IADSA Newsflash

December 2015

The sky has not fallen in!

10 years ago in 2005 the Codex vitamin and mineral supplement Guidelines were adopted. After many years of discussion in the Codex Committee on Nutrition, a single global text was agreed by the Codex Commission, which would define the way in which supplements should be treated in many aspects of regulation in the future.

Across the world, the development of supplement legislation can often be highly emotive. The creation of the Codex Guidelines was exactly this. With some claiming the agreement of a Codex text would at best destroy the sector and at worst kill people, this was a highly charged time. The accusations against IADSA for our role in this Codex process by these same extreme forces were strong; the accusations against governments were in some cases outrageous in a way we hope we will never see again in our sector.

But we rode the storm, we communicated the importance of science being at the heart of regulation and over time governments gradually reached consensus. This permitted the adoption of the Guidelines by all Codex governments, with the simple number CAC/GL 55 - 2005

What have the Guidelines achieved? First and foremost they have put our category well and truly on the map in global regulation. We have had many attacks across the world on our category since 2005 and Codex has been a cornerstone of arguments to protect it.

Second, the RDA as a basis for establishing maximum levels of vitamins and minerals is now limited to a small number of countries worldwide. This was not the case then, with many countries limiting food supplements to the low limits defined by 100% of the RDA. The Guidelines made it clear that this was not permitted and that scientific risk assessment has to be a basis for establishing maximum levels of vitamins and minerals.

Third, it showed clearly that when a sector identifies a challenge globally, as IADSA did at its creation in 1998, by working together across the world it was possible to achieve change and get a positive result.

There were many vocal people outside IADSA who said the “sky would fall in if the Codex Guidelines were adopted”. It has not.

International Alliance of Dietary/Food Supplement Associations
International Non-Profit Organisation
50 Rue de l’Association, B-1000 Brussels -Belgium
Tel: +32 2 209 11 55 Website: www.iadsa.org

IADSA

International Alliance of Dietary/ Food Supplement Associations

Regulatory news

ASEAN

Updates on ACCSQ TMHS PWG Meeting

The ASEAN Health Supplements Traditional Medicines Product Working Group (TMHS PWG) held it's 24th Meeting from 12th – 16th October 2015 at Makati City, Philippines. The Meeting continued discussed on Indonesia's concern on the legally binding agreement and the possibility for the ASEAN-X option, which means that Indonesia would opt out of the Agreement. At the last minute, Indonesia agreed to move ahead with both agreements on Health and TM being binding, a hugely significant move given the size of Indonesia.

The TMHS PWG has now finalized and endorsed the agreement (with the technical annexes). The ASEAN Member States will now proceed with the legal scrubbing. An inter-sessional meeting will be held in March for the endorsement of the legal text.
While this is a great result for the sector worldwide, it is also very clear that work in ASEAN led by AAHSA is far from over. The next stage - implementation of the Agreement – is a critical part of the ASEAN process.

ASEAN Community established

Thirteen years after the idea was agreed by Southeast Asian leaders, on 22 November a unified economic community in a region more populous and diverse than the European Union and North America was established.

The Declaration was signed by the 10 ASEAN countries in Kuala Lumpur, Malaysia. With 625 million people and a combined economic output of $2.6 trillion, ASEAN becomes the world's seventh-largest economy.

Indonesia

Processed food advertising only after obtaining marketing approval

Advertising of processed food may be permitted only after marketing approval from the national authority. Information contained in the advertisement must be in accordance with the approved label, correct and not misleading.
The draft also sets specific requirements related to the use of terms such as "natural", "only", "more", "healthy/smart" and bans the use of the words like magic, modern, new discovery.

The draft Regulation also states that advertising should not involve health workers, religious leaders or public officials, or act as health workers or public officials.

https://members.wto.org/crnattachments/2015/TBT/IDN/15_3693_00_x.pdf

Philippines

Draft Guidelines on the Regulation of Dietary/Food Supplements

The food division of the Philippines FDA (PFDA) is currently working on the Draft Guidelines on the Regulation of Dietary/Food Supplements.
The first draft illustrates the importance that the sector still have to play to ensure a successful implementation of the ASEAN agreement with some variations being seen in the text.
The Philippines is represented at the ASEAN TMHS meetings by the drug division and not food division, which may likely explain the current variances observed.

