RDAs to Safety

IADSA's central goal when it was founded was to coordinate work in Codex towards achieving safety based vitamin and mineral levels globally. It is now 10 years since the Codex Vitamin and Mineral Supplement Guideline was finally adopted and in that period we have seen significant improvements across the world in terms of understanding the scientific risk based approach to establishing maximum levels and also seeing such safety levels implemented in law.

However, there are still a number of countries for which higher than RDA levels immediately makes a product a drug. As we look at these countries, notably in some African, Asian and Latin American countries, it is important to analyse why these countries still maintain such an approach:

The challenge to change historic RDA-based legislation and the commercial interests that have developed around this. It is clear that for some companies which have build a business around drug registration of higher than RDA levels, opening up the opportunities for food supplements is not an immediately attractive option. Defending the status quo is almost always easier than creating change.

Lack of understanding of Codex and international obligations in this area. While Codex is considered important by almost all governments, it is hard for officials to manage and understand the huge number of Codex texts, which have been agreed historically, let alone understand those that are currently on the table.

Fear of consumer safety problems emerging due to dangerously high level products being sold unchecked across their country. There is a fear that because higher levels are available, all companies will formulate to these, even if this may not be desirable from a formulation, cost, marketing perspective.

Lack of education of consumers. This is not so much a question of whether consumers understand the role of vitamins and minerals and how to fit supplements into their diet. It is more a question of insufficient literacy in some parts of the world and fear that consumers will believe that if one supplement is good, two is better.

Belief that by permitting higher than RDA levels they will be contributing to a trend away from eating local foods, thereby breaking down cultural traditions. This is summed up best by a perspective of a senior official in Asia who said that the people in the village where he came from where healthy and happy: They did not need supplements.

It is easy to quickly dismiss many of the above. But that would be a mistake, since that will not resolve the outstanding challenges around maximum levels that exist today. The issues above are real to the officials facing them and while it may be one person who states them, there are very often many others who share the same views. Moving forward to achieve science-based regulation on vitamin and mineral maximum levels requires not just a clear scientific approach, but also cultural and commercial awareness. These things don't get fixed overnight, but through a process of engagement, education and confidence building.

When the Codex Vitamin and Mineral Supplement Guideline comes up for its 20th Anniversary in 10 years time, we trust that through the work being done across the world the number of countries which still maintain the RDA-based rules will have dwindled to a few or disappeared entirely.

CCNFSDU
IADSA priorities

37th Session
Bad Soden am Taunus, Germany

1. Proposed Draft Additional or Revised Nutrient Reference Values for Labelling Purposes in the Guidelines on Nutrition Labelling (Vitamin A, D, E, Magnesium, Phosphorous, Chromium, Copper, Chloride and Iron) at Step 4

2. Proposed Draft NRV-NCD for EPA and DHA long chain omega-3 fatty acids at Step 4

Regulatory news

Malaysia

Suspension of application of Organic Food Certification Scheme

Malaysia has recently announced that the application of the Organic Food Certification Scheme would be temporarily suspended to enable the Division to improve the production procedures for Organic Food Certification.

http://fsq.moh.gov.my/v4/index.php/component/k2/item/849-penangguhan-permohonan-skim-pensijilan-makanan-organik

Thailand

Thailand implemented Facilitation of Official Permission Granting Act

Thailand implements a new national policy to provide greater transparency on businesses that required permission from the government. According to the Facilitation in Official Permission Granting Act 2015, which came into effect on 21 Jul 2015, the authorities must provide details on applications for various services, such as the steps for submitting documents, the length of time, and service fees.

China

Publication of the Administrative Measures for Registration and Filing of Health Foods, on Health Food Labelling, and Health Food Raw Material Directory and Health Function Directory could be delayed

The 3 regulations for health food open for public consultation this summer are still under revision and may not be published before October. The new laws aiming at setting the regulatory requirements for the new registration and notification system as set under the new China Food Safety Law have raised concerns particularly on the ability of imported products to meet the requirements proposed under notification and registration of process.

