Demonstrating value

Our sector has always struggled to find a place in the hearts of regulators across the world. Many have in the past considered that supplementation wastes consumers' money and just provides products that they don't need since everything is available in a balanced diet. These attitudes are changing, but slowly. In the meantime they still create an environment where decisions on policy and regulation can penalize our products.

But you cannot entirely blame the regulators. For too long, too many companies have been marketing products with deeply concerning claims and there are too many highly questionable products easily available online to enforcement agencies to buy and test that have almost nothing to do with the supplement sector but which are labelled as supplements. While these are a tiny minority of the market, it is exactly this minority that regulators see most often.

The discussion in Ministries across the world focusses most often on the small number of serious problems rather than the vast majority of products which pose absolutely no risk. Dealing with this minority is always going to be extremely difficult, requiring massive resource and uncertain outcomes as the problem companies disappear in one place when challenged to reappear as another entity. It presents a joint challenge for both governments and industry associations.

A more successful strategy to changing the way our sector is seen is to focus on the value that we bring to health, nutrition, economics and society. Experience has shown us that when governments believe in the validity and contribution of the sector to society, acceptable, appropriate legislation and policy is far more achievable.

While this strategy is undeniably logical, it is hard to implement. Most associations across the world are understandably focused on reacting to the latest challenges and barriers. Demonstrating value is a target but it is hard to prioritize it and it does not come free.

The US associations have certainly led the way in this area through their investment in a whole range of scientific and technical publications and the groundbreaking work of the US CRN on measuring healthcare cost savings.

Increasingly, more associations across the world are engaging in this area but we run the risk that we are behind the demand. Senior government officials from China to Turkey have in the past months asked what value the sector brings for society and what contribution we can make to helping them achieve their nutrition and health goals.

The IADSA Annual Meeting has historically focused on regulatory issues, which is the origin and still the primary focus of most IADSA work.

In Prague in April, we will also be exploring the needs of consumers and society and the value our sector can provide. We will be looking at the evolution of nutrition and where it is heading, identifying the nutrition and health gaps that exist and where we can make a contribution to plugging them, and taking a first global look at our potential impact on healthcare cost savings.

While it would be unrealistic to believe that having answers to the above questions will change attitudes overnight, we can be sure that it has the ability to change the conversation that we often have with regulators and senior officials.

Regulatory news

ASEAN

AEC 2015

31 December 2015 marked the formal establishment of the ASEAN Economic Community (AEC). The AEC 2015 is not the be-all and end-all of ASEAN economic integration, but rather a milestone on a longer journey. It means that tariff barriers have been successfully reduced and that significant initiatives such as the Agreement on Traditional Medicines and Health Supplements are close to adoption and then implementation. A new Blueprint AEC 2025 has been agreed which identifies the next stage in the ASEAN integration process. Very significantly, this Blueprint includes among its strategic priorities enhancing the regulatory framework for health supplements. This is a major statement of confidence in the work that has been carried out in the region over the past decade.

China

Food Production Licensing Classifications published

According to the requirements of the new food production licensing, CFDA has published on its website the “Classified Categories for Food Production Licensing”. Under the new classification, food production are sub-divided into 31 categories, including health foods.

China releases its catalogue of Approved Health Food Raw Materials

The China Food and Drug Administration (CFDA) has recently released the first directory of approved health food raw materials. The list includes nutrient supplements for young children and clarifies that the major dosage form of nutrient supplements should be tablets, capsules, granules, powder or oral liquid rather than sustained-release preparations, controlled release preparations, sublingual absorption preparations, gastro-resistant preparations or sprays. The daily intake of nutrient supplements should be small. The total intake of nutrient supplements made in granular form and powder shall not be more than 20g per day.

Nutrient supplements in oral liquid shall not be more than 30ml per day. Limits of nutrients shall not exceed the amount set in the law.
The label shall comply with the "health food labelling regulations."

Together with this list, China has also notified WTO of draft provisions for Health Food Registration and Filing & drag provisions for Health Food Functional Claims List and Ingredients List.

