A new wind is blowing across the world

For many years the overwhelming drive in most regulation across the world has been to limit to the absolute minimum risk to consumers. In the vast majority of countries any recognition of the role that the private sector plays in providing jobs and economic growth was absent. This was not unique to the supplement sector, but was felt in a very intense way due to the wide range of regulation impacting food supplements.

We appear to now be witnessing a welcome change. In key markets, it is starting to recognize that the role of government is not to regulate businesses out of business but to help facilitate their role in economic growth. This does not mean that consumer protection is not still paramount in legislation. But it does mean that economic arguments around jobs, growth and innovation are being heard for the first time in a meaningful way.

The most significant change is in the EU. For many years economic arguments have had little weight in discussions in the EU. Regulators have worked hard to deepen consumer protection further and further with increasing regulations and tougher requirements. Concerns about the cost of these measures and if they even serve any genuine consumer protection purpose were often hardly considered. Today, with Europe challenged both politically and economically, issues around creating jobs and growth are now the first ones that regulators at the top of the EU hierarchy want to address.

Europe has woken up to the fact that you cannot speak about innovation unless you create a regulatory framework to encourage it. You cannot encourage exports unless you build a competitive regulatory framework in your region which creates strong companies ready to export. Will this impact the food supplement sector? For sure. How far and how positively will need to be seen and this will depend on the sector having the right kind of dialogue and partnership with government.

However, in other regions we are already seeing the results of a more business-friendly approach. The ASEAN Economic Community is being driven by a desire to create a single market and also a place for companies to invest and innovate. This approach has significantly influenced the structure of discussions on the single health supplement framework for the region.

In China, the adoption of the notification system for health foods as an alternative to the extremely costly and lengthy registration system, plus the promise of changes to this registration system are all hugely significant in global terms. And in India, it is still expected that the pro-growth drive of the Modi government will eventually help overcome the huge barriers and create a system of regulation that is workable and encourages investment for supplements.

There is a new wind blowing in much of the world. It is vital that we do our part in IADSA to help it.

Save the date
AGM 2016

Prague April 2016

26: IADSA Scientific Council (morning session)
26: IADSA event & dinner (afternoon session)
27: General Assembly Meeting
28: Company Council/Technical Group

We look forward to seeing you!
Regulatory news

ASEAN

Updates on ACCSQ TMHS PWG Meeting

The ASEAN Traditional Medicines and Health Supplements Product Working Group (TMHS PWG) held its 23rd Meeting in June in Kuala Lumpur, Malaysia during which it completed the separation of TM and HS annexes which included the technical requirements of the agreement. Due to the separation of the annexes, the signing of the agreement will now be delayed until February 2017.

As we reach the end of the process a number of critical issues are emerging which could impact consistent application of the Guidelines across ASEAN. In particular Indonesia appears to be looking for a broader range of exceptions to the ASEAN rules to permit it to maintain its national approach. Indonesia has a track record of such demands in other areas.

China

CFDA launches public consultation on food inspection agency’s accreditation conditions

According to the Article 84 of newly revised Food Safety Law, accreditation conditions and testing norms for food inspection agencies shall be determined by the CFDA. A public consultation was recently launched on a draft law setting criteria that agencies should meet in terms of inspection capabilities, quality management, personnel, facilities, equipment and reference materials.

CFDA published its food safety inspection

To further strengthen the monitoring of food safety sampling, CFDA released in June its “guidance on food safety inspection and information publication” laying down specific requirements for safety inspections by the Food and Drug Administration at state and provincial levels. The guidance specifically provides guidance on the type of inspections to be conducted, scope, sampling, testing and management measures for non-compliant products.

Local authorities instructed to target ginkgo products

CFDA recently unveiled results of an investigation on unqualified Ginkgo biloba extracts. Main issue was the use of non-traditional extracts used in health food products. Following the warning, it is understood that 200 million tablets have been recalled from the market.

India

Why companies are struggling

“The wonderful opportunity that was provided by the Food Safety and Standards Act to modernize the food sector with safety, transparency and inclusiveness as its prime objectives, seems to be on the verge of collapse. Reversion to the command and control approach of the old food laws is not an option either because it has been found severely wanting.” said PI Suvrathan the first Chair of Food Safety and Standards Authority of India. This article in the Times of India spelled out reasons for the chaotic regulatory situation and problems being faced at present by the Industry.


