IADSA NEWSFLASH

OCTOBER 2018

Codex Alimentarius: At a crossroads?

Codex is the global food standards setting body. As such, it develops standards and guidelines that all its 189 members should adhere to. Where a barrier to free trade arises, a Codex measure is taken as a key reference point in adjudicating who is right and who is wrong.

At the Codex Nutrition Committee in November in Berlin, two new initiatives are being tabled which could significantly impact elements of the future global regulatory framework for supplements. Argentina has put forward a proposal on probiotics that would establish harmonized probiotic guidelines for use in foods and dietary supplements. This would, for example, require government approved bodies to do pre-testing of products prior to marketing. Egypt has put forward a proposal to regulate protein in body building supplements, although it is unclear what the measures would involve.

For many years, Codex has been effective at developing so-called horizontal requirements for foods, including food supplements. Working with Codex and its member governments, we have made considerable progress on the additives that can be used in manufacturing supplements, the broad requirements for claims and many other issues.

However, these two new initiatives raise some specific challenges and questions about the future direction of Codex.

- Is it the task of Codex to regulate specific sub-sectors of the supplement category, in this case probiotics and protein supplements?
- If regulation is initiated on one part of the category, will this not begin a process of regulation on all parts?
- If government-approved testing is required for probiotics products, is there not a risk it will become a requirement for other products?

IADSA has been engaged in Codex for many years. We have worked hard to support Codex and its member countries to achieve results in legislation that are good for government, the supplement sector and the consumer.

We now appear to be at a crossroads. Coordinated work will be required across IADSA to ensure that supplement sector interests are protected.

CODEX NUTRITION
40th session

IADSA Agenda
Berlin, Germany
26 - 30 November 2018

1. Discussion paper on NRV-R for older infants and young children
2. Discussion paper on harmonized probiotic guidelines for use in foods and dietary supplements
3. Proposed Draft NRV-NCD for EPA and DHA long chain omega-3 fatty acids
4. Proposal for new work on the general requirements for protein supplements intended for bodybuilding

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

India

ICRM releases its ULs for Vitamins and Minerals

The Food Safety Science Authority of India (FSSAI) has issued a notice containing the Indian Council of Medical Research's (ICMR) study on the tolerable upper limits (TULs) of the nutrients applicable for products under the Food Safety and Standards Regulations, 2011, on health supplements, nutraceuticals, foods for special dietary use and special medical purpose, functional and novel foods.

The Indian TULs are very much in line with the values established by other international organisations. They have been specifically developed to review whether the maximum limits of vitamins and minerals in supplements should be raised above the current legal limit of 1x RDA.

India is one of the few countries where maximum levels are still not based on safety.

Supplements important for public health says Pawan Kumar Agarwal Chief Executive Officer, FSSAI

The CEO of the Food Safety and Standards Authority of India (FSSAI) has stated at a recent meeting of the Resource Centre on Health Supplements and Nutraceuticals, "The health supplement sector is very important for the country, not only from the industry growth, but also from the public health point of view. FSSAI has taken up the task and is collaborating with various countries to create a data bank of knowhow on the subject of health supplement and nutraceuticals."

This statement was reported in the national media following a conference held by ReCHaN in July.

Earlier this year, FSSAI signed a Memorandum of Understanding (MoU) with ReCHaN, the resource centre established by IADSA and the Confederation of Indian Industry CII to support best practices and enable effective science-based standards and regulations in the country.

South Korea

New requirements for Health Functional Ingredients

The Korean Ministry of Food and Drug Safety (MFDS) has revised its provisions related to the use of green tea extract, aloe vera leaf, garcinia cambogia extract, and probiotics: The daily intake of epigallocatechin gallate (EGCG) in catechins as functional ingredients is set at 300 mg together with warnings for consumption and directions for use. Directions of use for Aloe Vera Leaf and Garcinia Cambogia extract are added. The production method of probiotics has also been revised and directions of use are newly included. Enterococcus strains among the raw materials of probiotics should be used only when there is no antibiotic resistance gene or toxic gene.

