IADSA Newsflash

March 2017

The world's largest ever regulatory implementation process

China, India and in the near future ASEAN are starting the implementation process of their new legislation that will most likely decide the future framework for marketing and consumer access to products for more than 3.2 billion people, over 40% of the world's population.

China's new regulatory framework for the notification and registration of health foods is being implemented from May; India's new regulatory model for nutraceutical regulation is due to be enforced from the beginning of next year; and the ASEAN Agreement on Health Supplements is expected to formally begin its implementation journey next year. If the Pacific Alliance countries achieve their goal of agreeing their common regulatory framework this year, a further quarter of a billion of the world's population can be added to that total. This is a big number and for both the food supplement sectors located in these countries and for the sector globally, there is a lot at stake.

While the general direction and much of the content in the regulation of ASEAN, China and India is broadly good, success or not will depend quite significantly on how this legislation is implemented in detail. For ASEAN, the 10 member states will each take a national approach. Many of the officials who were involved in the decision making process at the regional level are no longer in place, and new officials and often new government departments will be taking this on. In China, while the legislation has been developed at

the national level, the regional FDA offices remain strong and powerful and the new approach has partly decentralised the notification of products to this level. In India, the major challenge is likely to arise around the definitions of the categories of nutraceuticals and how they interrelate. While decision makers in the capital may be clear on what is a nutraceutical and what is a food supplement, it may be far from clear that those who are responsible for implementation and enforcement in this vast country will necessarily share this approach. Considering that the 29 states also like to exert their independence from the centre, everyone in India is prepared for interesting times.

Over the years, we developed across IADSA a very strong expertise and track record in advising on the development of regulation. What we now see is that governments are looking for new support for implementation and enforcement. This means help for training and capacity for their officials in the regions; for support in helping deal with those companies intent on marketing dangerous products or fraudulent products; and for help in raising standards so that governments, consumers and the sector can be confident with the quality of products entering the market. With the opportunities ahead being so significant, investing in this direction can only be the right way to go.

IADSA Annual Week
Seoul |16 -18 May 2017

Tuesday 16 May
10.30-12.30
Issue Highlights Session

13.30-17.00
The Value of Supplementation: Mapping the Nutritional Landscape

Wednesday 17 May
08.30-12.00
Meeting of IADSA member associations

13.30-17.00
Annual General Assembly

Thursday 18 May
09.00-15.00
Company Council Meeting

VENUE
Grand Hyatt Seoul

Register for the event
http://events.iadsa.org

IADSA
International Alliance of Dietary/ Food Supplement Associations

Regulatory news

China

1st Batch of Approved Health Food Raw Materials and Function Claims published

The first batch of the Catalogue of Health-Food Ingredients and Claims has been released.

The Notice released on 12 January 2017 covers the list of forms and sources of vitamins and minerals that can be used in notified products together with the conditions of use (maximum and minimum) for each population group. The list also establishes for each form the related Chinese Standards to comply with. Health-food products using these ingredients in compliance with the defined conditions of use will be eligible to claim on their label the health function "Supplements vitamins, minerals".

Starting from 1 May 2017 – producers of health-food using ingredients will need to follow the new procedure for the registration/notification of health foods.

CFDA releases its draft Health Food Filing Guidance

The Draft Rules detail the procedure to follow for the notification of heath food. Applicants will firstly have to obtain their login account with CFDA to gain access to the online filing system (http://bjba.zybh.gov.cn).
The system will then generate the filing application form, product formula table, label and instructions as well as product technical requirements automatically after the applicant successfully uploads the requested information.

A 5 working day period is given to submit the document. The filing certificate will be issued on site if the submitted dossier is compliant with relevant requirements.

