IADSA NEWSFLASH

November 2023

Regulatory news

China

Stimulating innovation: New approach for new functions

The State Administration for Market Regulation (SAMR) has released detailed rules on the implementation of the technical evaluation of new function claims.

The new Rules cover six areas including "General Provisions", "New Function Research", "Material Acceptance", "Technical Evaluation", "Post-Market Evaluation", and "Supplementary Provisions". The Rules also include "Material Requirements and Technical Evaluation Points for New Function Applications".
Under the new provisions, any individual / organisation can apply for a new function. The registration of a related health food could be made simultaneously to allow a joint evaluation of the new functional claims and corresponding health food registrations.

New function claims are classed into one of the three categories: dietary nutrient, maintaining/improving body health, reducing disease risk factors.

Japan

Classified as drug

The Ministry of Health, Labour and Welfare (MHLW) has recently announced that Δ8-THCH and Δ9-THCH will be classified as designated drugs. The manufacturing, import, sale, possession, and non-medical use of the substances is strictly prohibited since August 2023.

Indonesia

Ban on imported goods below $100 on e-commerce platforms

According to Tech in Asia, the Indonesian Ministry of Trade plans to limit the sales of imported goods on e-commerce platforms with the aim to protect and increase competitiveness of local small and medium-sized Indonesian companies.

Indonesia is currently revising Regulation No. 50/2020 on Provisions of Business Licensing, Advertising, Counting, and Supervision of Business Acceptors in Trade Through Electronic Systems (MOT 50/2020). The revised regulation intends to include restrictions of online sales for imported goods below USD100 through e-commerce and social media platforms

Market supervision

To ensure consumer protection and compliance of products with safety and quality rules, BPOM has recently issued a regulation laying down requirements for health supplement products, as well as the responsibilities of marketing permit holders and overseas producers who are subject to BPOM inspection.

The new regulation includes the obligation to have marketing permit numbers, meet related safety, quality, and labelling requirements for health supplements, to ensure that products are not damaged, and have shelf life in accordance with the marketing permit. The inspection addresses the administrative checks of documentation and the fulfilment of good storage and shipping practices.

New requirements for supplements

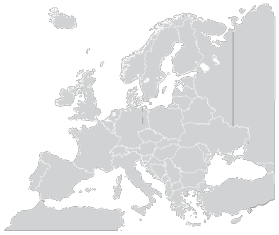
The Indonesian Food and Drug Administration (BPOM) has released a new Regulation No. 24 of 2023 on Safety and Quality Requirements for Health Supplements, which came into force immediately after its promulgation. The new regulation specifies general and specific requirements for the safety and quality of health supplements that are required to obtain the circulation permit for domestic and imported health supplements. These requirements include residue limits for solvents used to extract, maximum levels for additives, testing parameters for the finished products such as powders, tablets, pills, capsules, and gummies. For the three claims related to male stamina, slimming/fat reduction/diet, and gym/fitness, qualitative identification tests for certain substances are required.

Taiwan

Revision of rules for Health Food Permit

Taiwan has proposed an amendment to the Regulations for the Application of Health Food Permits. The proposal requires separate documentation for

health foods manufactured by different manufacturing plants in different stages, to demonstrate compliance with good manufacturing practice standards of each plant. Health food in Taiwan refers to food with health functions.



Armenia

Pharmacy only

Armenia's Ministry of Economy is working on a draft bill aiming to restrict sales of dietary supplements to pharmacies. Sales outside pharmacies would be treated as an administrative offence. Supplements are currently sold in Armenia with no restrictions (most retail sales are online). The ministry argues that dietary supplements are often found to contain pharmaceutical substances and measures need to be taken to fight the grey market.

Belgium

D-Mannose: Clarifying a grey area

The Mixed Committee of the Federal Agency for Medicines and Health Products (FAMHP) has issued new guidelines regarding the use of D-mannose in food supplements.

In its report, FAMHP acknowledges that products with a daily amount of D-mannose higher than 750 mg can have a significant physiological effect. Therefore, a maximum of 750 mg of D-mannose per day could be allowed in food supplements provided that no reference to UTIs is made (urinary tract infections, pain etc). The Agency clarifies that the use of such statements, made directly or indirectly to consumers through internet and social media or via testimonials, for example, would a priori classify the product as a medicine.