The amendment became effective on the date of publication on 5 September 2018.

*http://www.mfds.go.kr/brd/m_207/view.do?seq=14285&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=*1

Taiwan

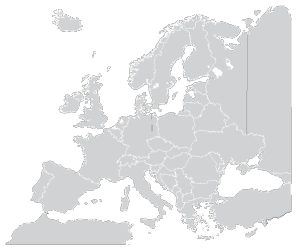
From 6 to 11 allergens

The Ministry of Health and Welfare has announced the revision of the Food Allergen Labelling Regulation, having in mind the need to align the regulation with international food allergen labelling guidelines and domestic food allergies clinical data.

The amendment expands the number of allergen substances from 6 to 11, namely:

- Crustacea and products thereof.
- Mango and products thereof.
- Peanut and products thereof.
- Sesame, sunflower seeds and products thereof.
- Milk, goat milk and products thereof, except lactitol derived from milk and goat milk.
- Egg and products thereof.
- Nuts and products thereof, including almond, hazelnut, walnut, cashew nut, pecan, brazil nut, pistachio nut, macadamia nut, pine nuts, chestnuts etc.
- Cereals containing gluten and products thereof, including wheat, barley, rye, oats etc.
- Soybean and products thereof, except highly refined or purified soybean oil (fat), tocopherols and their deviation, phytosterols and phytosterol esters.
- The use of sulphites and sulphur dioxide etc., at concentrations of 10 mg/kg or more in term of total SO2 which are to be calculated for final products.
- Fish and products thereof, except fish gelatine used as carrier for vitamin or carotenoid preparations; fish gelatine used as thickening agent in alcohol.

The new requirements will enter into force in July 2020.



European Union

Egg membrane hydrolysate up for authorisation as novel ingredient for supplements

The European Food Safety Authority has recently given the green light to egg membrane hydrolysate as a novel food at the dose of 450mg a day in food supplements.

Egg membrane hydrolysate is a protein-based, water-soluble, off-

white powder, with its main constituents' elastin, collagen and glycosaminoglycans, and is derived from the eggs of farmed hens *(Gallus domesticus)*.

The next step is for the European Commission to propose authorisation, which would require a qualified majority vote in favour by the European Union Member States.

Two novel foods get qualified majority

Member States agree to authorise two novel ingredients for supplements by qualified majority.

The applications are for pyrroloquinoline quinone disodium and 1-methylnicotinamide chloride authorised respectively at a maximum daily level of 20 mg and 58 mg.

Both applications, for which the European Food Safety Authority concluded they were safe under the proposed uses and use levels, have gained data protection for a period of 5 years.

EU corrects its Novel Food list

The European Commission has recently corrected its Union list of novel foods.

This amendment, made to correct a number of issues in the initial Union list (version of 20 December 2017), shall be binding in its entirety and directly applicable in all Member States.

EFSA looks at the safety of propane-1,2-diol alginate (E 405)

The European Food Safety Authority (EFSA) has recently confirmed that the use of propane-1,2-diol alginate (E 405) poses no safety concern.

The Authority has specifically indicated that the exposure estimates did not exceed the ADI of 55 mg/kg bw per day in any of the population groups studied.

The additive is currently permitted for use in supplements at 1000 mg/kg.

Safety of Astaxanthin to be re-established

EFSA has launched a call for data in view of the safety assessment of Astaxanthin as a novel food (NF) in the framework of Regulation 2283/2015.

http://www.efsa.europa.eu/en/consultations/call/180725

This follows a request of the European Commission seeking EFSA's advice on whether the safety of astaxanthin used as a novel food in food supplements at maximum levels of 8 mg/day is still in accordance with the requirements of the Novel Food Regulation, taking into account the overall cumulative intakes of astaxanthin from all sources, including from its approved uses in food supplements and in other foods.

EFSA raises red flag on the safety of Monocolin K

Monacolin K - for which health claims on the maintenance of blood LDL cholesterol concentration have been authorised - could lead to severe adverse effects on musculoskeletal system said the European Food Safety Authority (EFSA).