The dossier includes:
(1) the application form for health food filing, and legal liability commitment to the authenticity of the materials submitted by the applicant;
(2) the copies of the supporting documents proving the registration of the applicant;
(3) the product formula materials;
(4) the product production process of the materials;
(5) the safety and health functions assessment materials;
(6) the types, names and relevant standards of packaging materials in direct contact with health food;
(7) samples of the label and instructions;
(8) the product technical requirements materials;
(9) the test report that proves the product complies with the product's technical purpose
(10) details of the product name;
(11) other materials demonstrating product safety and health functions.

Interested parties had until 28 February to submit their comments.

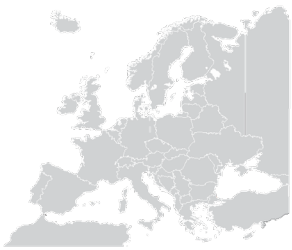
India

FSSAI consults on its draft regulations on approval for non-Specified Food and Food Ingredients

The Food Safety and Standards Authority of India (FSSAI) has launched a public consultation for comments, views and suggestions related to a draft regulations on approval of non-specified food and food ingredients. The proposed draft establishes in particular the procedure for approval with details on the supporting documentation required.

Non-specified food products or food ingredients are defined as those products which are not allowed to be manufactured, stored, sold, distributed or imported under any other Regulation under the Food Safety Act of 2006. These products will require prior approval from FSSAI. The various categories of food products covered under this category are:

- Novel food or food containing novel ingredients not having a history of human consumption in the country
- Food ingredients with a history of human consumption in the country but not specified in any other regulations made under the Act
- New additives and processing aids
- Food manufactured or processed with the use of novel technology



European Union

Fermented soybean extract approved as novel food

The European Commission has published their Implementing Decision (EU) 2017/115 of 20 January 2017 authorising the placing on the market of a fermented soybean extract as a novel food ingredient.

The ingredient is authorised to be marketed in food supplements in capsule, tablet or powder form intended for the adult population, excluding pregnant and lactating women, with a maximum dose of 100 mg fermented soybean extract per day.

EU Judgment rejecting the German amino acid prior authorisation scheme (C-282/15)

The Court of Justice of the European Union (CJEU) issued a judgment upon request of the Administrative Court of Brunswick, Germany. The request concerned the interpretation of Regulation (EC) No 178/2002 laying down the general principles and requirements of food law and Regulation 1925/2006 on the addition of vitamins and minerals and of certain other substances to food.

The question relates to an application for derogation from the prohibition on the manufacture and marketing of a food supplement containing an amino acid (L-histidine).

Under the German Act on Food and Feed, it is prohibited to use non-approved food additives, whereas the law further provides that amino acids and their derivatives are equally treated like food additives. Thus in the absence of a law or decree expressly approving amino acids, their use as food additives is generally prohibited in Germany unless a derogation is granted.

In its judgment the CJEU affirmed that national legislation is possible on matters that are not harmonized at EU level. A system of prohibitions with the possibility for derogations upon authorisation is not precluded in this

context. However the CJEU recalled that any prohibitions or restrictions should be based on a full risk assessment.

As a consequence the CJEU ruled that the German national legislation, which prohibits in general the manufacture, processing or marketing of any food supplement containing amino acids, unless a derogation has been issued by the national authority, is not in accordance with General Food Law Regulation.

The European Commission launches its botanicals stakeholder survey

Stakeholders are being asked whether the current treatment of botanicals under the EU's health claims rules is adequate for industry and consumers. The survey also focuses on the impact of the absence of harmonised rules, including on competitiveness, innovation and investment.

More than 2,000 health claims on botanicals are currently on the "on hold" list awaiting a Commission decision to allow them or not. Most of these claims are based on tradition, and are not currently regarded by EFSA as having sufficient evidence to substantiate of a claim.

Stakeholders were asked to respond to the survey by mid-February.

The European Commission opens a public survey on Nutrition and Health Claims

The European Commission has launched a survey to the public on Nutrition and Health Claims. The survey that runs until 1 June 2017 aims to collect the views of citizens on the ongoing review of the EU Regulation on nutrition and health claims made on foods and how plant substances used in foods are regulated in the EU.