FAMHP explains that 'D-mannose can have a pharmacological effect in the treatment and/or prevention of UTIs from a dose of 1.5 g/day, a higher dose being generally used (for example 2 g for prevention). Taking into account a safety factor of 2, it can therefore be assumed that products with a D-mannose concentration of up to 750 mg per day do not have significant pharmacological effects.'

Canarium indicum: illegal status reconsidered

The Belgian Advisory Commission for Plant Preparations has recently released on opinion on Canarium indicum L. dried nuts which reconsiders the dangerous status of the plant. This change of mind relates to an EU law authorising the use of dried nuts of Canarium indicum L. ('Kenari') on the EU market as a traditional food from a third country (Regulation EU 2023/667 of 22 March 2023).

The Advisory Commission has also aligned its recommendations with the EU conditions of use: dried nuts of Canarium indicum L. can be used in or as food providing that product bears a statement that nuts may cause allergic reactions to consumers with known allergies to hazel, cashew and pistachio.

The opinion focuses on nuts and excludes from its scope the use of extracts. It remains to be seen when this opinion will be reflected in the Belgian Royal Decree.

Stanols: read the label

According to Health Food Chain Safety Environment (FPS Public Health), the recommendations relating to the use of fortified foods containing sterols and stanols are insufficiently known, understood and followed by consumers.

At the request of the FPS Health, Ghent University carried out a new study on the consumption of foods enriched with sterols and stanols of plant origin within the Belgian population. The results highlight a lack of knowledge, understanding, and monitoring of recommendations.

FPS Health recalls that it is recommended to consume more than 3 grams of sterols and stanols per day. It also encourages manufacturers to make mandatory warnings on labels more readable and to use other means of communication to ensure better and correct use.

Worries about alcohol in supplements

"Tinctures, floral elixirs, syrups with plant extracts… many remedies are likely, even today, to contain alcohol" said the Belgian FPS Public Health, Food Chain Safety and Environment who has recently questioned whether they can be consumed without risk, especially by children.

While alcoholic drinks must, by law, clearly display their alcohol strength above a certain threshold, the FPS Public Health, Food Chain Safety and Environment highlighted in a recent opinion that food supplements in liquid form do not fall into this category and the consumption of such products can lead to significant doses of alcohol, ranging up to several grams per week.

Given the potential risk, the Superior Health Council (SHC) concluded that manufacturers justify that alcohol is absolutely essential in the preparation of these products or contributes to their real effectiveness. As a transitional measure, it is recommended that companies limit the concentration of ethanol in the preparations as much as possible. It is not clear yet whether the SHC recommendations will be translated into law.

Denmark

Time to take your vitamin D supplement daily

The Danish Veterinary and Food Administration (DVFA) has renewed its recommendation that all Danes take a vitamin D supplement of 5-10 µg daily during the winter months (from October to April) and some groups in the population need more. The recommendation came in 2020, when a study carried out by the Norwegian Cancer Society showed that almost every fifth Dane who does not take vitamin supplements has a vitamin D deficiency in the spring, when the summer's surplus has been used up.

While vitamin D is found in food, Denmark recognises that it is very difficult to meet vitamin D needs through food alone. Studies of Danes' diets show that they only meet a small part of their vitamin D needs via the food they eat. The Danish Food and Veterinary Administration therefore recommends that everyone from the age of 4 take a supplement of vitamin D from the beginning of October to the end April.

EU

Microplastics: Not applicable to supplemens

The Commission Regulation (EU 2023/2055) that regulates microplastics under Annex XVII of REACH and which contains a series of bans on the manufacture and marketing of products considered to be microplastics excludes foods and supplements from the need for information and reporting requirements.

Resuming the assessment of botanical claims?

The European Parliament has recently relaunched the discussion on the need to resume the assessment of botanical claims.

The recent draft report on the implementation of the regulation on nutrition and health claims made on foods issued by the Committee on Environment, Public Health and Food Safety (ENVI) points out that "The status quo is potentially harmful for consumers, who might falsely assume that these health claims have been properly assessed, detrimental to innovation, as uncertainty caused by the prolonged transitional regime dissuades from long-term investments and creates unfair competition among food business operators, faced with differing national provisions."