New regulatory requirement on the naming of health foods

China FDA in August announced that effective immediately, the CFDA will no longer approve registration of health foods bearing product names that indicate health functions. For such products that are already approved by CFDA, the company shall submit an application for change of product name by 31 December 2015. Effective from 1 May 2016, no companies shall manufacture health food products bearing product names that indicate health functions.
www.cfda.gov.cn/WS01/CL0087/127860.html

China updates filing management for Importers and Exporters

According to AQSIQ (China's General Administration of Quality Supervision) Notice No. 55, all food/drink producers, agents and domestic consignees are required to file their company information with the Bureau of Import and Export Food Safety of AQSIQ. This requirement comes into effect from 1 October 2012.
From 1 October, exporters and domestic agents will be required to fulfill the filing process with AQSIQ through a new online system (http://ire.eciq.cn) upgraded in accordance with the new Food Safety Law.
www.aqsiq.gov.cn/xxgk_13386/jlgg_12538/zjgg/2015/201508/t20150827_447977.htm

Japan

Claims progress in Japan

More than 85 products covering 42 functional ingredients/claims have been accepted so far by the Consumer Affairs Agency and more than 250 products are waiting their validity check.

Among those permitted claims, 13 related to functional claims referring to body parts, which would not have been approved in FOSHU.

The only downside of the new model seems relates to the duration of the validity check.

India

FSSAI seeks legal support

In the light of the recent judgment of the Bombay High Court related to product approval process, the Food Safety and Standards Authority of India (FSSAI) has issued an urgent public notice requesting interested legal firms and lawyers to assist the Authority in framing regulations related to product approvals, imports, procedures for issuing guidelines and administrative instructions.
The successful legal firm/ lawyer would have to undertake to not enter into any litigation/ legal advice against FSSAI, directly or indirectly, on food related matters at least for a period of five years from the date of notification of such regulations.

www.fssai.gov.in/Portals/0/pdf/Public_Notice_Legal_Firms_for_Regulations_31_08_2015.pdf

Product Approval discontinued in India

"It is no longer possible for FSSAI to continue with the process of Product Approvals" said FSSAI in its statement of 26 August. Products concerned by the statement are those covered under Section 22 of the Food Safety Law Act namely health supplements, novel food, genetically modified, irradiated and organic foods, foods for special dietary uses, functional foods, nutraceuticals and proprietary foods. This decision follows the Bombay High Court Judgment of 1 August 2014.

Companies have until 4 February 2016 to obtain their licence.

According to the Food Safety and Standards (Licensing and Registration) Regulations of 2011, no person or organization can start a food business in India without a valid license obtained from FSSAI. The process of issuing licenses started in 2012 with a first deadline of August 2012, which was extended twice.
Last August, FFSAI decided to extend for the third time the deadline with a cut-off day of 4 February 2016, applicable to all operators aiming at starting or continuing their activities in India.

Korea

Korea seeks to revise its heath Function Food Regulation

The Korea Ministry of Food and Drug Safety (MFDS) has recently announced

the revision of its health functional food regulations. The revision will include: a) New obligations for functional food companies to report product quality violations uncovered via self-inspection, or any production conditions that could impact product quality and the health of consumers; b) More severe penalties for non compliance with a product recall obligation; C) Mandatory implementation of GMP system for newly approved health functional food manufacturers.

New Zealand

Natural Health and Supplementary Products Bill to become law in 2016

The Natural Health and Supplementary Products Bill which has come alive again post the national elections last year, will go to Cabinet within the next few weeks, and once passed will await the all-important third reading.

The system will be a web-based notification system similar to others with a permitted list of ingredients. The list started with the Australian and Canadian permitted ingredients, together with other ingredients currently being sold in products in New Zealand at the moment and is being reviewed. Interested parties are able to request an ingredient is added to the list for review. The process for adding ingredients to the list once the new Bill comes into force is expected to be uncomplicated and inexpensive. The government is very aware of the need for the Bill to support export growth and provide even more reassurance for consumers that their products are safe, efficacious and will work according to any claims.
The fees for notification are expected to be between NZD120-180 per product. Products imported into NZ from will need to meet NZ regulations. Products from recognised regualtory regimes will find notification simpler (e.g. those from Australia or Canada). A list of permitted claims and named conditions will be a part of the notification system as well. Evidence to back claims will need to be available.