Hong Kong

New Regulatory Control of Products Containing Vitamins and Glucosamine

The Hong Kong DOH has announced that products containing vitamins (other than those specified by DOH) and glucosamine will not be considered as pharmaceutical products unless they are indicated for parenteral use or have medicinal claims for treating or preventing disease. Premarketing approval is no longer required for such products.

PIC/S GMP requirement for Pharmaceutical Products

Hong Kong DOH is now an official member of PIC/S, hence pharmaceutical products will need to comply with the Pharmaceutical Inspection Co-operation Scheme Good Manufacturing Practice standards with immediate effect. Some Food Supplements that are classified as Pharmaceutical Products, for example Food Supplements with Digestive Enzymes are expected to be affected by this new requirement.

India

Food supplements no longer be considered proprietary food

The Food Safety and Standards Authority of India (FSSAI) has recently amended the standards for proprietary food and implemented them with immediate effect. With this amendment, nutraceuticals, health, and food supplements are no longer considered as proprietary foods and will be approved under a separate category for which the draft Standard is still under discussion. It remains to be confirmed if food supplements will require products approval if the composition contains ingredients & additives listed in the Annexes.

Korea

Changes to GMO labeling requirements

South Korea has issued a draft Amendment to the Food Sanitation Law and Health Functional Food Act, which included the expansion the GMO labelling scope to foods and functional foods. In the past, GMO labelling was only required for food products which contain 3% or more of genetically modified material in each of the top 5 ingredients. After the draft regulation is formally implemented, all GMO ingredients used during the production or processing of foods or health functional foods must be labelled regardless of concentration.

Korea notifies WTO of proposed Amendments for "Standards and Specifications of Health Functional Foods"

The main proposed amendment of the "Standards and Specifications of Health Functional Foods" include revision of some part of the test methods for functional ingredients: Vitamin C, astaxanthin, ginsenoside, coenzyme Q10, probiotics number, flavonol glycoside, ethyl acetate, vitamin A, niacin, folic acid and vitamin B12.

Malaysia

New Product Classification Application Process

Malaysia BPFK has introduced a new application form for product classification application. This form is required per product and a processing fee of RM 300 per application is imposed with effect from 1 January 2016. In the past, no fees have been collected by BPFK for product classification enquiries.

Belgium

Belgium challenges the safety of red yeast rice

The safety of red yeast rice has once again been flagged up, this time in Belgium.

In its report just published, the Superior Heath Council (SHC) recommends that food supplements containing red yeast rice should simply be banned and classified as drugs, which it claims would provide better guarantee in terms of composition, therapeutic effect and safety. However, aware that the decision to reclassify these supplements may not be possible for legal or economic reasons, the Council made a number of recommendations including the need for the setting of qualitative and quantitative standards and that the consumption of such products should be under medical supervision. This is not the first time that concerns have been raised about the safety of red yeast rice and monacolin K. The European Commission and Member States are reflecting on options for the inclusion of safety warnings to the conditions of use of health claims for this ingredient.

Vitamin D supplements can contain a daily dose of 20 µg

Products containing maximum 20µg of Vitamin D per day could be classified as food supplements provided that they are not intended for the prophylaxis and/ or treatment of vitamin D deficiency diseases said the Federal Office of Consumer Protection and Food Safety (BVL). Only products classified and regulated as Foods for Special Medical Purposes (FSMP) may contain dosages exceeding the 20µg per day, provided that this can be justified for the target population.

Spain

Spanish Scientific Committee published its opinions on 15 substances

In the European Union, the use of substances other than vitamins and minerals is not harmonised. A number of countries have considered regulating their use at national level. Among them, Spain who notified in 2013 the Commission and Member States about its draft Regulation on which a number of concerns were raised by the sector. To assist the Spanish authorities in its work, the scientific Committee of AECOSAN has recently published its risk assessment for 15 substances. This publication could likely re-open discussions related to the establishment of the positive list.