In particular, it seeks to obtain information on how citizens, as potential consumers of foods marketed with nutrition or health claims, understand these claims and other nutrition information provided on the label of a food product, how they perceive the healthiness of foods making such claims and what specific elements drive their food choices.

Basic methacrylate copolymer (E 1205) - revised specifications

The European Commission has recently revised the specifications of the food additive basic methacrylate copolymer (E 1205).

The revision includes an amendment to the description of the manufacturing process and particle size limits, due to a modernization of the manufacturing process.

Basic methacrylate copolymer is currently authorised for use in food supplements as a glazing agent/coating agent in solid food supplements at a level of 100 000 mg/kg. The additive plays in particular a technological role in supplements by moisture protection and taste masking of nutrients.

The amended Regulation (Reg. 2017/324 enters into force on 17 March 2017.

EFSA public consultation on setting a DRV for Vitamin K

EFSA has launched a public consultation on its draft scientific opinion on dietary reference values for vitamin K. This document proposes dietary reference values for vitamin K for adults, infants and children, pregnant and lactating women: An AI of 70 µg/day is proposed for all adults including pregnant and lactating women, 10 µg/day for infants aged 7-11 months, and 12 µg/day for children aged 1-3 years and 65 µg/day for children aged 15-17 years. Interested parties were invited to submit comments by 24 February 2017

EFSA call for data on food additives (Batch 6)

EFSA has launched its 'Call for data on food additives usage level and/or concentration data in food and beverages intended for human consumption' (Batch 6). The list of food additives for which usage levels and/or concentration data are requested can be found at the following link:
https://www.efsa.europa.eu/en/data/call/170223
The deadline for submitting data in respect of this call is 30 November 2017.

EFSA to revise guidance documents for the substantiation of health claims

Following a recent revision of the EFSA scientific and technical guidance for the preparation and presentation of a health claim application, EFSA has now scheduled the revision of the guidance related to claims for specific functions EFSA will start with the one related to antioxidants, oxidative damage and cardiovascular health.

10-minute survey to help EFSA better explain scientific uncertainty

EFSA has recently launched a 10 minute survey 'How certain are you? Help us to better explain scientific uncertainty', available in English, French, German, Greek, Romanian and Spanish and accessible via the following link:
http://www.efsa.europa.eu/en/press/news/170223

EFSA is seeking help, to improve how they communicate and explain scientific uncertainties in risk assessments. The questions are mainly focused on ranking expressions by how helpful they are for understanding the risk, in order of the clarity of information and on ascertaining the usefulness of providing additional information.

EFSA clears safety of Taxifolin-rich Extract and Tolerase G as novel food ingredients

The European Food Safety Authority has cleared the safety of Taxifolin-rich Extract and Tolerase G as novel food ingredients for use in supplements.

Belgium

Belgium updates its guidance on tolerances for food supplements

The Belgian Federal Agency for the Safety of the Food Chain (FASFC) are in the process of updating their national guidance documents relating to compliance with the EC guidance with regard to the setting of tolerances for nutrient values declared on a label

The current guidance of FASFC, FR and NL versions are available here:
http://www.afsca.be/denreesalimentaires/circulaires/_documents/2014-09-02_Annexe-3_tableau_decisionnel_tolerance_FR.pdf
http://www.afsca.be/levensmiddelen/omzendbrieven/_documents/2014-09-02_Omzend_tol_Bijlage-3_Beslissingsboom_toleranties-NL_000.pdf

Concretely, a large MU is applied (30% instead of 20% in the current approach).

Italy

National rules for caffeine claims

While the European Commission is consulting member states on information about caffeine claims for energy drinks being made on national markets, Italy has decided to move ahead with its own recommendation for the Italian market.