Provided the Bill passes this year it is expected to come into effect in the middle of 2016.

Europe

Europe recommends monitoring of Arsenic

The European Commission has published a Recommendation on the monitoring of Arsenic in food including food supplements. While limits for Cd, Hg and Pb exist, maximum levels for Arsenic have not been harmonised yet.

Nordic Countries review allergen labelling

Nordic countries will launch in Autumn a joint campaign on allergen labelling and the use of the labelling statement ' May contain traces of" for which there is currently no specific legislation.
The purpose of these controls is to protect consumers who are hypersensitive or allergic and increase companies' awareness of accurate labeling.
The outcome of the project may also help develop a basis for specific regulations, which could govern the use of the statement "may contain".
In the first instance, controls will focus on food products but this may not exclude the control of food supplements available on the market.
Results of this project are expected to be released in May 2016. A similar project was already implemented in 2012.

France warns about Shiitake mushroom

The French authorities have recently published a warning statement regarding the use of the mushroom shiitake (*Lentinula edodes*) usually found on the market in dried forms or in food supplements.
They have reported that the consumption of this mushroom - in fresh, dried, rehydrated forms, in powder or infusion - can cause dermatitis characterized by itching skin lesions on the whole body. This toxic reaction occurs about 3 days after the consumption of the mushroom and usually disappear in a fortnight without treatment.

EFSA publishes a report on the occurrence of PAs in food & food supplements

EFSA has recently published on its website a report on the occurrence of Pyrrolizidine Alkaloids (PAs) in food and food supplements.
This report follows an internal mandate proposed by EFSA to the CONTAM Unit. Given the limited occurrence data on PAs in food in Europe, EFSA decided to outsource a study on the occurrence of PAs from different regions. Results are now available. 191 food supplements containing botanicals and bee products were tested. Conclusions showed that Botanical food supplements were often contaminated with PAs (60 %), but the concentrations were highly variable. Supplements containing oil-based extracts of PA-producing plants were generally free of PAs.
PAs belonging to the lycopsamine-type (lypcosamine, intermedine, echimidine) were the most frequently found. PAs were often present as mixtures of free bases and N-oxides.
It is now to be seen how EFSA and the Commission will use these results together with the data collected by the Member States.

Recently the Dutch National Institute for Public Health and the Environment suggested that from a scientific point of view it would be possible to adopt a slightly less strict limit value (5 µg/kg) of pyrrolizidine alkaloids in herbal preparations including food supplements. It is today prohibited to market in the Netherlands herbal preparations included supplements containing more than 1 µg/kg of pyrrolizidine alkaloids.

Silicon Dioxide authorised as anti-caking in rosemary extract

EU Commission has recently published an amendment of Annex III to Regulation on additives authorising the use of silicon dioxide in extracts of rosemary (E392) at a level of 30 000 mg/kg in the preparation.

The use of silicon dioxide would allow the powder extract to remain free flowing over a longer period of time without massing/congealing during its shelf life.

EFSA releases scientific opinions on Dietary Reference Values for Magnesium and Phosphorus

The European Food Safety Authority has proposed a series of adequate intakes (AIs) for Magnesium and Phosphorus:

Magnesium: 350 mg/day for men and 300 mg/day for women. For pregnant and lactating women, the same AI is set for them as for non-pregnant, non-lactating women, considering that there is no evidence for an increased need for magnesium.

Phosphorus: Due to insufficient data, DRVs for Phophorus were calculated based on the DRVs for calcium and considering a molar calcium to phosphorus ratio of 1.4:1 to 1.9:1.Based on this assumption, an AI of 550 mg/day is proposed for adults, pregnant and lactating women.