China

Updates of National Food Safety Standards

China National Health & Family Planning Commission (NHFPC) has been in the process of revamping about 5,000 national food safety standards since 2010. Since then, NHFPC has issued more than 600 new and revised food safety standards, and many more are still under consultation and reviews.
In October, 135 new food safety standards were published, including specifications for food additives, nutrient enhancers and food products, testing methods for contaminants and food components, and general hygienic practice for the production of food contact materials and related products.

Implementation of the food safety law delayed

Delays are now occurring on the next steps of the provisions to implement a notification system in China for health foods/food supplements. With drafts circulating which would cause challenges to companies both manufacturing in China and those exporting to China, it is not expected that progress will be made until 2016.

CFDA strengthens its food safety system

To better implement the new Food Safety Law and effectively protect public safety, CFDA is considering strengthening the supervision and the management of its food safety system. The changes with focus on the foundation of the food safety system itself, the responsibility for food producers and traders, the involvement of third-party or industry associations and penalties for infringers. The draft measures setting those changes is open for public consultation

India

Zinc could be removed from the contaminant list

FSSAI has recently launched a call for views on the removal of zinc from the contaminants list. The objections or suggestions should be made before 13.01.2016.

Pakistan

Need to set up a Pakistan Halal Authority

The National Assembly passed early December a bill to establish the Pakistan Halal Authority to promote imports and exports of Halal food products with foreign countries and inter-provincial trade and commerce. The Pakistan Halal Authority will be tasked to develop and implement polices, strategies and programmes for promotion of imports and exports, trade and commerce of Halal food and processes, recommend Halal standards

based on Islamic rules, develop and recommend mechanism of certification of Halal products, authorize a halal logo and inspect and test Halal products and processes. According to the bill, the Standards will define the basic requirements that should be met at each stage of the food chain. Products cover by the Bill include dietary supplements, food additives & enzymes.

Tawain

FDA revises its supplement shipping policy

Taiwan Food and Drug Administration (TFDA) has recently announced the revision of its current supplement shipping policy. From 1 December, the volume of foods in tablet and capsule forms which can be imported for personal use will be adjusted from 1200 tablets (up to 12 bottles) to 36 bottles. Those who fail to follow the regulations will be fined. Products imported to Taiwan through these channels must not be resold.

South Korea

Korean FDA consults on its new additive Standards

The Food and Drug Division announced the alignment of Food Additives classification system with international standards. The current system currently classifies additives as either "natural " or "synthetic " forms. Under the new rules, food additives will be classified into 31 technical functions. The current list which today contain 605 compounds will be extended to 607 additives with the inclusion of neotame and the new designation of sodium ferrous citrate. Comments on the new draft can be submitted until 27 January 2016.

New Zealand

New Zealand consults on draft Regulation of Natural Health Products

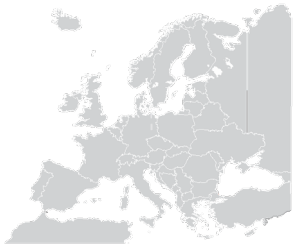
The third reading of the Bill could hopefully be expected prior to Easter. Feedback is sought on what the regulations and notices will specify, labelling requirements, fees associated with manufacturing and selling permitted NHPs, type and quality of evidence used to support health benefit claims, manufacturing requirements, permitted substances and conditions about which claims can be made. Consultation closes on 5 February 2016.

Australia

Vitamin B3 can save $2 in healthcare costs for every $1 spent

New health economics analysis, presented to members and senators in Parliament House in November, showed that vitamin B3 (nicotinamide) can save $2 in healthcare costs for every $1 spent. The economic modelling was based on the ONTRAC study, an Australian research paper, which was published in the New England Journal of Medicine and showed a 23% reduction in the risk of new skin cancers.