Only claims with conditions of use related to an intake of caffeine not exceeding the maximum national permitted level of 200 mg/day should be allowed. In Italy the two caffeine claims challenged by the Parliament on alertness and concentration will be permitted. The non-challenged claims related to endurance performance and capacity where a dose of 3 mg/kg is required to substantiate the health benefit (intake exceeding 200mg /day for a person > 67 kg) will no longer be authorised.

Last July, the European Parliament voted to oppose the authorisation of two claims on concentration and alertness because they said they were used on energy drinks. The decision of the Parliament to reject the text authorising the use of the claims had not removed the claims from the market because they were put on the EU's on hold list. The Commission and Member States are still reflecting on what to do about these caffeine claims.

Poland

Code of Good Practices for the Advertising of Supplements

In order to bring more confidence to the category and better control aggressive and misleading communication in Poland, the supplement industry has published its Code of Good Practices for the Advertising of Food Supplements. The code has been endorsed by the four associations active on the market.

Poland notifies a change in its food supplements law: setting of minimum amounts for vitamins and minerals

Poland has notified a new draft national law to Brussels amending the Regulation on the composition and labelling of food supplements. The new rules includes the inclusion of (6S)-5-methyltetrahydrofolic acid (glucosamine salt) to the list of chemical forms of vitamins that can be used to manufacture food supplements. It also establishes minimum level of vitamins and minerals in food supplements (15% of the Reference Value) and harmonises the nomenclature and the manner of describing vitamins and minerals. The draft was notified on 9 January with a three-months standstill period.

No safety concerns for guar gum (E412)

There are no safety concerns for the general population. The European Food Safety Authority has indicated that there was no need for a numerical ADI for guar gum. However, concerns were raised for the use of additives in infant formula for very young babies.

Guar gum is currently permitted for use at *quantum satis*. It may not be used to produce dehydrated foods intended to rehydrate on ingestion.

Portugal

Portugal sets limits for the use of CoQ10, Arginine and 5-HTP in food supplements

The Portuguese authorities 'Borderline Products' Working Group has issued reports defining the borderline between medicines and food supplements regarding three substances, therefore setting conditions of use for their notification and use in food supplements on the Portuguese market.

Coenzyme Q10: up to 15 mg CoQ10 per day with a maximum of 5 mg per unit dose, and provided these are not intended for children.

Arginine: up to 1250 mg of arginine per day and provided that these are not intended to children.

5-HTP: up to 50 mg of 5-HTP per day and provided that these are not intended to children.

Food supplements not complying with these conditions but which have been notified up to the date of publication of these reports (10 Jan. 2017) can be marketed until exhaustion of stocks, if they are already placed on the Portuguese market or if they are produced before 30 June 2017.

Norway

Norway publishes the last batch of opinions relating to 'other substances'

Norway has released the last batch of opinions on the safety of the following 'other substances' including Glycine, Creatine, Collagen, L-tyrosine, L-lysine, L-serine, L-proline, L methionine, L-citrulline.

Overall no safety concerns have been identified at the doses currently present on the market except for the daily intake of:

- Creatine at doses = or > 5 g / day in adults and > 3 g / day in children
- L-tyrosine = or > 1250 mg / day in all groups
- Methionine: VKM maintains the guidance level from 2013 at 210 mg / day

These opinions are part of the risk assessment programme requested by the Norwegian Food Safety Authority in May 2015 to VKM (The Norwegian Scientific Committee for Food Safety) regarding the use of substances not harmonised in the EU.

Norwegian microorganism assessments for addition to food supplements

"It is unlikely that microorganisms in supplements have negative health effects for healthy population with mature intestinal flora." This is the conclusion of the recent assessment conducted by the Norwegian Scientific Committee for Food Safety (VKM) for 12 microorganisms found in supplements on the market in Norway.

VKM referred to the EFSA QPS (EFSA Qualified Presumption of Safety provided that literature did not identify new information pertinent to safety.

This risk assessment, together with those on 'other substances in food supplements and energy drinks' is expected to serve as a background for the development of the Norwegian legislation on 'other substances'.