Nordic Countries

Sweden, Denmark and Norway question the safety of green tea extracts and infusions

The three above countries have sent a request to the European Commission regarding the possible harmful effects associated with the intake of green tea extracts and infusions. The concern appears to be about a group of polyphenols, mainly EGCG and other cathechins ((-)-Epigallocathechin-3-gallate), at levels greatly exceeding those under normal conditions of consumption of a balanced and varied diet, which includes green tea infusions. It now remains to be seen if the application fulfilled the necessary conditions to allow the Commission to initiate the procedure aiming at restricting or putting under scrutiny or even prohibiting the substances of concerns.

Norway

Norway Notifies the European Commission and the EU Member States about an amendment to their national food supplement legislation

Even though Norway is not a Member of the EU, it must notify its laws to the EU prior to implementation. The proposed amendments reflect the work of the Norwegian authorities in cooperation with the Scientific Committee for Food Safety (VKM) on the levels for vitamins and minerals. The main changes are to the revision of minimum recommended daily levels for vitamins and minerals (except for Vitamin D and fluoride); the introduction of a min/max level of 400 µg of folic acid which is only valid for food supplements for women who are planning a pregnancy, or who might become pregnant; and a the significant change of the maximum level of magnesium from 600 to 250 mg per day.

Europe

EFSA draft guidance on the requirements for novel foods applications nearly ready

In the context of the revision of the novel food Regulation, EFSA have been working on draft guidances for the preparation and presentation of an application for authorisation of a novel food, and for the preparation and presentation of a notification of traditional foods from third countries.

EFSA publishes guidance for Claims applications

Two new guidance were published during the course of January, one on health claims applications and another on the scientific requirements for Health Claims related to the gastro-intestinal tract, the immune system, and defence against pathogenic microorganisms. These reflect the experience that EFSA has gained in evaluating many dossiers since the introduction of the EU nutrition and health claims regulation

EFSA opens public consultation on its draft opinion for setting DRV for Vitamin B6

EFSA has opened a public consultation on a draft opinion for setting a DRV for Vitamin B6. EFSA has launched an open consultation on its draft scientific opinion. The document proposes dietary reference values for vitamin B6 for adults, infants and children, pregnant and lactating women. The deadline for this consultation is 16 March 2016.

EFSA opens public consultation on a draft opinion setting DRVs for Choline

EFSA has launched a public consultation on a draft opinion on dietary reference values for choline.

For all adults, EFSA sets a proposed Adequate Intake (AI) of 400 mg/day based on the average observed choline intake in healthy populations in the European Union and in consideration of the amounts of choline needed to replete about 70% of depleted subjects who showed signs of organ dysfunction in a depletion/repletion study. The public consultation runs until 21 March.

Orthosilicic acid -vanillin complex (OSA- VC), a possible new source of silicon

EFSA has recently been requested to assess, by 30 May, orthosilicic acid - vanillin complex (OSA- VC) as a novel food ingredient and as a source of silicon added for nutritional purposes to food supplements. According to the applicant, silicon is estimated to be the third most abundant trace element in the human body. In 2009, EFSA recognised the bioavailability of silicon from choline-stabilised orthosilicic acid that is authorised in Europe as a source of silicon in food supplements. A bioavailability study carried out by the applicant indicated that the supplement is well tolerated, with no evidence to indicate that it interferes with the bioavailability of other nutrients in the diet.

3 forms of silicon are currently permitted in Europe: choline-stabilised orthosilicic acid, Silicon dioxide and Silicic acid.

Five flavourings removed from approved EU list

The European Commission has decided to remove five flavourings from the authorised Union list due to a lack of data and decisions of the companies responsible for placing those substances on the market to no longer supports their use. The flavourings are vetiverol, vetiveryl acetate, methyl-2-mercaptopropionate, 2-acetyl-1,4,5,6 tetrahydropyridin and 2 propionyl pyrroline 1% vegetable oil triglycerides.