A Phase 3 Randomized Trial of Nicotinamide for Skin-Cancer Chemoprevention. N Engl J Med 2015; 373:1618-1626, 22 October, 2015, DOI: 10.1056/NEJMoa1506197



France

Beyond 1 mg per day melatonin becomes a medicine

The lack of clarity on the dispensing of melatonin has now come to an end. The substance, classified on List II of poisonous substances, cannot be given without a prescription for doses exceeding 1 mg. In addition, a prescription is required, renewable for one year.
Similar restrictions to limit the use to 1 mg/day have been taken in Italy and Spain in 2013. In 2011 EFSA acknowledged that a cause and effect relationship was established between the consumption of melatonin and reduction of sleep onset latency for a dose of 1 mg of melatonin consumed close to bedtime.
The authorization of this claim raised at that time many concerns among the EU Member States who consider melatonin as a medicine. To address this issue the EU Commission included a recital in the Regulation establishing the list of permitted claims stating that any decision on a health claim does not constitute an authorisation to the marketing of the substance on which the claim is made, a decision on whether the substance can be used in foodstuffs, or a classification of a certain product as a foodstuff.

Norway

Import of Vitamin and mineral Supplements to Norway challenged

Import of some products with higher levels of vitamins and minerals than those permitted in Norway have been prohibited under the falsified medicinal product Directive 2011/62/EU. Under this Directive, falsified medicinal products are defined as medicinal product with a false representation of:(a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;(b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or(c) its history, including the records and documents relating to the distribution channels used.'

The Norwegian Scientific Committee for Food Safety (VKM) releases its first opinion on the safety of "other substances" found on the Norwegian market

12 out of the 44 risk assessments of other substances foreseen have recently been released by the Norwegian Scientific Committee for Food Safety (VKM). Among these EPA, DHA, DPA, -Carnitine, L-Carnitine-L-tartrate, CoEnzyme Q10, Caffeine, Inositol, Taurine. The risk assessment has been performed on specific levels found on the market. While the Norwegian approach obviously differs from those models aiming at setting ULs, the approach remains interesting and confirms that, in most cases, levels on the market in supplements for adults do not raise safety concerns. These results of these evaluations will form the basis for a national regulation for these other substances.

Switzerland

Food Supplement Ordinance adjusts to EU Regulation

Switzerland has notified its new law on food supplements to the European Union and to WTO in order to adjust its

Ordinance to the structure of EU Legislation. This notification is part of the ongoing total revision of the Swiss food legislation. As soon as the entire legislation package is adopted, food supplements will be regulated as common foods and will be governed by a specific Regulation. In the newly shaped Regulation on Food Supplements (Verordnung des EDI über Nahrungsergänzungsmittel (VNem)) food supplements will not be anymore considered and regulated as special food or as food for people with special nutritional needs, as was the case in the past. The basic elements of this new law include a positive list of nutrients with maximum levels (annex 1) and allowed chemical forms, a positive list of other substances, including lutein and CoQ10, and a negative list of plants. This list has been based on the German plants list and contains some plants that are accepted and included in the Belfrit list. Criteria for live micro-organisms are also proposed.

Turkey

MINFAL publishes its revised Regulation and Communique for supplements.

The awaited revision of the Regulation and Communique setting rules for Food Supplements confirm the success of the IADSA efforts to resolve one of the key challenges faced by the sector over the past two years. Changes include the simplification of the market access procedure, the improvement in a number of key regulatory requirements - in particular on tolerances - and also an extension of the implementation of the new provisions to December 2016.

Europe

Roadmap to review the Nutrition and Health Claims legislation

8 year after the entry into force of the EU Nutrition and Health Claims regulation, the Commission has launched a roadmap with a specific focus on botanical health claims and nutrient profiles. This roadmap is a first step in the evaluation process and outlines the purpose, content and scope of the evaluation. Stakeholders have been able to submit their comments on a dedicated webpage. This exercise will be a key step to define the future of botanical use in food supplements.

It is to be recalled that due to differences in legal requirements between health claims and Traditional Herbal Medicinal Products (THMPs), the European Commission decided in September 2010 that it was not possible to continue with the assessment of health claims for plant and herbal substances. Since that date, those claims have been put on hold until the Commission and Member decide how to address the issue.