New tolerable upper intake levels could be proposed for vitamin E and B6

VKM is proposing to adopt the tolerable upper intake level of 300 mg/day for vitamin E and 25mg / day for vitamin B6 for adults.

The Norwegian Scientific Committee for Food Safety (VKM) has, at the request of the Norwegian Food Safety Authority (NFSA), evaluated the intake of vitamin E and B6 in the Norwegian population and conducted scenario calculations to illustrate the consequences of amending the maximum limit up to 300 mg/day for

vitamin E and 25 mg/day for vitamin B6.

The existing maximum limit for vitamin E in food supplements is 30 mg/day and 4.2 mg/day for vitamin B6

The Netherlands

Proposal for a national maximum level for vitamin B6 in food supplements

The Dutch authorities are discussing the safety of vitamin B6 in food supplements, with a view to introducing a national maximum level for the use of vitamin B6 in food supplements.

Currently, the Dutch Commodities Act Regulation Exemption of Vitamins (Warenwetregeling Vrijstelling vitaminepreparaten) stipulates maximum levels and mandatory warning statements for vitamins A and D only.

This proposal is based on a risk assessment conducted by the agency for risk assessment and research programs (BuRO) with input from the Dutch National Institute for Public Health and the Environment (RIVM), commissioned by the Netherlands Food and Consumer Product Safety Authority (NVWA),

The level of 21 mg per recommended daily dose for supplements targeting adults was discussed, with potential warning statements for food supplements containing more than 3 mg per Recommended Daily dose (not suitable for children up to 4 years) and 13 mg (not suitable for children up to 19 years).

Turkey

Turkey publishes its health claims Regulation

The Turkey authorities have set rules for making nutrition and health claims in a new law which is very similar to the EU health and nutritional Regulation in term of content and procedure for the authorisation of new health claims.

The new law provides data protection for a period of five years for applicants who wish to register a health claim not included in the list.

Food operators have until the end of 2019 to comply with the new provisions. Food that is labelled or marketed prior to 31/12/2019 may be sold in the market until the end of its shelf life.

South Africa

Draft General Regulations to the Medicines and Related Substances Act

The Ministry of Health has published the draft General Regulations on the Medicines and Related Substances Act (GoN 50, GG. 40577, 27 January 2017), This set of proposed regulations aim to allow for the promulgation of the 2008 and 2015 Amendment Acts and launch the South African Health Products Regulatory Agency (SAHPRA) that will replace the Medicines Control Council (MCC).

The industry has been given 3 months to comment.
http://www.gov.za/sites/www.gov.za/files/40577_gon50.pdf

Brazil

Lacose declaration became mandatory

On 9 February the regulation implementing a lactose declaration on food labels, including raw materials, food additives and food supplements was published. The declaration, for absence and/or presence of lactose, must be placed below the list of ingredients. In addition, lactose and galactose content must be declared in grams and as a percentage of the Daily Value. As from 9 February 2019 all labels shall comply with this new regulation.

Chile

Legislative proposal to restrict the marketing of food supplements

On 21 December 2016, Senators from 3 different political parties, filed a legislative proposal to regulate the marketing of products containing additives or "stimulant substances" (caffeine, taurine and thiamine), referring especially to food supplements and energy dirnks. It is proposed to:
- Ban their marketing and advertising to children
- Ban their marketing inside schools
- Add new warning statements on the label of food supplements and energy drinks, referring to the effects in risk populations, such as pregnant women.
The proposal is being discussed at the Commission of Health at the Senate.