EFSA clears synthetic trans-resveratrol as novel ingredient for food supplements

The European Food Safety Authority (EFSA) has cleared the safety of synthetic trans-resveratrol as a novel food ingredient for use in supplements. The ingredient is proposed to be marketed as a supplement in capsule or tablet form at daily doses up to 150 mg/day, about 50 times higher than the high percentile background intake from foods. Resveratrol occurs naturally in grapes, grape juice and wine with low amounts found in peanuts, pistachios, and in blueberries.
http://www.efsa.europa.eu/en/efsajournal/pub/4368

Di-magnesium malate proposed as a new source of magnesium

EFSA has recently received a request for the use of di-magnesium malate as a novel food and a new source of magnesium for food including food supplements. The EFSA scientific opinion is expected to be ready in June.

EFSA has published its two draft guidances on Novel Foods for public consultation

The draft guidance for the preparation and presentation of an application for authorisation of a novel food is intended to replace the old guidance elaborated by the Scientific Committee for Food in 1997 and included in Recommendation 97/618.

The draft guidance for the preparation and presentation of a notification for an application of Traditional Foods from third countries is obviously new and intends to lay down the requirements for such notifications.

The guidance documents and public consultation details can be found at the following links:
http://www.efsa.europa.eu/en/consultations/call/160218
http://www.efsa.europa.eu/en/consultations/call/160218a

Turkey

Turkey publishes its permitted list of substances to be used in supplements.

Following the revision of the Regulation establishing rules related to the composition and labelling of food supplements, the Turkish Ministry MINFAL has recently published a restricted list of substances that may be used in supplements. The list is available on the Authorities web page.

Turkey about to adopt the European Claims Regulation

Turkey has recently notified WTO of its draft Regulation on nutrition and health claims. The draft, only available in Turkish, reflects the European Union Regulation in this area with a list of claims mirroring those permitted in the EU.

Turkey notifies WTO of its revised list of botanicals

Turkey has recently notified WTO of a procedure for the safety assessment of botanical materials and botanical preparations. This Communiqué also establish a permitted list of botanicals and their conditions of use.

Jordan

Approval required for the advsertising of supplements

The Jordanian Food and Drug Authorities (JFDA) published a notice

on 7 January 2016 banning any promotion or advertising for any registered food supplements in the media before obtaining an official approval from the JFDA for any advertisement on the registered product in the Kingdom.

Lebanon

Lebanon updates tis Food Additives Standards

The Lebanese authorities are revising their Food additives Standard NL 761 which is based on CODEX STAN 192-1995. Companies are advised to submit their requests for the addition of any food additive that is not included in the standard accompanied by supporting documents such as scientific reports to the technical committee at LIBNOR (The Lebanese Standards Institution). The food additive standard is being reviewed once a year. The updated standard would be published within 2-3 months.

Argentina

Electronic register of food products mandatory

From 7 April, all food products including food supplements will have to be electronically submitted to the National Food Institute (INAL) through the SIFeGA (Federal Information System for Food Control Management). Each product will be assigned a unique number (RNPA) of 11 digits that will have to be indicated on the label of the products. The number is valid for a period of 5 years, after which it will have to be renewed.
http://portal.anmat.gov.ar/Sifega_pdf/Preguntas_Frecuentes_RNPA.pdf

Bolivia

Notification to WTO about GMO labelling regulation in Bolivia

Bolivia notified last October to the World Trade Organization (WTO) the regulation on the labelling of GMOs. The National Service of Agricultural Health and Food Safety (Servicio Nacional de Sanidad Agropecuaria e Inocuidad Alimentaria) received comments from international delegations until December 22, 2015.

Chile

Chile to improve the definition edible marine oils

Chile is consulting on a draft amendment of the definition of marine oil. The proposal aims to incorporate other sources of oil such as shellfish in order to harmonise these rules with the Codex Code of Practice on Fish and Fishery Products (CAC / RCP 52-2003)

Costa Rica

"Fast track" procedure for the registration of foods with low health risks not applicable to food supplements

The Ministry of Health approved early February a "fast track" procedure for the registration of foods with low health risks. Approvals are expected to be granted within 5 days.
The fast track registration does not apply to food supplements, products bearing claims, or products specifically targeted at under -3s.