The EFSA opinion confirms the conclusion of several member States in the EU that raised concerns about the existence of adverse effects linked to the intake of the ingredient.

The EFSA conclusions could lead the Commission to prohibit the use of monacolin K from red yeast rice in food supplements.

Novel Food approval for lactitol powder

EU authorises lactitol powder as novel food ingredient in supplements

The green light to market has been given to lactitol powder as an ingredient in food supplements.

This authorisation is an extension of a Decision published in March 2017 authorising the use of lactitol in capsules or tablet food supplements at a maximum level of 20 g/day.

Lactitol is also authorised as a food additive in several foods, including food supplements. The Novel Food Decision authorises its use for nutritional/physiological purposes.

EU authorises Low-substituted hydroxypropyl cellulose (L-HPC) for supplement tablets

The European Commission has recently updated its permitted list of food additives to include Low-substituted hydroxypropyl cellulose (L-HPC) E 463a for use in food supplements in tablet forms at a maximum use level of 20,000 mg/kg.

The additive is water insoluble cellulose that facilitates the manufacturing of solid food supplements in tablet form due to its good compressibility and binding properties.

France

The Food Safety Agency issues alert on the risk of excess iodine intake

The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) has recently published an opinion on the risk of an excess iodine intake linked to the consumption of seaweed in foodstuffs.

In this opinion ANSES calls against the consumption of seaweed and seaweed-based food supplements by certain at-risk populations (as specified in the press release), and recommends that regular consumers remain vigilant.

Furthermore, ANSES highlights that seaweed based supplements are not appropriate for correcting iodine deficiency.

It now remains to be seen if the competent authorities wish to further consider any warning statements or other regulatory measures to address this issue.

https://www.anses.fr/en/content/seaweed-consumption-remain-vigilant-risk-excess-iodine-intake

Italy

Italy revises its plant Decree

The new plant Decree recently published is fully replacing the previous national plant Decree of 9 July 2012 (as last amended by the Decree of March 2014).

The key changes relate to the details in the Annex, which now provide a single positive list of plants permitted for use in food supplements (around 1300 species). This includes details for each plant of the Latin botanical name and family, Latin synonym names, permitted 'traditionally used plant parts' and special labelling / warning statements and/or other indications, if any.

The new law now also integrates into legislation an updated version of the Ministry of Health Guidelines on the

required 'documentation supporting the use of substances and plant preparations (botanicals) in food supplements'.

While the documentation is not required to be included in the notification file of the standard food supplement notification procedure, an electronic or hard copy dossier including this documentation may at any time of marketing be requested by Italian competent authorities, such as the Italian Ministry of Health or other Italian control authorities.

Latvia

Latvia notifies draft rules for botanicals

Latvia has notified in the TRIS system (2018/421/LV) a new Regulation relating to plants, parts of plants and other substances prohibited or restricted for use in foods.

This new Regulation seeks to introduce more specifically a list of 62 plants and parts of plants which may not be used in foods. Most of these plants are well known for their toxicity. It also lists 16 plants and parts of plants whose use in foods is restricted and 13 species that can be used only in food supplements.

The entry into force of the Regulation is planned for 1 January 2020.

New mandate for EFSA to look into particle size and distribution of Titanium Dioxide

The Authority has formally received a new mandate to look at the particle size of Titanium Dioxide (E171). This mandate relates to an opinion of 2016 where the Authority said that the particle size and distribution should be characterised in the specification. The opinion should be finalised within 9 months.

Titanium Dioxide has been subject to mounting concerns in France over the last months. The government has requested EFSA to reopen its opinion which concluded that the additive did not cause cancer. In July, EFSA reiterated the safety of the additive.

The Netherlands

Limits for Vitamin B6 introduced

The Netherlands has recently published their final legislative text imposing a maximum level of 21 mg Vitamin B6 per daily recommended dose on food supplements for adults and lower limits for products specifically targeting children of various age groups.

