a simple guide that explains how the process of re-classification should be requested to the sanitary authorities, highlighting the main points to be assessed, such as permitted ingredients (including the maximum levels) and authorised claims. If the product needs to be re-classified, the company will have a period to adapt the product and/or to comply with the regulation in force. Once the product has been re-classified, the interested company would have 90 days to register the product as a food supplement.

El Salvador

Guidelines for food supplements issued

The Sanitary Authority of El Salvador have launched for public consultation a guideline to assist the industry in the registration of food supplements. It sets a minimum level of 15% and maximum level of 150% of the Recommended Daily Intake for vitamins and minerals, as well as provisions for the use of probiotics and others bioactive substances. It also proposes to restrict the use of caffeine in certain food supplement products.

Peru

Ireland's RDI considered for the classification of food supplements under medicines law

The Ministry of Health has updated the list of countries of 'high sanitary surveillance' which serves as a reference for the classification of food supplements. When a product exceeds the Recommended Daily Intake (RDI) from countries of 'high sanitary surveillance', it is considered as a "dietetic product" falling under medicines law.

Products with levels below the RDI would be considered as food. Ireland has been added to the list that already includes Australia, Belgium, Canada, Denmark, France, Italy, Japan, Netherlands, Norway, Spain, Sweden, Switzerland, United Kingdom and the United States.

Uruguay

Draft of regulations of dietary supplements under review

Uruguay is working on a new version of its proposed draft of regulations of dietary supplements. The draft not only covers a definition for the supplement category but also proposes among others a positive list of vitamins and minerals, amino acids, additives.

The proposal also clarifies that the components of the dietary supplements must be authorised as food ingredients. It will not be necessary to provide safety studies in case the components are regarded as New Foods or New Ingredients in the lists of ANVISA or the European Union.



United States

Biotin may interfere with Lab tests

The FDA is alerting the public, health care providers, laboratory personnel, and laboratory test developers that biotin can significantly interfere with certain tests and cause incorrect test results which may go undetected.

The FDA has seen an increase in the number of reported adverse events related to biotin interference with lab tests.

The FDA is working with stakeholders to better understand biotin interference with laboratory tests, and to develop additional future recommendations for safe testing in patients who have taken high levels of biotin when using laboratory tests that use biotin technology.

FDA extends comment period for proposed rule to revoke authorised health claim regarding soy protein and coronary heart disease

The U.S. Food and Drug Administration is providing an additional 60 days for public comment on the agency's proposed rule to revoke the authorised health claim on the relationship between soy protein and reduced risk of coronary heart disease.

The FDA published the proposed rule, "Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease," on 31 October 2017 in which it highlighted that the current publicly available scientific evidence does not support previous determination that there is significant scientific agreement (SSA) among qualified experts for a health claim regarding the relationship between soy protein and reduced risk of coronary heart disease.

The FDA is extending the comment period in response to requests from stakeholders for additional time. The comment period will now close on 19 March 2018.

FDA denies qualified health claim petition for intake of vitamin D to reduce the risk of multiple sclerosis in healthy people

The U.S. Food and Drug Administration has denied a request for use of a qualified health claim that consumption of vitamin D may reduce the risk of developing multiple sclerosis (MS), a chronic autoimmune disorder that damages the body's central nervous system.

FDA clarified that "Qualified health claims are claims supported by credible scientific evidence, but do not meet the more rigorous "significant scientific agreement" standard required for an authorized health claim.

As such, qualified health claims must be accompanied by a disclaimer or other qualifying language so that the level of scientific evidence supporting the claim is accurately communicated. In the case of this qualified health claim petition, because there is no credible scientific evidence to support the claim, the claim is misleading and no disclaimer or qualifying language could mitigate the misleading concerns of the claim itself to prevent consumer misunderstanding."

FDA announces draft guidance on best practices for convening a GRAS Panel

The U.S. Food and Drug Administration issued for public comment a draft guidance on best practices to follow when convening a panel of experts to evaluate whether a substance is "generally recognized as safe" (GRAS) under the conditions of its intended use. Specifically, the draft guidance highlights best practices that will help parties interested in convening a GRAS panel. The FDA is also making available on its website a guidance document that highlights the GRAS regulatory framework and may be used as a reference of key resources for evaluating the safety of a substance under the conditions of its intended use.