India consults on draft standards for supplements

India has launched a consultation on draft standard for supplements. At present India has no norm. The standards under discussion will therefore be the first ones setting out specific requirements for the labeling and the composition of health supplements. It is now to be seen whether the product approval would still apply to supplements since standardized foods are not required to go through the approval process.

Japan

Positive lists for food contact materials

Japan’s Ministry of Health, Labour and Welfare (MHLW) discussed last June its future regulation of food-contact materials, including the introduction of a positive list. This list will take into account information on chemical identity, use levels, migration levels and toxicity. Japan does not have a positive list of substances authorized for food contact material. Voluntary industry rules are currently in place including a positive list of food contact materials, incorporating substances authorized by Title 21 of the U.S. C.F.R., the European Union additive list and substances listed on national legislation in the UK, Germany, Italy, Holland, Belgium and France.

The New Health/Functional Claims System in Japan

As of 22 July, 59 products have been accepted by CAA through the new procedure. New functional claims, which were not authorized for FUSHU, like eye health, support to keep moisture of skin have now been accepted as functional claims.

New Designated Food Additive

Triethyl Citrate (CAS NO. 4468-02-4) was designated as a new food additive for its emulsifier, Stabilizer, Flavour.

Philippines

Philippines FDA issues draft Administrative Order on the “Revised Regulatory Guidelines Concerning Food Additives”

In view of the current guidelines on food additives Bureau Circular (BC) No. 2006-0016 and Administrative Order (AO) No. 88-As 1984 need updating to meet the current and emerging trends in food manufacturing, the Philippines FDA has issued a draft Administrative Order “Revised Regulatory Guidelines Concerning Food Additive. The proposed guidelines also include requirements for application of new food additives, which have not been approved by the Philippines FDA or GSFA. The draft guidelines are now published at the following link: www.fda.gov.ph/drafts-for-comments/250887-revised-regulatory-guidelines-concerning-food-additives.
Taiwan

New GM Labeling Rule to Take Effect 31 December 2015

The Food and Drug Administration (FDA) has announced that the new Genetically Modified (GM) food labeling rules for pre-packaged foods will take effect from 31 December 2015. Under the new rules, all GM foods must be properly labeled. Foods that use GM material but contain no transgenic DNA fragment or transgenic proteins in the final product due to processing will have to be declared as “this product’s raw materials contain GM XX, but do not contain any transgenic DNA fragment or transgenic proteins”. Products that do not use GM ingredients and contain no more than 3% GM materials due to unintentional contamination can be labelled “non GM”.

Taiwan sets Fee Standards for Inspections, Registrations and Licenses

Two notices issued by Taiwan FDA on fee standards for the inspection, registration and licenses for foods, food additives and health foods took effect on 1 July.

Fee standards for food and food additive inspection, registration and license for Inspection and registration of capsule or tablet food are set at NT$4,000.

Belgium

Mercury limits in food supplements could be decreased by 60%

The EU Commission is discussing the revision of the maximum level of Mercury (Hg) in various food products including food supplements. A possible future limit of 0.04 mg/kg is proposed instead of the 0.1 mg/kg laid down in Regulation 1881/2006. Based on the available occurrence data, the non-compliance rates for 0.050 mg/kg and for 0.040 mg/kg of Hg could be respectively 4.2 % and 4.9 % while it is today reaching 2.5%.

EFSA tweaks its general scientific guidance on health claims

EFSA has recently launched a public consultation on its draft general scientific guidance for stakeholders on health claim applications. The guidance aims to explain the general scientific principles applied by the NDA Panel for the evaluation of all health claims and outlines steps for the compilation of health claim applications.

Australia & New Zealand

Revised Food Standards Codex

Food Standard Australia New Zealand (FSANZ) has revised the Food Standard Code, which will come into effect on 1 March 2016. The revision is made mainly on Chapter 1 and 2 of the Food Code, with the purpose of clarifying the key areas such as the provisions relating to food additives, processing aids and nutritive substances.


FSANZ proposes to permit rebaudioside M

Food Standards Australia New Zealand (FSANZ) has called for submissions on whether to permit a steviol glycoside, rebaudioside M (Reb M), as a new intense sweetener.

FSANZ Chief Executive Officer Steve McCutcheon said FSANZ had assessed an Application to allow Reb M to be added to the same food categories and at the same maximum levels as the currently permitted steviol glycosides. The closing date for submissions is 10 August 2015.