Proposal to establish conversion factors for nutritional labeling purposes

The Ministry of Health opened for public consultation the conversion factors for the energy calculation of carbohydrates, proteins, fats, alcohol, organic acids, polyols, erythriyol, tagatose, allulose, soluble fiber, fructooligosaccharides, inulin and polydextrose. The Ministry has taken the conversion factors from FAO Food and Nutrition Paper 77 “Food energy – methods of analysis and conversion factor”. Link to the proposal:
http://web.minsal.cl/wp-content/uploads/2016/12/RSA-consulta-pública-115-fact-atwat.pdf

Proposal to ban the marketing of food supplements in vending machines

The Ministry of Health opened for public consultation a proposal to introduce provisions for the marketing of foods in vending machines. It is proposed that foods classified under Title XXVIII “Foods for Special Diets” from the Sanitary Regulation of Foods, like gluten free foods, and Title XXIX “Food Supplements”, would not be allowed to be marketed through vending machines.
Link to the proposal:
http://web.minsal.cl/wp-content/uploads/2016/12/CP-74-eliminación-74aby75.pdf

Colombia

INVIMA's guidelines for the use of claims

In January INVIMA, the Colombia National Food and Drug Surveillance Institute issued guidelines for the evaluation and use of health and nutrition claims in food supplements, aiming to provide regulatory guidance for the use of claims for food supplements.

Procedures for importing and exporting food products and raw materials for human consumption

The Ministry of Health and Social Protection has notified to the World Trade Organization the draft Decree establishing the sanitary procedures for importing and exporting foods and raw materials for human consumption, aiming to simplify market access procedures. It proposes different requirements for importers and exporters, and also specific provisions for manufacturing plants producing products of animal origin abroad.

Ecuador

Technical regulation for food supplements issued

The authorties have recently released its Technical Standard for Food Supplements.

This standards foresees:

- A broader definition for food supplements, including but not limited to the following nutrients/ingredients: vitamins, minerals, amino acids, proteins, carbohydrates, essential fatty acids, plant concentrates and extracts and probiotics.
- Different presentation forms allowed: tablets, capsules, powder, granulated, jelly, gel, liquids (drops, solutions, syrup) and others
- Organoleptic, physico-chemical and microbiological specifications
- Contaminants limits
- Maximum limits for vitamins and minerals based on Upper Levels taken from US IOM
- Permitted additives: the ones foreseen in Ecuadorian technical Norm NTE INEN-Codex 192, recently approved.
- Permitted claims: the ones from norm INEN 1334-3. Claims approved by EFSA will also be accepted.

The above-mentioned specifications have been taken from the voluntary INEN standard 2983 on food supplements issued during 2016.

Nutrition and health claims rules under public consultation

The Ecuadorian Institute for Standardization (INEN) has opened public consultation on the modification of the Ecuadorean Technical Standard INEN 1334-3 on Nutrition and Health Claims. The main changes proposed are:

- To include the nutrition claim "Without …. Added" for sugars and sodium
- To remove the positive list of health claims and propose the criteria and documents to be presented for the evaluation of health claims.

Mexico

New additives permitted in the category of food supplements

On 24 February COFEPRIS published the updated version of the food additives regulation, which includes modifications for the use of certain additives in the category of food supplements. This update provides new provisions for the use of the following food additives in the category of food supplements: konjac flour (INS 425), anionic methacrylate copolymer (INS 1207), basic methacrylate copolymer (INS 1205) and steviol glycoside (INS 960).

Paraguay

Draft Regulation for Allergens Labeling

The National Food and Nutrition Institute (INAN) has opened a public consultation on the Draft Technical Regulation that aims to establish the requirements for the labelling of food allergens and sulfites in processed foods. It is proposed to make mandatory the declaration of food allergens on processed foods labels in all products. The declaration shall state "CONTAINS...(common name of the food)" or "CONTAINS DERIVATIVES OF… (common name of the food)". If cross-contamination could exist, the following declaration shall be used "IT MIGHT CONTAIN…(common name of the food)". There is no specification for the placement of the declaration; it just proposes that it should be on a visible part of the label.

Peru

Food supplements and sweeteners category re-classified as foods

On 7 January the Legislative Decree re-categorizing food supplements from medicines to foods was published. Before this date, food supplements were regarded either as foods or medicines, depending on their composition and presentation form. The Ministry of Health will have 60 days to expedite the regulation for food supplements under foods.