The MLs applying to Vitamins A and D remain as they are in law today (1.200 µg RE Vitamin A and 75 µg Vitamin D). The law published in August comes into effect on 1 October 2018.

United Kingdom

Change of status for glucosamine products

The Medicines and Healthcare products Regulatory Agency (MHRA) has recently announced that products containing doses equal to or greater than 1178mg/day of base glucosamine (equivalent to 1500 mg glucosamine sulphate) will now be considered to be medicines.

Food supplements containing levels below 1178 mg/day can continue to be sold. However, in order to observe a difference with registered medicinal products, the industry trade organisations are recommending that food supplements should contain no more than 1100 mg/d of base glucosamine (equivalent to 1400 mg glucosamine sulphate.)

This MHRA statement follows a judgment of a Court of Appeal that is based both on the evidence of pharmacological effect of glucosamine on the body and the fact the substance is used by for a medicinal purpose.

This new position will require the reformulation or change of status of those products affected in the UK. This would in principle not change the situation and legal status of glucosamine in other Member States.

UK seeks views on post Brexit food law

The UK Food Standards Agency has launched a public consultation on the proposed approach to 'retained' EU law for food and feed safety and hygiene.

FSA emphasizes that '*subject to negotiations with the EU, the UK will redefine and formalise a close working relationship with EFSA based on exchange of information and expertise, contribution to scientific networks, and cross-European collaboration*'.

FSA also proposes to '*allow the appropriate UK authorities (rather than the EU Commission) to set safety levels (for instance relating to hygiene or contamination) which foods must comply with and provide approvals*'.

In June 2016, the UK held a referendum with a majority vote to leave the European Union in March 2019. A process called Brexit under which food safety management functions today performed by the EU will return to the UK.

Brazil

New regulation for food supplements released

On 27 July, Brazil issued a new "package" of rules for food supplements which brings more clarity to the regulatory framework for this category. The new regulation provides a positive list of permitted ingredients and substances, specific labelling provisions, a list of permitted nutrition and health claims and a positive list of food additives. For many ingredients on the permitted list, a maximum and minimum level has been set. The maximum limits for vitamins and minerals are now higher than they were previously in Brazil and are now more aligned with other regulations in the region. Significantly, the majority of food supplements will not be subject to registration, but to a simpler notification process. However, food supplements containing enzymes and probiotics will still need to be registered. ANVISA has in addition issued a specific regulation for the use of probiotics in all food products, including food supplements. It provides the requirements for the assessment of probiotics, including the demonstration of safety in addition to the health benefit provided by the strain. Recently ANVISA has published a FAQ related to the application of this new package of rules as a way to provide clear guidance.

Mexico

Regulation for food additives is updated once again

During July, the sanitary authorities from the Federal Commission for the Protection Against Sanitary Risks (COFEPRIS) updated the regulation for food additives, which impacts all food categories, including food supplements. Changes have been introduced for the use of polysaccharides from tamarind seed, which can be used according to GMP, with the following functional classes: thickener, emulsifier, stabilizer and gelling agent. In addition, it has been added the glucoamylase from Trichoderma reesei containing glucoamylase gene isolated from Fusarium verticillioides for use in the manufacturing of corn sweetener, with a maximum limit of 0.16 GAU/g of dry starch.

Uruguay

Draft regulation for food supplements

In August, the Ministry of Health opened for public consultation a draft regulation for food supplements. The proposal included a definition that foresees the use of enzymes, probiotics, bioactive substances, extracts, in addition to vitamins and minerals. The ingredients allowed should be authorized as food ingredients and in the case of novel ingredients, those approved by Brazil and/or the European Union would be accepted. Maximum limits for vitamins and minerals are based on NOAEL. For the use of health claims, only those allowed by the European Union, the Food and Drug Administration from the United States, the Public Health Agency from Canada and ANVISA from Brazil would be allowed. The consultation closed on 14 September.