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EFSA consults on DRV for iron

The European Food Safety Authority (EFSA) has given a 7 July deadline for comments on a draft opinion on DRV's for iron. The opinion proposes a PRI for adults of 11 mg/day, 16 mg/day for postmenopausal women from 6 mg/day in infants to 10 mg/day in adolescent boys. For pregnant and lactating women, it is assumed that iron stores and enhanced absorption provides sufficient additional iron, and the DRV's are the same as for premenopausal women.

Belgium reviews its dietary recommendations for vitamins and trace elements

The Superior Health Council (SHC) in Belgium has recently released its review of dietary recommendations for vitamins and trace elements which also provides guidelines on maximum levels for those nutrients. While in some cases limits are increased, in many other cases a lower level (e.g. vitamin A, B5, B6, Iron, Selenium, Zinc) is proposed. Of critical importance is how it will be decided to translate these recommendations into law.

France notifies EU of its draft Regulation for other substances used in supplements

France notified the EU Commission and Member States of a draft Order setting out the list of other substances permitted in food supplements and information that should be available to the inspection authorities regarding the nature and quality of the substances used.

The Regulation specifies that any substance with a nutritional or physiological effect, other than those listed in the annex I, may be used in supplements provided they are not Novel Foods. The provisions of this Order are expected to enter into force on 1 July 2016.

Dutch Authorities notify new warning statements for vitamin A and D supplements

The Dutch Authorities have notified the Commission and Member States about their new draft Regulation

Comments can be submitted by 11 September.

revising the warning statements for supplements containing vitamin A and vitamin D maximum levels.

Concretely, the new draft introduces the following requirement ‘This supplement is not suitable for children up to 3 years’ for products containing more than 600 µg RE in the form of retinoid.

The Authorities have also decided through this new proposal to increase the maximum permitted level of vitamin D form 25 to 75 µg per recommended daily dose. Additionally such products should be accompanied by the following statements:

For products containing more than 15 µg of vitamin D: This supplement is not suitable for children under 1 year.

For products containing more than 20 µg of vitamin D: This supplement is not suitable for children up to 10 years.

These 2 statements would replace the current one applicable to products with above 15 µg: “not suitable for children up to 10 years”.

A transition period will be foreseen for non-compliant products marketed or labeled prior to 1 October 2016. Member States have until 30 September 2015 to submit their comments.

**EFSA publishes its scientific opinions on DRVs for vitamin E and B12**

EFSA has recently published its 2 final opinions on DRVs for vitamin E and vitamin 12.

- α-tocopherol: Adequate intakes (AIs) of 13 mg/day for men and 11 mg/day for women are proposed. For infants and children the AIs range from 5-13 mg/day.
- Cobalamin: An AIs of 4 µg/day for adults (18 years and above) is suggested and between 1.5 and 4 µg/day for infants and children.

**EFSA launches public consultation on uncertainty in scientific assessments**

EFSA’s Scientific Committee has recently developed a draft guidance document on how to characterize, document and explain all types of uncertainty arising in EFSA’s scientific assessments. The document provides a framework and principles for uncertainty analysis, with the flexibility for assessors to select different methods to suit the needs of each assessment. One case study (Melamine) has been included as detailed illustration. The document may be relevant in the context of uncertainties on exposure assessment of vitamins and minerals (e.g. for the purpose of setting maximum levels).

The public consultation runs until 10 September.

**Czech Republic launches nutrivigilance project**

Czech Republic Public Health Institute (SZU) has launched a new website relating to a nutrivigilance project of the Center of Health, Nutrition and Food in Brno.

The purpose is to gather information about adverse effects linked to intake of certain food products (including novel foods, food supplements and food containing food additives). The Institute has developed an electronic form for reporting undesirable health effects. Notifications of adverse effects can come from consumers and health professionals. Each report will be carefully assessed and inserted into a database for monitoring. The information will also be forwarded to the health authorities for further follow up. It is foreseen that the collected information will also be shared with other EU Member States. For the time being, reports of adverse effects will not be disclosed but be treated confidentially. This initiative fits into the coordinated activity of a number of Member States to work on systems as already in place in France.

**EFSA releases its final opinion on Caffeine**

The European Food Safety Authority has adopted its opinion on caffeine with little changes to the draft version despite some points of contention for some Member States.

Conclusions remain unchanged namely:

- 400 mg/day of caffeine intake from all sources for habitual consumption does not raise safety concerns (while 200 mg is stated for single doses), except for pregnant women;
- up to 200 mg/day for pregnant and lactating women (for habitual consumption and single
EFSAs also concludes that other constituents of “energy drinks” at the doses commonly present and/or moderate habitual alcohol consumption would not affect the safety of habitual caffeine consumption up to 400 mg per day.