EFSA launches a public consultation on requirements for the assessment of food for special medical purposes.

EFSA has launched a public consultation on the draft scientific and technical guidance for the assessment of products notified as food for special medical purposes in the context of Article 3 of Regulation (EU) No 609/2013. This request followed concerns raised by Member States on the increasing number of products, including food supplements, notified in their territory and doubt on their compliance with the definition of FSMP. The EFSA recommendations will be used for the preparation of a guidance document on which the Commission is currently working to assist Member States in their enforcement task.

EFSA is expecting to deliver its final opinion by 31 October 2015.

Lithuania seeks to ban food supplements form pharmacies

The State Food and Veterinary Service (SFVS) requested last August the Minister of Health to pass an order prohibiting the sale in pharmacies of food supplements bearing no claims or claims for which the EU assessment has not yet been completed.

4 options are under consideration:

Option 1: Applicable to pharmacies only. This option would require that food supplements with pending health claims and those without health claims should be kept on separate shelves with a clear marking, e.g. 'Food supplements with claims pending assessment of their scientific evidence'.

Option 2: Similar to option one but applicable to all distribution points of sale.

Option 3: Applicable to pharmacies only - setting down rules to prohibit the sale of food supplements bearing no claims or claims subject to the EU transitional period (claims whose evaluation by EFSA or whose consideration by the Commission has not yet been completed)

Option 4 : Status quo - which may entail the possible assessment of the product by the National Food and Veterinary Risk Assessment Institute (NFVRAI) following the notification of the food supplements.

Similar approaches have been advocated by the Pharmacists Council in Poland. However no final action was taken so far.

Norway aligns its NF Regulation with EU provisions

Norway (which is not an EU Member State) has harmonised its Novel Food rules with the EU provisions.
While in the EU Novel Foods are defined as foods that has not been consumed to a significant degree by humans prior to 15 May 1997, Norway fixed the cut-off day of 1 January 1999. With the new Norwegian revision (FOR- 2015-07-01-892) that became effective on 1 September, the following rules apply: a) For novel foods and novel food ingredients which are approved in the EU via the full authorisation procedure, approvals in Norway should be granted within 30 days. b) Request for an opinion on whether a food or food ingredient is substantially equivalent to an existing food or food ingredient should be directed to Mattilsynet. c) Norway will have the authority to prohibit or restrict the sale of a product that has been approved under Regulation (EC) No. 258/97, if it use constitutes a health hazard or a risk to the environment.

Melatonin supplements still permitted on the Dutch market for the time being

Products containing between 0,3 and 5 mg of melatonin can still be sold for the time being in the Netherlands. Those products were expected to be removed from the market from 1 October. However the Arnhem court has recently imposed upon the Health Inspection an order to permit the sale of products containing up to 5 mg melatonin. However the threat of a ban still remains until the Court determines whether the reasons used by the Dutch Health Inspection - to consider products containing over 0,3 mg of melatonin as medicinal products - were justified.

The Dutch melatonin market is estimated to be worth more than 20 Million EUR. Melatonin is allowed in food supplements in some EU countries mainly thanks to the procedure of mutual recognition via Italy, which in 2013 reduced to 1 mg per day the authorisation of melatonin on its market.

Portugal and Greece revise their notification system

While France is still awaiting the launch of its online notification system announced several months ago, Portugal and Greece have moved ahead with a revision of the rules governing the market access of food supplements on their market.

Portugal
More elaborate but also more stringent than the previous one, the new system requires the submission of more detailed information through a more procedural approach. According to the revised law, the processing will take 60 days. Within this period, the authorities will inform the applicant if further information would be required. If there is no reaction within the 2 months, the product is deemed to be in conformity with the national provisions and can be placed on the market. From 1 September, the list of notified products will be published by the authority DGAV and will be updated regularly. The notification - free - will still have to be submitted electronically.