SIECA - Central American Secretariat for Economic Integration

Update in the food additives regulation

The resolution Nº 379-2016 modifications to the Central American Technical Regulation RTCA 67.04.54:10 on Food Additives has been approved by the Council of Ministers of Economy and Trade of Central America (COMIECO). This Resolution modified Annex I "Additives permitted for use under specific conditions in certain food categories" and Annex II "Food categories or individual food items in which food additives are permitted" introducing new permitted food additives and revised maximum limits and categories. This modification was made after the request received by the authorities to update the regulation on food additives. The new provisions came into force on 24 February 2017, except in Panama,which has not agreed the modifications.

Digital Platform to improve market access procedures

Member States of SIECA signed an agreement to promote the development of a Digital Platform for the Central-American Trade aiming to facilitate the trade in the region, reducing costs in the operations. This would be an electronic platform with integrated information of customs, sanitary and phytosanitary controls, etc., which will improve the market access procedures for goods, including food

Australia

Melatonin not available without a prescription

Melatonin will not be made available to Australian consumers without a prescription. This follows a decision by the Advisory Committee on Medicines Scheduling that melatonin for human use will for now remain in Schedule 4 of the Poisons Standard. Reasons stated for this move include that there is a lack of chronic use data, possible significant effects on multiple body systems at relatively small doses, risk of inappropriate intake potential for underlying sleep conditions not being diagnosed and potential interaction with other drugs (e.g. fluvoxamine, which can increase bioavailability of melatonin by 17-fold)

Canada

Natural and Non-prescription Health Products Directorate: Upcoming activities.

The Natural Health Products Directorate (NHPD) who has changed its name to the Natural and Non-prescription Health Products Directorate (NNHPD) subsequent to its recently expanded mandate to include the oversight of non-prescription and disinfectant drugs, has recently published an overview of its anticipated activities for the period covering January to June 2017.

During this period, the NNHPD will be examining a new approach to monograph development. This may include updates to existing monographs and incorporate publicly available information submitted in product license applications.

The publication of the following monographs is also scheduled to be posted as soon as ready: Multi-Vitamin/Mineral Supplements, Antioxidant monograph, Cognitive function products, Green Tea Extracts Selenium

USA

FDA reopens comment period on draft guidance for industry: fruit juice and vegetable juice as colour additives in food

The Food and Drug Administration reopened the comment period on its draft guidance for industry: fruit juice and vegetable juice as colour additives in food for 60 days to allow interested persons additional time to submit comments. The draft guidance, when finalized, will clarify when juices from fruits and vegetables may be used as colour additives in food under existing authorizations without additional premarket review and approval from the agency under its colour additive petition process.

Public meeting to discuss use of the term “healthy” in food labelling

The U.S. Food and Drug Administration announced a public meeting to discuss the use of the term “healthy” in the labelling of food products. The public meeting, held on 9 March, discussed the use of the term “healthy” in the labeling of human food products.

CFSAN to issue PDF Export Certificates for Food Products

From 20 February 2017, certificates of free sale (COFS) for food products regulated by the U.S. Food and Drug Administration’s Center for Food Safety and Applied Nutrition (CFSAN) will be issued online as downloadable PDFs.

Some countries require a certificate as part of the process to import a product. FDA will provide assistance to exporters that are unable to use the new PDF system.