United States

FDA Issues Draft Guidance on the Labeling of Dietary Supplements Containing Live Microbials

The U.S. Food and Drug Administration has issued draft guidance on the Labeling of Dietary Supplements Containing Live Microbials.

The draft guidelines require firms to declare in the Supplement Facts label the quantity of live microbials in colony forming units (CFUs), in addition to the quantitative amount by weight required by regulation.

Eurasian Economic Union

Commission adopts readability criteria for food labels

The July meeting of the Eurasian Economic Commission Board considered the latest version of amendments to its technical regulation on food labelling, which specifies the requirements of legibility and understanding as applied to food /food food supplement labels.

As per the amendments:

- the criteria of legibility are based on the use of a minimum font size and the use of a contrasting background;
- They apply to any message or representation,
- the product's name, quantity, manufacture date and expiry date are to be displayed in a font size not smaller than 2 mm in height;
- The font size must not be smaller than 0.8 mm height for lowercase letters. This applies to information related to the product's composition and storage conditions, name and address of the manufacturer / entity/ importer, recommendations and/or restrictions, as well as the contact details of the manufacturer, date and expiry date.

If passed into law the amendments will require manufacturers to redesign their product labels.

EEC launches major revision of technical regulations to account for new procedures of conformity assessment

The Eurasian Economic Commission (ECC) Board has proposed for public discussion a draft resolution which calls for amendments to the Customs Union technical regulations and introduces the new conformity assessment formats and procedures based on the recently adopted standard (EEC Council's Resolution On standard conformity assessment procedures).

There are no deadlines for the introduction of amendments, which are to be introduced "as available". The amendments are to be drafted by the EEC in conjunction with the EAEU member states.

The rules governing the issuance of state registration certificates for foods for special dietary purpose (including dietary supplements) will be amended to limit the validity of such certificates to five years.

Belarus

Belarus harmonises law on consumer rights protection with EAEU technical regulations

Amendments to the law on consumer rights protection have recently been published on Belarus's National Legal Internet Portal.

In particular, the amendments specify the information to be provided to consumers by manufacturers (vendors or suppliers). This includes:

- the product's composition, nutrition declaration (for foods intended for infants, for therapeutic and dietetic use, additionally the calorific value and the presence of vitamins);
- statement of the presence of GMO, if any,
- information about special properties (special nutrients, indications and contraindications for individual age groups and for certain ailments), including for dietary supplements, and claims for foods for special uses provided such claims are supported by documented evidence.

Codex Alimentarius at a glance

IADSA
International Alliance of Dietary/ Food Supplement Associations

The Codex in numbers for Food Supplements

Codex held its first Session in **1963**

IADSA first participation **20 years ago**

1 — Specific Guidelines

56 — Food additive provisions specifically for food supplement

239 — Food addtives that may be used in supplements (Cat.13.6 + Table 3 Provisions)

15% — Codex recommended minimum level of each vitamin and/or mineral contained in a vitamin and mineral food supplement per daily portion (CAC/GL 55 - 20)

2005 **Guidelines for Vitamin and Mineral Food Supplements CAC/GL 55 - 2005**

SAFETY

Maximum amounts of vitamins and minerals in food supplements shall be set taking into account upper safe levels of vitamins and minerals established by scientific risk assessment.

How Codex works

Codex & Science

1955
JECFA

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) was established in 1955. JECFA's work is of fundamental importance to the Codex Alimentarius Commission's deliberations on standards and guidelines for food additives, contaminants and residues of veterinary drugs in foods.

1963
JMPR

The Joint FAO/WHO Meetings on Pesticide Residues **(JMPR)**. JMPR meets regularly since 1963 to review residues and analytical aspects of the pesticides, estimate the maximum residue levels, review toxicological data and estimate acceptable daily intakes (ADIs) for humans of the pesticides under consideration.

2000
JEMRA

The Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (**JEMRA**) began in 2000 in response to requests from the Codex Alimentarius Commission and FAO and WHO Member Countries and the increasing need for risk based scientific advice on microbiological food safety issues. JEMRA aims to develop and optimise the utility of Microbiological Risk Assessment (MRA) as a tool to inform actions and decisions aimed at improving food safety.