Since 2012, botanical claims have been put on-hold, allowing their use under the conditions applying before adoption of the list of permitted health claims. The reason for this 'on-hold' list was primarily due to the differences in legal requirements between health claims for food and Traditional Herbal Medicinal products for which traditional data is considered as sufficient evidence. Given the risk of a potential confusion for consumers, the European Food Safety Agency was asked in 2010 to suspend all opinions on claims on botanicals. To address this divergence, the ENVI report suggests exploring the concept of 'traditional use' data in the substantiation of claims on botanicals in foods, currently considered as insufficient evidence.

Looking at the question on safety, the report raises the absence of a common list of permitted botanicals among Member States and the lack of an EU-level monitoring system for negative effects of botanical and food supplements. The report notably calls for a harmonised approach on botanical food supplements and to set up an EU-level monitoring system on the adverse health effects of botanical food supplements.
The creation of guidelines for the enforcement of the NHCR online and the creation of a platform to share best practices and encourage collaboration among the Member States' competent authorities is also proposed to ensure that the NHCR remains relevant online.

The report and its proposed action will be proposed for a vote at the end of November. If voted through, it will increase pressure on the European Commission to act further in this area.

EFSA confirms UL for vitamin D unchanged

EFSA has recently completed its final opinion on the tolerable upper intake level (UL) for vitamin D, including the derivation of a conversion factor for calcidiol monohydrate. The UL remains unchanged with limits of 100 µg/d for Adults (≥ 18 years including pregnant and lactating women)
A conversion factor of 2.5 for calcidiol monohydrate into vitamin D3 is proposed for labelling purposes. This would means 1 µg vitamin D equivalent (VDE) = 1 µg cholecalciferol (vitamin D3) = 1 µg ergocalciferol (vitamin D2) = 0.4 µg calcidiol monohydrate = 40 IU.

Creatine monohydrate not novel

Germany has recently confirmed the non novel status of creatine monohydrate used in food and supplements. The non novel status applies to creatine monohydrate obtained by chemical synthesis, which is at least 99,9 % pure.

Hemp leaves not novel but ...

The discussion of the Working Group on Novel Food that concluded that hemp leaves cannot be regarded as a novel food raised concerns among Members States. While some reiterated that hemp leaves are considered drugs in their jurisdiction, others indicated that risk assessment studies on the consumption of hemp leaf tea is showing that the acute reference dose (ARfD) for THC could be exceeded. Others emphasised that if milk was to be added, the extraction could be higher again.
It was questioned whether data on Δ-8 THC in hemp leaves was also available. The Commission replied that if data show that significant amounts of Δ-8 THC occur and if Δ-8 THC has a comparable activity to Δ-9 THC, this would be included in the future discussion.

EFSA procedure: Make it easier

Applying for a novel food, a new additive or a claim has been one the industry's headache over the past 2 years. Under Transparency Regulation 2019/138, all studies in support of an application for authorisation of novel food, an additive, or a health claim carried out after 21 March 2021 had to be notified to EFSA. This has led to major delays and in some cases the rejection of applications.

The updated version of the EFSA Questions and Answers on EFSA's Practical Arrangements introduces updates that should make the procedure easier for an applicant. The changes exempt the notification of some studies (e.g. validation methods, characterisation studies) previously required for new applications.

Establishing safe intake levels for Manganese

EFSA is holding a public consultation on their draft scientific opinion on the tolerable upper intake level for manganese. The opinion finds that there are no adequate data to establish a UL, safe levels of intake of manganese were therefore provided instead ranging from 8 mg/day for adults ≥ 18 years (including pregnant and lactating women) and between 2 and 7 mg/day for other population groups.

In order to be able to derive an upper intake level (UL), EFSA has also released a technical report. This document focuses on the collection and appraisal of scientific evidence that could be used to derive an upper intake level (UL). A lack of human studies examining association between exposure during sensitive time windows such as pregnancy and lactation was identified as a major data gap. While some case reports suggesting that relatively high manganese intake from supplements over longer periods may cause adverse neurological symptoms were identified, the report highlighted that limited conclusions can be drawn from case reports alone.

France

Vitamin D & endocrine disruption

As part of its objective to inform consumers of the presence of endocrine disruptors in the products they purchase, the French authorities have pursued the decision to publish the decree to classify vitamin D3 (cholecalciferol) as an endocrine disruptor. The decision was primarily due to the use of the vitamin D3 overdosage as a rodenticide in some European countries.