Greece
Greece, like many other countries, has also recently introduced an online system for the notification of food supplements (Greek Ministerial Circular 36563/27.05.2015). As from 29 June 2015, only electronic notifications are accepted. Requirements seem to be similar to the previous system, namely: Packaging description, Labelling, Suitability evidence for parents products, Specifications of raw materials, Certificate of analysis, Quality control method, Fee deposit

Luxembourg

Notification procedure simplied for supplements notified in EU in LU, FR or DE languages.

Companies that have notified their food supplements in another Member State of the EU do not need to fill in the Luxembourg form to notify their supplement assuming that the notification dossier is written in one of the of three official languages of Luxembourg (LU, FR, DE) and contains the same information as in their national template.

Turkey

MINFAL notifies WTO of a draft Communiqué amending the Communiqué on Food Supplements

For over a year now Turkey has been working to improve its regulatory approach for food supplements. A draft Regulation clarifying the role of the Scientific Committee has been open for public consultation. An amendment of the Communique setting specific labelling has also been notified to WTO. The proposed provisions in these 2 drafts aim at putting in place a system more workable for companies. The publication of the revised laws is foreseen for October.

GCC notifies WTO of its draft Regulation on Halal Food

The State of Kuwait has notified WTO of a draft technical regulation related to general requirements for Halal Food which must be followed in each stage of the food chain for halal foods, transportation, storage and labelling.

https://members.wto.org/crnattachments/2015/TBT/KWT/15_3108_01_e.pdf

Argentina

New resolution for Advertising of Food Supplements

On August 13, 2015 ANMAT published resolution No. 6516/15, which establishes the obligation to notify the agency of the advertising regarding food supplements.
Companies products subject to sanitary surveillance shall notify all advertising to ANMAT and present the corresponding advertising piece in the format to be broadcasted.

The notification must be made within 48 hours starting from the diffusion of the advertising.

Bolivia

Labeling of foods with genetically modified organisms (GMOs)

On July 15th Bolivia published the Decree N°2452 setting labelling provisions for foods containing genetically modified organisms. This applies to all products for human consumption, including food supplements.

The declaration must be made through a triangle with a red background including the acronym GMO and the words "genetically modified organism". In addition it should indicate, "This product contains genetically modified material". The National Food Safety Authority (SENASAG) is responsible for the sanitary surveillance regarding this point. The period to adjust the labels begins on January 2, 2016 and will run until December 31, 2017.

Brazil

ANVISA updates the Technical Report No. 64 regarding the list of chelated minerals

The National Health Surveillance Agency of Brazil has put into effect the Technical Report No. 64, published last December 2014, on the use of chelated minerals in foods.

The update released by ANVISA on August 6, includes in the positive list of mineral compounds that can be used in foods magnesium gluconate and sodium hydroxide but excludes all sources of boron compounds.

United States

Owner of a supplement company sent to prison for fraud

A federal judge has sentenced the owner of a dietary supplements company to 40 months in prison, to be followed by 12 months of supervised release for his role in the sale of diluted and adulterated dietary ingredients and supplements.
The plea deal came also with an agreement to pay a fine that exceeds $1 million.

FDA Takes Action on Bulk Pure Powdered Caffeine Products

FDA issued warning letters to five distributors of pure powdered caffeine, stating its position that these products are dangerous and present a significant or unreasonable risk of illness or injury to consumers. The agency stated that the difference between a safe amount and a toxic dose of caffeine in these pure powdered products is very small and safe quantities can be nearly impossible to measure accurately. If violations exist, the FDA said it would pursue enforcement action, such as seizure of the product or an injunction to prevent the firm from continuing to manufacture or market the product.

FDA consults on Nutrition Labeling Regulations for Small Amounts of Nutrients and Dietary Ingredients

The Food and Drug Administration (FDA) announced the availability of a draft guidance for industry entitled "FDA's Policy on Declaring Small Amounts of Nutrients and Dietary Ingredients on Nutrition Labels: Guidance for Industry." The draft guidance, when finalized, will explain to manufacturers of conventional foods and dietary supplements the policy on determining the amount to declare on the nutrition label for certain nutrients and dietary ingredients that are present in a small amount.

http://www.regulations.gov/#!documentDetail;D=FDA-2015-D-1839-0002

Industry efforts helped amend Louisiana law banning consumer access to common botanical supplements.