2010
NUGAG & JEMNU

In 2010, the Joint FAO/WHO Expert Meetings on Nutrition **(JEMNU)** was established. JEMNU aims to strengthen the role of FAO and WHO in providing scientific advice on nutrition to Member States and bodies such as the Codex Alimentarius Commission. The process is described in the document, "FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition".

Codex also considers scientific advice from the WHO Nutrition Guidance Expert Advisory Group **(NUGAG)**, established in 2010 "*to strengthen the evidence based on effective and safe nutrition actions to counteract the public health effects of the double burden of malnutrition.*" NUGAG's work includes updating the dietary goals for the prevention of obesity and diet-related noncommunicable diseases (NCDs) and the WHO guidelines on sugars and fatty acids.

IADSA
International Alliance of Dietary/
Food Supplement Associations

Contaminants in Foods – CCCF
Netherlands

Food Additives – CCFA
China

Food Hygiene – CCFH
USA

Food Import and Export Inspection and Certification Systems – CCFICS
Australia

Food Labelling – CCFL
Canada

General Principles – CCGP
France

Methods of Analysis and Sampling – CCMAS
Hungary

Nutrition and Foods for Special Dietary Uses – CCNFSDU
Germany

Pesticide Residues – CCPR
China

Residues of Veterinary Drugs in Foods – CCRVDF
USA

Statutes of the Codex Alimentarius Commission ARTICLE 1

The Codex Alimentarius Commission shall ... be responsible for making proposals to, and shall be consulted by, the Directors-General of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) on all matters pertaining to the implementation of the Joint FAO/WHO Food Standards Programme, the purpose of which is:

(a) protecting the health of consumers and ensuring fair practices in the food trade;

(b) **promoting** coordination of all food standards work undertaken by international governmental and non-governmental organizations;

(c) **determining priorities** and initiating and guiding the preparation of draft standards through and with the aid of appropriate organizations;

(d) **finalizing standards** elaborated under (c) above and publishing them in a Codex Alimentarius either as regional or worldwide standards, together with international standards already finalized by other bodies under (b) above, wherever this is practicable;

(e) **amending** published standards, as appropriate, in the light of developments.

Codex process Steps 8

Standards take an average of **4.2** years to develop

Discussion paper

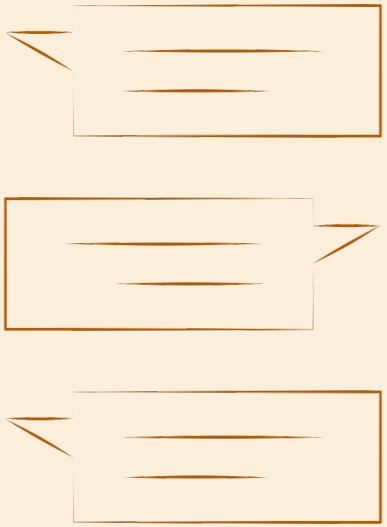
including
purpose + scope of the standard
Time frame/ priority /relevance
Identify need for technical/ scientific imput

STEP 1 Project document

Proposed draft Standard

The Secretariat arranges for the preparation of a proposed draft standard - usually through electronic working groups

STEP 2



Comments

the draft text is circulated for comment through the Codex Online Commenting System (OCS)

STEP 3

Comments

the draft text is amended by the organisation that has been assigned to develop the Standard

STEP 4

draft text

Draft text presented to the Executive Committee for critical review and to the Commission for adoption

STEP 5

Comments

The draft text is circulated to members and observers who have another opportunity to comment

STEP 6

Critical review

The comments are considered and final amendments are made

STEP 7

Codex Standard

Draft text presented to the Executive Committee for critical review and to the Commission for adoption as a Codex Standard

STEP 8

STEP 5/8

Steps 6/7 can be omitted. This practice speeds up the adoption process