Dominican Republic

Standards for food addtives open for comments

The Dominican Institute for Quality (INDOCAL) is consulting on its draft Standard on food additives. Comments can be submitted until 31 March 2016.

Peru

Peru consults on regulation for implementing Good Manufacturing Practices

On January 26, the Ministry of Health from Peru sent to public consultation the new regulation for implementing Good Manufacturing Practices on pharmaceutical products, which applies to food supplements that are regulated under the medicines area. The public consultation will be open for comments until 24 April 2016.

US Marshals seize dietary supplements containing kratom

The U.S. Food and Drug Administration has seized nearly 90,000 bottles of dietary supplements labeled as containing kratom.
Mitragyna speciosa, commonly known as kratom, is a botanical substance that grows naturally in Thailand, Malaysia, Indonesia and Papua New Guinea. The FDA is warning consumers not to use any products labelled as containing kratom and requests health care professionals and consumers to report any adverse events related to products containing kratom to the FDA's MedWatch programme.

NCCIH interactive quiz for consumers on drug supplement interactions

The National Institutes of Health National Center for Complementary and Integrative Health (NCCIH) has launched an interactive quiz where individuals can test their current understanding of drug-supplement interactions. NCCIH also reminds consumers to inform their health care providers about all dietary supplements and drugs they take.

https://nccih.nih.gov/health/know-science/how-medications-supplements-interact

Comment Period on Use of the Term "Natural" on Food Labeling Extended Until May 10, 2016

In direct response to requests from the public, the FDA has extended the comment period for the Use of the term "Natural" on Food Labelling. The comment period will now end on 10 May 2016. The consultation seeks comments on questions such as whether it is appropriate to define the term "natural," If so, how the agency should define "natural," and how the agency should determine appropriate use of the term on food labels.

FDA Establishes the Office of Dietary Supplement Programs (ODSP)

The U.S. Food and Drug Administration announced in December the creation of the Office of Dietary Supplement Programs (ODSP), elevating the program as a division under the Office of Nutrition Labeling and Dietary Supplements. The creation of the ODSP will help "enhance the effectiveness of dietary supplement regulation by allowing ODSP to better compete for government resources and capabilities to regulate this rapidly expanding industry." said the US FDA.

Possible revision of supplement regulation

Following the announcement of the creation of the Office of Dietary Supplement Programs
U.S. Senators Richard Blumenthal (D-Conn.) and Dick Durbin (D-Ill.) released a statement stated that
dietary supplements have also outgrown the two-decades old law that was supposed to oversee this industry and protect consumers. Comprehensive new legislation is needed to provide the necessary oversight of this $35 billion industry, and we intend to introduce legislation in the new year."

Russia

Government reports on market compliance

The Russian consumer rights regulator Rospotrebnadzor has published its final report on monitoring the quality and safety of dietary supplements for 2015.
Acoording to the report, in 2015 Rospotrebnadzor staged scheduled and surprise inspections at dietary supplement manufacturers and at pharmacies, which sell them.
In the second half of 2015, the agency staged inspections at 7,034 facilities. Breaches of the applicable regulations were revealed at 83% of the facilities inspected, including at 47% of all inspected pharmacies and at 56% of all inspected manufacturing facilities. A total of 13% of all dietary supplement samples taken failed to meet the microbiological and sanitary chemical requirements, as well as the requirements for the content of biologically active agents.
The regulator cancelled the state registration certificates of a number of falsified dietary supplements which contain synthetic inhibitors prohibited in food supplements and not declared in the course of the state registration procedure. Given the growing number of instances of prohibited medical substances found in food supplements, Rospotrebnadzor completed the development of a technique capable of detecting medical substances in dietary supplements,