New Novel Food Regulation published

The new novel food Regulation has finally been adopted by the European Parliament and the Council after years of discussions with the goal of addressing the criticism around the current process which is seen as complex, expensive and time-consuming. To achieve this objective a centralised authorisation system involving EFSA will be put in place for the scientific risk assessment of the new applications. Data protection provisions are also included in the new Regulation. Newly developed scientific evidence and proprietary data will not be able to be used for the benefit of another application for 5 years after the novel food has been authorised.

The new Regulation can be found at: *http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R2283&from=EN*

New phospholipid-rich oil extracted from Antarctic Krill authorised in supplements

Phospholipid-rich oil extracted from Antarctic Krill (Euphasia superba) has recently been approved as a novel food ingredient under Article 4.2 of the Novel Food Regulation which allows the marketing of a novel ingredient if no objection is raised by the Commission or other Member States. The application was submitted in February 2014 to the Finnish Food Safety Authority, Evira, and presented to the EU Member States on 3 December 2014. The new novel ingredient is permitted for use in supplements under the following conditions: General population (Maximum EPA+ DHA 3000 mg/daily dose, Pregnant and lactating women 450 mg/daily dose)

Europe sets PAH limits for food supplements

Following the efforts of the sector the limits of PAHs in supplements have been limited to 2 categories of supplements: Food supplements containing botanicals and their preparations and food supplements containing propolis, royal jelly, spirulina or their preparations. Food supplements non-compliant with the new requirements but lawfully placed on the market prior to 1 April 2016 may remain on the market after that date until the end of their shelf-life. According to the Commission, high levels of PAHs have been found in some food supplements which contain or are derived from botanical ingredients. It was therefore considered appropriate to establish maximum levels for PAHs in these products.

Isoflavone containing food supplements for post-menopausal women safe

The awaited EFSA opinion on the risks for postmenopausal women from taking food supplements concluded in October with the safety of isoflavones from soy and red clover in food supplements at doses currently used for post-menopausal women.The EFSA assessment was requested by the German Bundesintitut für Risikobewertung (BfR) and has investigated the possible health risks associated with the intake of isolated isoflavones in food supplements by peri- and post-menopausal women, in particular focusing on possible harmful effects on mammary gland, uterus and thyroid. EFSA was also requested to provide an estimate of exposure of the target populations and, if possible, give advice on a safe intake levels. The opinion is available at the following link: *http://www.efsa.europa.eu/en/efsajournal/pub/4246*

EFSA opinions on Carmine (E120), Ascorbyl palmitate (304i &ii) and Thaumatin (E957)

EFSA has recently published the conclusions of its safety assessment for three additives.

Carmine, Cochineal and carmine acid E120. The Colour is permitted for use in Category 17.1 (solid form) at 300 mg/kg, Category 17.2 (liquid) at 100 mg/kg and category 17.3 (chewable forms and syrup) at 300 for solid and 100 mg/kg for liquid forms

Ascorbic palmitate 304(i) & 304((ii) No safety concern for the use of ascorbyl palmitate (E 304(i)) and ascorbyl stearate (E 304(ii)) as food additives at the reported uses and use levels has been raised by EFSA for these antioxidants permitted in all food supplements at *Quantum Satis*.

Thaumatin E957. The extension of use, proposed for different food categories including categories 17.1 and 17.2 at 400 mg/kg, would not represent a

safety concern according to EFSA. The sweetener is today permitted in supplements in Category 17.3 at the level of 400 mg/kg.

24 food additives in supplements for infants and young children to be assessed by EFSA

Following a request of the Commission related to the development of the draft Regulation for food additives in supplements for infants and your children, EFSA has confirmed its working plan to assess the safety of 24 food additives that could potentially be authorised for use in food supplements designated for the age group. The current additives legislation does not foresee the use of additives in such products. The proposed legislation would aim to authorise the use of certain additives and address therefore the requests of some Member States who recommend the intake of certain vitamins, minerals and other substances formulated as food supplement. The EFSA opinion is foreseen in 2019. However given the lack of clarity on the status of products present on the market, the Commission may move with the development of the legislation before the conclusions of EFSA are known.

Gulf Cooperation Council

GCC adopts Food Additive Regulations

On 5 November, the Gulf Cooperation Council's GCC Standardization Organization (GSO) adopted its new regulations on Additives Permitted for Use in Food Stuffs (2500/2015). The documents replace previous standards. Regrettably it is understood the new provisions are not always in line with Codex GSFA Standards.