Legislation was recently signed into law allowing certain herbal ingredients that had been banned by the state to again be sold in dietary supplement products. Louisiana Act 373 amended legislation passed in 2005 and 2010 that had sought to remove from the market synthetic substances and herbs thought to have hallucinogenic properties. The law inadvertently included some botanicals that have long been used in dietary supplements.

NCCIH recommends Consumers considering a probiotic dietary supplement to consult a health care provider first

'If you're considering a probiotic dietary supplement, consult your health care provider first. This is especially important if you have health problems. Anyone with a serious underlying health condition should be monitored closely while taking probiotics noted National Center for Complementary and Integrative Health. According to the agency, some probiotic products have been found to contain smaller numbers of live microorganisms than expected or strains other than those listed on the label. NCCIH however acknowledged that there is preliminary evidence that some probiotics are helpful in preventing diarrhea caused by infections and antibiotics and in improving symptoms of irritable bowel syndrome.

Ukraine

Ukraine developed registration procedure for novel foods

A draft decree on adopting the state registration procedure for novel foods has been put up on the website of the Ukrainian Health Ministry for public discussion.

Under Ukrainian Law 1602-VII "On amending certain legislative acts in relation to food products" of 22 July 2014, a novel food product or ingredient is a food product or ingredient essentially different from those present on the market that requires an assessment of its impact on consumer health.

The law introduces the following criteria:

1) a food product or ingredient has no prior history of safe consumption in Ukraine and is characterised by substantial differences in its composition and/or effect as a result of: a) using an animal breeding and/or plant growing process which has not been previously used for this purposes; b) a manufacturing process which has not been previously used for the manufacture of this type of product or ingredient;

2) a food product or ingredient has no prior history of safe consumption in Ukraine but has a history of safe consumption in one or more other countries and is characterised by substantial differences in its composition and/or effect.

The decree comes into force,simultaneously with Ukrainian Law 1602-VII.

Russia

Roszdravnadzor may be entrusted with supervision of dietary supplement market

The State Duma's (lower house of the Russian parliament) Committee on Health Protection is drafting a bill on amending the principles of state regulation as applied to the dietary supplement market.

According to the Committee chair the bill will include a clause moving the function of allowing dietary supplements on the Russian market from the consumer watchdog Rospotrebnadzor to the medicines market regulator Roszdravnadzor. Roszdravnadzor's laboratories will be responsible for running tests on dietary supplement products.

One of the primary reasons why the bill is being proposed is that independent tests conducted by several public organisations have revealed the use of prohibited medical substances in several dietary supplement products allowed onto the Russian market.

Under the bill, Roszdravnadzor, as distinct from Rospotrebnadzor, will not just register new dietary supplements but also check the composition of every such product already on the Russian market or planned for the introduction to the market for any medical substances.

Russian government wants to set up mega- regulator for consumer market

The Russian government is considering setting up a mega-regulator that would supervise the safety of foods and drugs, an equivalent to the US Food And Drug Administration (FDA). The new agency could be vested with the powers of three existing regulators – Roszdravnadzor (responsible for the medicines market), Rospotrebnadzor (consumer rights protection), and Rosselkhoznadzor (the agricultural market). The move would streamline the regulatory system and save budget funds through merging the three agencies' regional representative offices.

Another possible outcome voiced in the government is that the three existing agencies, rather than merging into a single regulator, might be stripped of certain supervisory functions, which would be delegated to the new structure. The project is still in the discussion phase
The idea to create the mega-regulator was first disclosed after the president and prime minister instructed the government to optimise the regulatory system, eliminate functional overlaps, and cut the number of staff in the supervisory agencies.
Minister for Open Government Affairs has been entrusted to supervise the regulatory reform jointly with the Ministry of Economic Development, the Labour Ministry and the Finance Ministry. The government expects to receive the ministries' report by 15 October.