Despite the concerns raised by French physicians, the scientific community and industry, the decree confirms that the presence of vitamin D3 in products and supplements, at above the threshold of 0.1% by weight, will need to display through a specific app 'Scan4Chem' together with the following statement "Contains the substance Cholecalciferol.This substance has health benefits when used according to the precautions and dosage specified on the package leaflet or product labelling. If in doubt, seek the advice of a health professional.".

'Scan4Chem' app has been developed as part of the EU LIFE AskREACH project to help EU consumers to track down harmful substances by scanning the product's barcode and request information from the supplier about the presence of substances of very high concern (SVHCs).

There is concern that this decision may cause consumers to mistrust vitamin D supplementation, which will be particularly problematic given the high prevalence of vitamin D deficiency among the population.

Poland

Prohibited substances

As part of a draft Regulation aiming to address the mandatory addition of vitamins and minerals to certain foods, Poland has issued a draft list of substances prohibited for used in food and supplements.

This list includes: yohimbine hydrochloride and the yohimbine group, methyl pepper (Piper methysticum), also known as kava kava, pancreatin, ibutamoren (ibutamoren mesylan), DMAA (particularly referred to as: 1,3-DMAA; 1,3-dimethylamylamine; 1,3-dimethylpentylamine; 2-amino-4-methylhexane; 2-hexanamine, 4-methyl-(9CI); 4-methyl-2-hexanamine; 4-methyl-2-hexylamine; dimethylamylamine; geranamine; methylhexanamine; methylhexanenamin), ligandrol (LGD-4033) and ostarin (enobosarm).

Spain

Online notification only

The Spanish Agency for Food Safety and Nutrition (AESAN) has introduced a new electronic online notification procedure for food supplements and foods for special groups. All applications or communications submitted to the AESAN must be submitted only by that means, and no other means will be admissible.

UK

Improving enforcement on non-compliant claims

The Office for Health Improvement and Disparities is consulting on a proposal on nutrition and health claims enforcement.

Currently in England, the regulations enable the requirements of the retained EU Regulation on nutrition and claims to be enforced only by means of a criminal prosecution (fine or imprisonment). However, the current enforcement procedure does not align with other food labelling enforcement. Under the proposed reform, the enforcement authorities would be able to act more quickly to deal with non-compliance.

Parallel to this process, the Office for Health Improvement and Disparities is also seeking public consultation on redundant tertiary legislation from the statute book. Historically, each EU decision to authorise or reject a nutrition or health claim resulted in EU Commission regulations, 60 of which were either about 1) rejected claims or 2) approved claims which were added to the list of permitted health claims in annex to Regulation 432/2012 establishing this list. The government is therefore proposing to revoke the 60 pieces of tertiary legislation which have no legal impact as the Regulation EU 432/2012 was also retained when the UK exited the EU.

CBD consumption limit lowered

UK recommends adults to not consume more than 10 mg of Cannabidiol CBD a day. The Food Standards Agency (FSA) has dropped its advised daily limit of Cannabidiol CBD from 70 mg to 10 mg which is about 4-5 drops of 5% CBD oil, citing risk to liver and thyroid issues. The updated advice has been based on the average lifetime exposure to food products containing CBD, such as drinks, oils, sweets, bakery items or drops.

FSA said "there is no acute safety risk" with consuming more than 10mg of CBD a day, based on the data they have assessed to date. However, above this level and over a period of time, "there is evidence of some adverse impacts on the liver and thyroid. The higher the dose that is consumed and the more often higher doses are consumed will increase the risks of experiencing an adverse health effect."

FSA recommends consumers to check labels and consider their daily intake in light of this updated advice. All CBD products must apply for authorisation before they can be sold legally in Great Britain. FSA had given the CBD industry a deadline of 31 March 2021 to submit valid novel food authorisation applications. Only products which have submitted a valid application have been allowed to remain on the market.

Turkey

Ban of Titanium dioxide

Turkey has published an amendment to its food additives regulation. TIO2 is excluded from the permitted additive list.

A transition period is introduced until 1 April 2024. Products on the market can remain on the market until their expiry date.