Belgium publishes the results of its risk assessment on arsenic in algal-based supplements

The Superior Health Council (HSC) of Belgium has recently published the results of its risk assessment report on the presence of arsenic and other elements in algae and supplements based on algae following questions raised on the current national maximum level for As (1mg/kg) in supplements. Main conclusions were:

- Maximum levels should be based on “tAs, reduced by AsB” instead of “tAs”, as it is the case in current legislation.

- Exposure to IAs is linked to the consumption of edible algae belonging to the red algae (Rhodophyta) such as Nori, and to the brown algae (Phaeophyta) such as Arame, Kombu and Wakame.

- Consumers of algae-based FS are not exposed to a substantial additional intake of the most toxic As species, IAs (inorganic As - i.e. arsenate, AsV and arsenite, AsIII).

- Appropriate measures based on the findings of the report should be taken at national and European level.

Levels for Arsenic have not been harmonized at the European level yet. This harmonization process is currently at its first stage, and discussions are ongoing about maximum levels for certain food products.

The Netherlands looks at less strict limit for Pyrrolizidine Alkaloids

The Dutch National Institute for Public Health and the Environment (RIVM) has recently published the results of an investigation on whether the maximum levels for pyrrolizidine alkaloids were still in accordance with the latest scientific insights. The investigation has revealed it would be possible to adopt a slightly less strict limit value: 5 mg per kilo for herbal teas and botanical food supplements instead of the 1 mg per kilo as set nationally. Taking these conclusions into consideration, a revision of the national provisions could be foreseen.

Norway reflects on methodology for the assessment of the safety of other substances

Norway is reflecting on the establishment of a risk assessment system for the evaluation of the safety of other substances. Following the publication of the ‘Overview of previous risk assessments of “other substances”’ revised in January 2015, the Norwegian Food Safety Authority (NFSA) has now mandated the Norwegian Scientific Committee for Food Safety (VKM) to prepare a guidance document outlining the methodology to be used for the safety assessments of “other substances” (Phase 2) and assess the safety of “other substances” present in food supplements. Only substances with a purity of minimum 50% or concentrated 40 times or more will be considered. The assessment will exclude substances regulated by other legislation like those for novel foods, food additives, aromas, foods for special medical purposes, etc.

The completion of this task is expected in December 2016 and will be used for the preparation of an eventual regulation. In 2011, food supplements containing “other substances” constituted more than 50% of the market share in Norway.

Argentina

National Food Commission (CONAL) Meeting

On 6 July the National Food Commission (CONAL) held its 107th meeting in order to discuss the comments received in public consultation on the draft resolution regarding Food Supplements. After reviewing the comments, the CONAL decided to continue with the administrative process of the resolution for their approval and publication in the Official Gazette of Argentina. The final document is still confidential and will be published in the course of August.

Brazil

Allergens labeling Regulation published

On 3 July, ANVISA published Resolution RDC Nº 26 of 2015, which addresses the requirements for the mandatory labeling of the main food allergens. The Resolution applies to foods, including beverages, ingredients, food additives and processing aids, packaged in the absence of the consumer, including those destined to industrial manufacturing and food services. By 3 July 2016 all labels must be adapted.

Paraguay

Decree Nº3586 on Food Supplements

On June 15 the National Sanitary Surveillance Agency in Paraguay (Dinavisa), published the Decree Nº3586, which establishes “the rules for manufacturing, the arrangements for the acquisition and renovation of sanitary registration, quality control, disease control and marketing of products called food supplements.” Among the main points mentioned, the Decree emphasizes that the criteria for establishing maximum levels of vitamins and minerals will be based on safety and food supplements will be able to use claims, which will be identified in a list to be developed with reference to FDA and EFSA.

Venezuela

Public Consultation on Food Supplements

On 25 June, the Institute for Standardization of Venezuela published for public consultation the Draft 3863: 2015 Food Supplements. The document, which has been developed by a Technical Committee of the industry and the authorities of Venezuela, will extend the current regulatory framework of Venezuela which provides only vitamin and mineral supplements. With the proposed amendment, food supplements may also include other substances with physiological and nutritional effects as well. Comments can be sent via the form published on the website until 6 August: http://www.fondonorma.org.ve/linknormalizacion.php
Dubai

On-line Purchases

The Ministry of Health (MOH) has warned the public against buying food supplements on line at the Emirates International Conference on Combating Drug Counterfeiting held in April in Dubai.