The Emirates Standardization Metrology Authority for (ESMA) notify WTO of their procedures for the nutrition labeling

The Emirates Standard Metrology Authority has recently notified WTO of their revised draft rules for nutrition labelling which are applicable to food supplements. The draft states in particular that the amounts for vitamins and should not deviate from 5% ± 20% of the declared value.

Argentina

Argentina – Electronic registration for food products in force

The National Agency for Drugs, Foods and Medical Technology (ANMAT) implemented the Federal Information System for the Control of Foods (SIFeGA) through which it is launched the electronic registration of food products and of establishments, including also dietary supplements, in order to make more efficient and faster the process of registration. This system entered into force last 30 November.

Argentina – New regulation for the control food labels

The Secretary of Trade approved last October the System for the Control of Labels of products under sanitary surveillance, including food and dietary supplement products. This new regulation establishes the control of products labels prior to their marketing, as a supplement measure in addition to the work of the ANMAT for the registration of products.

Pacific Alliance

Harmonisation moves a step closer

The 7th Meeting of the Food Supplements Sector of the Pacific Alliance Business Council (CEAP) took place last October in Colombia.

The key issues addressed by the meeting included the maximum levels

of vitamins and minerals, GMPs, the safety of bioactives and botanicals, the definition of 'physiological effect', and the profile of the supplement industry in the four PA member states. The proposal will now presented to the governments during the course of 2016. The Pacific Alliance is on an ambitious timeframe for the adoption of the text.

United States

New Supplement Education App for athletes to reduce risk of testing positive

To strengthen its programme launched in 2011, Supplement411.org, aiming at educating and alerting athletes on dietary supplements that that may pose a risk to their health or their sporting career, USDADA has launched a mobile app containing photos of supplements and a bar code scanner to make it easier for athletes to recognise products containing enhancing substances such as stimulants, steroids, hormone-like substances.

FDA updates webpages to reduce confusion between legal dietary supplements and illegal drug-spiked products

The Food and Drug Administration (FDA) has recently updated language on several pages of its website (links below) to more accurately describe illegal, drug-spike products and to remove references to these as dietary supplements after the American Herbal Products Association (AHPA) requested the changes.
www.accessdata.fda.gov/scripts/sda/sdnavigation.cfm?sd=tainted_supplements_cder
www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/default.htm

On these pages, FDA recalled its concerns about fraud products and the

need for consumers to exercise caution before using certain products.

FDA Database for products illegally marketed for serious Diseases

FDA has launched a new enforcement database to identify companies that fraudulently market products for treatment or prevention of serious diseases.
Companies that do not cease illegally marketing products after 30 days of receiving an advisory letter from the FDA will see their name listed in the database together with advisory letter. Advisory letters posted on FDA's website says the agency reviewed company websites, product labels, catalogs, brochures, flyers, package inserts, audio and video, e-commerce and social media accounts.
http://www.fda.gov/ICECI/EnforcementActions/AdvisoryLetters/default.htm

FDA launches public consultation on use of the term "natural" on food labelling

In direct response to consumers who have requested that the FDA explore the use of the term "natural," the agency has launched a public consultation to provide information and comments on the use of this term in the labeling of food products.
In its request, FDA stated not to have a longstanding policy concerning the use of "natural" in human food labelling. The FDA has considered the term "natural" to mean that nothing artificial or synthetic (including all colour additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in that food. The US Agency added that this policy was not intended to address food production methods, such as the use of pesticides, nor did it explicitly address food processing or manufacturing methods, such as thermal technologies, pasteurization, or irradiation. The comment period closes on 10 February 2016. Comments can be submitted at:
http://www.regulations.gov/#!submitComment;D=FDA-2014-N-1207-0001

Request of US trade associations elevation of DDSP to "Office" Status within FDA

The Secretary of Health & Human Services has recently notified Congress of its desire to implement this reorganization within FDA and elevate the Division of Dietary Supplement Programs (DDSP) to an "Office" status within the Food and Drug Administration's (FDA).