Refusal of Inspection? FDA clarifies

The FDA Food Safety Modernization Act (FSMA) gives the FDA the authority to refuse imported food admission into the United States if the agency is not permitted to inspect the foreign establishment that produced the food.

What actions by a foreign food establishment or government constitute a "refusal of inspection"? The agency has issued a draft guidance to address the question. The draft guidance provides a list of examples to illustrate some of the situations that the FDA may encounter when attempting to conduct inspections.

<https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm588115.htm>

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm586599.htm>



Russia

Special GMO symbol to be introduced on labels of GM foods

In December 2017, the Eurasian Economic Commission Board approved amendments to the EAEU regulation 'On food labelling' introducing a mandatory label symbol for products manufactured with the use of GMOs and / or containing GMOs. The amendments introduce additional labelling requirements.

For such products, a special symbol reading "GMO" will need to be displayed on the label together with one of the following statements: "genetically modified produce", "produce manufactured with the use of GMO" or "produce containing GMO components". The GMO symbol is to be displayed if the concentration of GMO in the product exceeds 0.9%. The new requirement is aimed at informing consumers about the presence of GMOs and helping them make more informed purchasing decisions.

Ukraine

Revised recommended intake levels for nutrients, vitamins and minerals come into force

Ukraine has introduced new recommended intake levels for the key nutrients and energy.

For the first time in the past 18 years, the ministry has revised the daily intake levels as applied to different groups of the population: children and adolescents, pregnant women, and people employed in physically demanding jobs.

The new standards also revise the recommended intakes of minerals and vitamins for children and adults by lowering the level for Vitamin A and raising the level for Vitamin D and folic acid. The standards are intended as a guideline in the development and labelling of baby foods, food supplements and fortified foods.

Ukrainian bill introduces notion of functional foods

A bill introducing the notion of functional foods was submitted to the parliament in December 2017. According to the bill functional foods are described as "foods and drinks fortified with nutrients or substances which have a potentially positive effect on health, thus supplementing such products' basic nutritional value". The bill likewise introduces a list of functional foods and stricter requirements for manufacturing and labelling thereof.

The authors stress that manufacturing functional foods requires evidence of safety for vulnerable consumers and involves mandatory monitoring of such foods. For this reason, food manufacturers need to meet the HACCP standards, which require systematic identification, assessment and management of hazardous factors affecting product safety.

The bill calls for the introduction of harsher administrative penalties for sales of functional foods whose labels contain false information about the content of harmful substances and for introducing criminal liability for the manufacture and sales of foods which fail to meet the safety and quality requirements.

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5

Good things that happened in 2017

ICN International Congress of Nutrition

Since its first meeting in 1948 in London, the International Congress on Nutrition (ICN) has been held 20 times. In Buenos Aires last year, IADSA for the first time organised a specific session on issues around the science of supplementation and the regulatory and policy framework impacting the sector. With supplements playing such a significant role in the lives of so many consumers, it is increasingly important for the sector to engage with the nutrition science community.



A new Resource Centre on Health Supplements and Nutraceuticals (ReCHaN) was launched in July to fill a gap identified by the head of the Food Safety Standards Authority of India. ReCHaN is run jointly by IADSA and the Confederation of Indian Industry in Delhi and has already developed a number of tools to provide guidance on the application of regulation and manufacturing quality. ReCHaN will also be engaged in work to address the value of supplementation in India.



Pacific Alliance

The EU took over a decade to agree legislation, even ASEAN has still not finally signed the Health Supplement Agreement, but in the Pacific Alliance things move at a rapid pace. In 2017, the four member governments of Chile, Colombia, Mexico and Peru signed a single framework for food supplements. While this does not yet have the detail of ASEAN or the EU, it establishes a common approach and areas where further agreements will be discussed by the four parties.

1st IADSA Grant

The first IADSA Grant was awarded to the Vietnamese Association VAFF at the IADSA Annual Meeting in Seoul in May and the project has moved forward effectively, establishing a roadmap for the implementation of ASEAN legislation in Vietnam and engaging government in this process.



Turkey

In September, a group of more than 10 officials from the Ministry of Agriculture, Ministry of Health and the government scientific advisory bodies engaged in a study tour to understand better approaches to regulation and manufacturing in France, Germany, Italy and Switzerland with representatives of the newly-formed Turkish association. At a session provided by IADSA in Italy, it became clear that there is a simple power in bringing together officials from different ministries to see and learn first-hand how things work in other countries and debate together how best to address issues at home.