Ukraine

Revised hygienic requirements for dietary supplements come into force in Ukraine

The Ukrainian Health Ministry's Decree "On adopting the hygienic requirements for dietary supplements" of 19 December 2013 came into force on 24 January 2016. The decree is aimed at harmonisation of the hygienic requirements for dietary supplements with Ukrainian Law "On the fundamental principles and requirements applied to the safety and quality of food products".
However, some of the requirements' clauses fail to meet earlier food regulations adopted in Ukraine. Thus the new requirements mention a registration procedure for dietary supplements withdrawn by the law.
The Health Ministry is now trying to retrofit the requirements with a clause on the abolition of the registration procedure. Those dietary supplements failing to meet the new requirements which were manufactured and/or released into circulation within 12 months of the decree's entry into force may remain in circulation in Ukraine until their expiry date. The requirements list the vitamins, minerals, and their formulations permitted for use in the manufacture of dietary supplements.
The requirements mandate that dietary supplement labels bear a warning not to exceed the recommended daily intake; a statement to the effect that dietary supplements cannot substitute for a balanced diet; and a warning to keep the product out of reach of children.
The requirements do not include an official expert evaluation procedure for dietary supplements newly released into circulation which means that the manufacturers and importers will be fully responsible for the compliance of both new products and those which were manufactured and imported earlier.

IADSA Annual Week, Prague

26 April 2016

08.00 - 11.00
Scientific Council Meeting
Scientific Council members only

11.30 - 13.00
The evolution of nutrition
Limited capacity of 30 participants

14.00 - 17.45
From science to economics:
The potential value of supplementation
Limited capacity of 80 participants

19.00 Dinner

27 April 2016

09.00 - 16.00
Annual General Meeting
IADSA members only

16.30 - 18.30
Executive Council Meeting
Executive Council members only

28 April 2016

09.00 - 15.00
Company Council Meeting
Company Council members only

09.00 - 15.00
Technical Group Meeting
Technical Group members only

THE WORLD TRADE ORGANISATION (WTO)

Dealing with the rules of trade between nations

Predecessor

GATT (General Agreement on Tariffs and Trade)

From GATT to WTO

While GATT has a dispute settlement system with experts delivering opinions on matters related to infringements of international trade law, the system did not provide compulsory procedure. Unlike the GATT system, the WTO created a system closer to a legal process with enforceable decisions made by a Dispute Settlement Body (DSB).

WTO Functions

- Administering WTO trade agreements
- Forum for trade negotiations
- Handling trade disputes
- Monitoring national trade policies
- Technical assistance and training for developing countries
- Cooperation with other international organization

DID YOU KNOW?

Facilitate world trade

Created in 1995

Located in Geneva

162 members, significant growth over the last 18 years

TECHNICAL BARRIERS TO TRADE AGREEMENT (TBT)

The TBT Agreement aims to ensure that technical regulations, standards and conformity assessment procedures are non-discriminatory and do not create unnecessary obstacles to trade.

The TBT notification procedure was created to help prevent the creation of international technical barriers to trade. It was introduced by the Agreement on Technical Barriers to Trade (the TBT Agreement), a multilateral agreement administered by the WTO. It provides essential information on new technical regulations or conformity assessment procedures proposed by member countries.

The Procedure

1 Notification

The draft legislation, which could potentially contain technical barriers to trade, is submitted to the other WTO Members.
The notifications are available on the TBT database.
http://tbtims.wto.org/web/pages/search/notification/Search.aspx

2 Comments

A period of 60 days is recommended. During this period the decision process is frozen. Written comments can be sent on the proposed measure. Comments are sent directly to the notifying Member.

3 Dialogue

Members shall discuss the comments received and take these written comments as well as the results of these discussions into account.

4 Adoption

The notifying Member may decide, following the receipt of comments, to change its content, postpone its entry into force or even withdraw the measure.

DID YOU KNOW?

Most active notifying Members, 1995 -2014
US (2170), Brazil (1208), Europe (1171), China (1115), Israel (978)

WTO members notified 2,237 trade measures to the TBT Committee in 2014

Over 25,000 draft regulatory measures have been notified to the TBT Committee over the past 20 years