Russia

Russia proposes amendments to regulations on food supplements

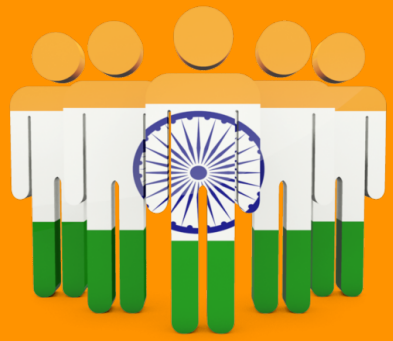
The Federal Research Centre for Nutrition and Biotechnologies has developed draft amendments and additions to three food regulations: CU TR 021/2011 On food safety: amendment 4, revokes special requirements for food supplements; CU TR 022/2011 On food labelling: amendment 3, revokes special requirements for food supplements; CU TR 027/2012 On safety of certain types of foods for special use, including dietary therapeutic and dietary prophylactic foods: amendment 1 introduces special requirements for dietary supplements, their manufacture, sales and labelling.
The document covers different aspects of safety, quality and circulation as applied to food supplements.
In particular, the document introduces food categories which are new to the Eurasian Union and Russian legislation: food supplements (nutraceuticals); food supplements (phytonutraceuticals); functional foods whose positive effect on human health has been demonstrated; and various types of foods for special use intended for athletes.

The draft amendments to the food labelling regulation deal with different aspects of labelling; in particular, they introduce the minimum font size; the notion of “information about distinctive features and efficacy” complete with the requirements for such information; new daily intake requirement values for nutrients and calories, etc.

The draft amendments are to be submitted to the Eurasian Economic Commission (EEC) for their first review and to be further presented for public discussion.

IADSA
International Alliance of Dietary/ Food Supplement Associations
Gridiron Building
One Pancras Square
London N1C 4AG, UK
www.iadsa.org

Focus on India



India is the world's largest democracy and according to UN estimates, its population is expected to overtake China's in 2028 to become the world's most populous nation.

Population 1.3 billion

The Law

Food Safety & Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) - Published in the Gazette on 23 December 2016.

Companies have until 1January 2018 to comply with the new requirements.

The regulation covers 8 categories

- Health Supplements
- Nutraceuticals
- Foods for Special Dietary Use
- Food for Special Medical Purpose
- Speciality Food containing plants or botanicals
- Foods containing Probiotics
- Foods containing Prebiotics
- Novel Foods

IADSA

International Alliance of Dietary/ Food Supplement Associations

2 categories to define supplements

Health supplements
are to be used to supplement the normal diet of a person above the age of five years

Nutraceuticals
are to be used for providing physiological benefits and to help maintain good health

FORMS & COMPOSITION
- Products in small dosages designed to be taken in measured unit quantity
- Composed of vitamins, minerals, probiotics, botanicals or other ingredients with a nutritional or physiological effects
- Use alone or in combination

MAXMUM LEVELS
- For vitamins & Minerals: 1x RDA

INGREDIENT LISTS
- Health Food + Nutraceuticals: Schedule I or Schedule II or Schedule IV or Schedule VII or Schedule VIII or
- Enzymes only of Schedule VI for supplements
- All substances in Schedule VI for nutraceuticals
- For ingredients not on the list, they will have to be approved via the Regulations on Approval for Non-Specified Food and Food Ingredients still under discussion.

CLAIMS
- **Statements relating to the structure or function or the general well being of the body may be allowed by the Food Authority if the statement is supported by the generally accepted scientific data**

THE SCHEDULES
- Schedule I vitamins and minerals and their components including permissible overages
- Schedule II amino acids and other nutrients
- Schedule IV plant and botanical ingredients
- Schedule VI nutraceutical ingredients
- Schedule VII probiotic strains
- Schedule VIII prebiotic compounds
- Schedule VA, VE, VF food additives for health supplements

IADSA

International Alliance of Dietary/ Food Supplement Associations

THE LABELLING - Should contain
- The word “HEALTH SUPPLEMENT” or “NUTRACEUTICAL”
- The common name of the product
- The amount of the nutrients or substances with a nutritional or physiological effect present in the product
- An advisory warning ‘NOT FOR MEDICINAL USE’ prominently written
- The quantity of nutrients, where applicable expressed in % of the relevant RDA and a warning “Not to exceed the recommended daily usage”
- A statement that the health supplement is not be used as a substitute for a varied diet
- Warnings/restrictions of use where appropriate (incl. drug interactions)
- A statement that the product is required to be stored out of reach of children