New system for food quality management to be established

The development of a national system of food quality management is underway. The system would create a single policy for tracking products. The government is expected to report on progress of the development and introduction of the systems for traceability of quality and safety of products to the Russian President by 10 November.

Focus: How brands referring to health function are regulated?

There is increasing interest across the world in setting rules governing the use brands referring to health function. Below an overview of how such brands are treated.

EUROPE

Brand names that suggest or imply that a relationship exists between the food supplement or one (or more) of its constituents and health are regarded as “health claims” covered by the provisions of the Nutrition & Health Claim Regulation 1924/2006 EC. Use of such brand names is lawful if they are accompanied by at least one related nutrition or health claim, which complies with the provisions of the Regulation.
Products bearing trademarks or brand names existing before 1 January 2005 which do not comply with the Regulation may continue to be marketed until 19 January 2022. The benefit of the transition period can be granted where it can be demonstrated that a given trade mark or brand name had been either registered or used in at least one Member State prior to 1 January 2005.

BRAZIL

As part of the labelling information, the name and brand must not contradict the general food labelling principles, including the prohibition of use of words, names, illustrations or other graphic representations that could make the information false, incorrect, insufficient, or that could lead the consumer to error, confusion or fraud regarding the true nature and composition of the food. Labels conferring effects or properties that the product does not have, or that cannot be demonstrated, are prohibited.

USA

A product name should be truthful and not misleading. Health function can be used in the product name. Dietary supplement labels or labeling may bear statements that describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or that characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, provided that such statements are not disease claims, that they are substantiated and are truthful and not misleading. If the label or labeling of a product marketed as a dietary supplement bears a disease claim the product will be subject to regulation as a drug unless the claim is an authorized health claim for which the product qualifies.

CHINA

Not permitted
See China section of this newsflash

Brand

EURASIAN ECONOMIC UNION (EAEU)

TR CU 022/2011 “Labeling of food products” lays out general principles of food labeling in the EAEU. TR CU 022/2011 provides for the possibility of labeling a food product with information about a distinctive property - information that describes unique properties, which allows distinguishing one food product from another (including nutritional value, place of origin, composition and other properties). A health function can therefore be mentioned in a product name of a dietary supplement (e.g. “hair health”, “healthy eyes”, “healthy teeth”, “healthy blood vessels”, “healthy joints», “healthy liver) provided it has been approved during the state registration process by the consumer market authority Rospotrebnadzor. The name with a direct reference to the therapeutic effect is not permitted.

CANADA

Brand name is the name used to distinguish the product. The brand name should appear on the label as the identifiable name of the product. When there are multiple brand names used for the product, each should be listed on the proposed label. The brand name of a Natural Health Product (NHP) must not be misleading to the public: (a) No person shall label, package, treat, process, sell or advertise any natural health product in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety. (b) A natural health product that is not labeled or packaged as required by, or is labeled or packaged contrary to, the Natural Health Products Regulations shall be deemed to be labeled or packaged contrary to subsection (a). Reference to a function claim to name a NHP is allowed as long as the function claim has been approved.

ARGENTINA

Disposition ANMAT Nº 4980 of 2005 regulates dietary supplements advertising. There is no legal framework yet for the use of health claims on supplements labels in Argentina. Therefore, health claims are generally not permitted on supplements labels. This would also apply to the product name / brand.

ASEAN

ASEAN do not have specific requirements for naming a product. However the regional guidelines on labeling requirements for traditional medicines and health supplements specifies that traditional medicine and health supplement (TMHS) products “shall not be described or presented on any label or in any labeling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any aspect”. The guidelines do not preclude the possibility to use heath functions in product/ brand names. The product and brand names should be deemed appropriate by the respective Member States.

MEXICO

In practice, health claims are not allowed on food supplement labels (although not clearly specified in the law). This would in principle also apply to the name and brand of the product.

IADSA

International Alliance of Dietary/ Food Supplement Associations