USA

Response on NMN Status delayed

Due to “competing agency priorities”, the Food and Drug Administration (FDA) has not been able to reach a decision within 180 days of receipt on a citizen petition aiming to clarify the status of nicotinamide mononucleotide (NMN) in dietary supplements. The petition specifically requested FDA to determine that NMN is not excluded from the definition of dietary supplements and to commit to exercising enforcement discretion with products marketed and sold as dietary supplements.

TiO2 removed from banned list

The California Food Safety Act (Assembly Bill 418), which would ban several substances from inclusion in the manufacture, distribution or sale of foods, has moved through the state legislature and it is expected to pass into law. In its final version the provision banning titanium dioxide has been withdrawn from the bill.

NY bans sale of weight-loss supplements

New York State has passed a new bill banning the sale of supplements for weight loss and muscle building to consumers under the age of 18. The ban excludes protein powders, protein drinks & foods marketed as containing protein unless the protein powder, protein drink or food marketed as containing protein contains an ingredient other than protein which would, considered alone, constitute a supp lement for weight loss or muscle building.

Australia

Improving businesses' environmental claims

The Australian Competition and Consumer Commission has recently consulted the industry on draft principles-based guidance to assist businesses making environmental claims. The draft guidance sets out steps that businesses can follow to ensure that claims are true, accurate and easy for consumers to understand. The guidance includes examples of good practice, as well as examples which may mislead consumers.

New Zealand

The marathon has kicked off

In July, the Therapeutic Products Bill received Royal assent, becoming the Therapeutic Products Act (2023). Most provisions in the Act will not come into effect until mid-2026. Until then, Manatū Hauora (the Ministry) will be developing the necessary rules and regulations to support the new therapeutic products regulatory regime. In its recent communication, Manatū Hauora clarified that many of the issues raised by the sector during the Act’s development must be addressed in secondary legislation. The Ministry will also be establishing the Regulator to administer the Act, and a digital platform and services that will be needed to support it.

Argentina

Health Claims: Mirroring EU?

The National Administration of Medicines, Foods and Medical Devices (ANMAT) has tabled a proposal to update the rules for health claims aiming to ban their use for infant foods and foods for medical purposes, but also in foods impacted by the front-of-pack labelling (as approved in the Law on Healthy Eating).

The regulation would apply to the advertising of food products (as it is currently) but also for the presentation of labels during the registration process,

The Commission in charge of evaluating the requests will consolidate and maintain a public register covering both approved and non approved health claims. Similarities with data required by the European Food Safety Authority (EFSA) for the substantiation of heath claims is to be noted.

No claims for supplements!

Argentina has banned claims for food supplements. The final approved regulation appears to be (ANMAT Disposition 8095/2023) different from the one proposed in August and includes a significant change: The ban of health claims in food supplements, among other food categories such as foods for medical purposes and foods requiring Front of Pack labelling.

So far, the use of claims has been permitted for supplements on a case-by-case basis, with several reduction of disease risk claims approved. It is now unclear what will happen to those food supplements with health claims that are currently in the market. We understand this is now in force with immediate effect.

Chile

Green light for hemp

Chile has issued a new Decree (Decree 80/2023) which modifies the Sanitary Regulation of Foods in order to add Article 170 bis. This includes the authorisation of use of hemp derivatives in all food products, including food supplements. It also introduces the THC limits for hemp oil, hemp seed, shelled hemp seed and hemp flour or hemp protein, being the following ones:
- Hemp oil: 10 mg/kg
- Hemp seed: 5 mg/kg
- Shelled hemp seed: 2.5 mg/kg
- Hemp flour or hemp protein: 3.5 mg/kg.

Hemp oil was already authorised in Chile, but other hemp derivatives were approved on a case-by-case basis. With this change, all the above-mentioned derivatives are now permitted.
Enforcement date: 26 December 2023.

Brazil

Limit of Ethylene oxide in additives

The National Sanitary Surveillance Agency (ANVISA) is aiming to establish a maximum tolerable residual limit for ethylene oxide in the following food additives permitted for use in supplements:

INS 432 Polyoxyethylene sorbitan monolaurate, INS 433 Polyoxyethylene sorbitan monooleate, INS 434 Polyoxyethylene sorbitan monopalmitate, INS 435 Polyoxyethylene sorbitan monostearate, INS 436 Polyoxyethylene sorbitan tristearate, INS 1209 Polyvinyl alcohol (PVA)-Polyethylene glycol graft copolymer and polyethylene glycol (PEG)

The maximum tolerable residual limit of ethylene oxide in food additives proposed is 0.01 mg/kg, expressed as ethylene oxide and determined on the basis of the sum of ethylene oxide and 2-chloroethanol multiplied by 0.55 (oxide of ethylene + 2-chloroethanol x 0.55). This decision is based on WHO publications and the latest changes in the European Union.