The decision was endorsed by the US dietary supplement trade associations, who stated in the letter sent to the congress in support of request that *"elevating DDSP's status to an Office could help increase FDA's abilities to take more aggressive enforcement action; raise the visibility and attention for dietary supplement safety and compliance measures at FDA".*

Department of Justice and its federal partners sweep away fraudulent supplements

In mid November the Department of Justice and its federal partners went after 100 makers and marketers of dietary supplements containing ingredients other than those listed on the product label or misleading claims.

To promote its actions, an infographic has been developed for consumers to help them better understand the range of dietary supplement and claims, the potential risks of taking supplements and questions to ask a health professional before taking them.

FDA releases its guidance on voluntary labelling indicating whether food has or has not been derived from genetically engineered plants

Food manufacturers may voluntarily label their foods with information about whether the foods were not produced using bioengineering. The FDA guidelines have been developed to guide those manufacturers that wish to voluntarily label their plant-derived food products or ingredients (for humans or for animals) as having been made with or without bioengineering. This guidance does not establish legally enforceable responsibilities and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

FDA consults on the term "Natural"

FDA is asking the opinion of the public on the use of the term "natural" following a citizen petition requesting clear rules for the use of the term "natural" and to prohibit its use on some food labels.
In its requests, FDA stressed that it has not objected to the use of the term if the food does not contain added colours, artificial flavours, or synthetic substances.

Ukraine

Ukraine developed registration procedure for novel foods Dietary supplements registration issues discussed in Kazakhstan

Earlier this year Kazakhstan introduced a standard for the product registration. The document contains a number of ambiguous provisions resulting to product registration hold-ups and numerous registration denials. It appears that the major reasons for denials were around the borderline between supplements and medicines, breaches in the product labelling requirements and in the requirements of technical regulations. The committee proposed drafting requirements for scientific reports, which are among mandatory documents to be submitted together with the application for state registration in Kazakhstan.
This initiative has now stimulated discussion on the feasibility of drafting a technical regulation for dietary supplements.

Russia

Russia boosts inspection of supplement manufacturers

According to the Russian consumer rights regulator Rospotrebnadzor, over 1,300 inspections of dietary supplement manufacturers and pharmacy chains selling dietary supplements were staged in the first half of 2015, with over 3,800 dietary supplement samples tested. 42 batches were found to be defective, and 618 fines imposed worth more than 764,000 roubles in total (USD $11,000 at the current exchange rate). Scheduled and surprise inspections of manufacturers and pharmacy chains are focused on the quality, safety and labelling of dietary supplements.

APPROACH TO BORDERLINE

Factors that governments generally take into account to distinguish a supplement from other product categories

---

Product Composition

Product Representation

Product Purpose

Product Format

Public Perception and History of Use

APPROACH TO BORDERLINE

CANADA

As in most countries, it is a combination of factors that defines the product classification in Canada. A key element of this approach is the public perception and history of use. If a product has a historical pattern of use as a food or if the public perception associated with the use of a product in the marketplace is that it is a food, these are indications that the product is a food rather than a Natural Health Product.

EUROPE

In Europe food supplements are defined as foodstuffs to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form.

This definition includes 3 characteristics to distinguish food supplements from other categories.

The product purpose: To supplement the diet.

The composition: Namely a concentrated source of nutrients and active substances.

The presentation: Doses to be consumed in small dosage forms. In some cases, the instructions present on the labelling recommend the dilution of supplements in 1 L or 1.5 L of water. This recommendation is often seen to be in contradiction with the concept of doses taken in small measured quantity.

In case of doubt, where the characteristics of a product suggest that it may be either a medicinal product or a food, by default the product should be regulated as a medicinal product. However, there are multiple examples where the dual use of ingredients both in food and medicine is accepted given that the purpose of those products is different.

To note: Food and food supplements law also include a prohibition on claims to treat, prevent or cure disease.

US

Under section 201ff)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff)(2)(B)), the term “dietary supplement” means a product that, among other requirements, “is not represented for use as a conventional food or as a sole item of a meal or the diet. To assist companies in addressing borderline between Liquid Dietary Supplements and Beverages, FDA issued in January 2014 two guidance documents. These documents, entitled, “Distinguishing Liquid Dietary Supplements from Beverages” and “Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements”.