Guatemala

Identification of supplements

Guatemala has updated its 2002 Standards on Identification of Pharmaceutical Products. It applies to all products classified as pharmaceuticals, including dietary supplements. It defines the criteria to name and identify such products at the time of the registration. Compared to the previous text, the update provides more detailed guidelines on which names, logos, denominations and brands can be used, aiming to avoid misleading statements. Specifically for dietary supplements, it mentions that the name and logo cannot have therapeutic connotations. This standard complements the main piece of legislation for dietary supplements, which is Technical Standard 14-2022.

Kazakhstan

Trade ministry drops mandatory ID tagging of dietary supplements

The Ministry of Trade and Integration published for comments draft amendments to decree No. 568 dated 10 September 2020, which lists goods that must be labelled with ID tags.

The previous version of the amendments underwent public discussion this summer and included "foods classified under harmonization code 2106 intended for pharmaceutical or preventive treatment purposes". This was interpreted to include dietary supplements and foods for special dietary purpose. The updated draft no longer contains this provision.

Moldova

Notification for vitamin/mineral supplements

Moldova has reconfirmed that registration is required for: novel foods; dietary supplements except those that contain vitamins and/or minerals; and food additives, enzymes and flavourings. Supplements that contain vitamins and minerals would only require notification.

Russia

Enforcing mandatory ID tagging of dietary supplements

Following the publication of decree No. 886 of last May, which approved the ID Tagging Rules for Dietary Supplements, only supplements that bear a state-issued ID tag on consumer packaging will be allowed on the Russian market.

Supplements withdrawn from the market should also be recorded in the system (the requirement comes into force on 1 March 2024). Dietary supplements without ID tags brought to the market before 30 September 2023 may remain on the market until their best before date. The decree took effect on 1 September 2023.
The Kazakhstan government is also seeking to implement similar ID tags. A draft amendment to decree No. 568 dated 10 September 2020, which approved the list of goods subject to the ID tagging aims to include "foods classified under harmonization code 2106 intended for pharmaceutical or preventive treatment purposes". It is also believed that a pilot for the ID tagging for supplements could be considered by the Kazakh government.

Disagreement between Russian ministries slows down adoption of dietary supplement regulation

The Russian Ministry of Economic Development completed a regulatory impact assessment of amendments to the Eurasian Union food regulations that introduce special requirements for dietary supplements, their manufacturing, sales, and labelling.

In their opinion, Rospotrebnadzor, the authority leading the drafting process, should reconsider comments and proposals of the Russian Union of Consumer Market Operators and the Oil and Fat Union, which were earlier dismissed as unacceptable.
Under pressure, Rospotrebnadzor has agreed to:

Limit a new requirement to dietary supplements which was originally intended to cover all foods: "Pharmaceutical substances that have no natural analogues and are not nutrients, psychoactive, narcotic, poisonous and superpotent substances, as well as plants and products derived from them and containing any of the above may not be used for the manufacturing (production) of foods" (clause 3 of the draft amendments to CU TR 021/2011);

Reword a requirement for botanical supplements as follows: "The concentration of biologically active substances in the daily intake of dietary supplements derived from plants and/or their extracts must be within 10% to 50% of their minimal one-off therapeutic dose established in a single-component medication for oral administration";

Implement a new provision in CU TR 027/2012 On safety of foods for special dietary use: "a name identical or confusingly similar to a trade name of a registered medicine may not be used for a dietary supplement". Importantly, the warning about dietary supplements not being a medicine must be printed out "in a font of at least 2 mm (lower case letters) next to the supplement's name". The statement "dietary supplement is not a medicine" is currently mandatory, but experience shows that manufacturers use it in a fine print on the back-of-pack.
Four other Eurasian Union Member States have issued positive opinions on the draft amendments.

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IADSA
International Alliance of Dietary/ Food Supplement Associations