“The majority of online pharmacies are not registered and many of the drugs and food supplements sold are fake” said Dr Ameen Hussain Al Amiri, Assistant Undersecretary for Public Health Policy and Licensing Sector at the Ministry of Health.

An increasing share of the supplement trade is developing on Internet. Concerns of Dubai are not isolated. Many governments and regions have difficulties to control this market and are looking at solutions for improving the effectiveness of their controls.

GCC notifies WTO of a draft Regulation for labeling of all prepacked foodstuff

The state of Kuwait has recently notified WTO of a draft technical regulation regarding the labeling of all pre-packaged foods, general requirements, mandatory and voluntary information.

Consultation will run until 9 September.

https://members.wto.org/crnattachments/2015/TBT/KWT/15_2652_00_e.pdf

United States

Ohio passes ban on pure caffeine

Pure powdered caffeine won’t be legally sold in Ohio under legislation signed by Gov. John Kasich. The measure also aims to prohibit sales of powdered alcohol.

Federal regulators have warned consumers to avoid pure powdered caffeine, which is typically sold online. According to FDA, even a teaspoon of the powder could be lethal with a single teaspoon of pure caffeine is roughly equivalent to the amount in 25 cups of coffee.

USP Quality Standards for Dietary Ingredients and Dietary Supplements to be expanded

USP will expand the development of standards for dietary ingredients and dietary supplements, focusing on new and high-impact areas. The resolution is part of the 5-year plan adapted by the USP Convention membership in April.

Products containing CBD are outside the definition of a dietary supplement

FDA has recently ruled that products containing cannabidiol (CBD) cannot fit under the legal definition of dietary supplements and therefore cannot be marketed as such under the federal Food, Drug and Cosmetic Act.

In a question and answer on marijuana posted on FDA’s site, the US agency announced that a substance that has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public cannot be marketed as dietary supplements.

While the federal law carves out exemptions for substances “marketed” as a dietary supplements or as a conventional food before the new drug investigations were authorized, the FDA concluded that the exception could not apply to cannabidiol (CBD) based on the evidence offered.

Industry helps oppose amendments to limit military access to dietary supplements

Proposed amendments to limit military access to dietary supplements was rejected after a concerted opposition from the dietary supplement industry.

The amendments, introduced by Senators Richard Blumenthal and Dick Durbin to the National Defense Authorization Act (NDAA) on 3 June, called for monitoring military supplement use, for restricting the sales of supplements sold on military bases and for recording adverse events related to dietary supplement intakes.

Ukraine

Ukraine continues attempts to regulate sales of dietary supplements

The bill on amending Article 21 of the Ukrainian Law “On advertising”, aimed at preventing sales of dietary supplements via call centers was submitted by the Ukrainian Health Ministry to the State Regulatory Service for regulatory impact assessment analysis prior to its submission to parliament.

The bill introduces the following provisions: “Contact telephone numbers shall not be mentioned in advertisements of dietary supplements. Contact telephone numbers shall not be mentioned in printed publications, in broadcast news and analysis programs and in programs devoted to medical topics, for the exception of advertisements by health care institutions which are licensed to provide commercial medical services.”

The authors of the document believe the passing of the bill in its current form will authorize the Ukrainian Interior Ministry to launch criminal proceedings over instances of dietary supplements being advertised and sold via call centers.

Russia

Responsibility for advertising food supplements as medicines to tighten

The Russian consumer rights watchdog has drafted amendments bolstering the responsibility of advertisers and media which sell food supplements for medicines. According to the law on advertising, it is not allowed to sell food supplements for medicines or advertise their curative qualities.

Warning against such a misinterpretation should accompany any promotional material or published advertisements.

The service highlights numerous cases of non-compliance in this area, with the elderly being frequent victims of such fraud.
FOCUS: NRVs-NCD

What are NRVs-NCD?
NRVs-NCD spells out for Nutrient Reference Values- Non-communicable Disease.

NRVs-NCD refer to NRVs that are based on levels of nutrients associated with the reduction in the risk of diet-related non-communicable diseases not including nutrient deficiency diseases or disorders.

Difference between NRVs-R & NRVs-NCD?

Nutrient Reference Values - Requirements (NRVs-R) refer to NRVs that are based on levels of nutrients associated with nutrient requirements. They are used for labeling purposes to help consumers make choices that contribute to an overall healthful dietary intake.

BASIS FOR NRVs-NCD

Need for:

- Relevant convincing/ generally accepted scientific evidence or the comparable level of evidence under the GRADE classification for the relationship between a nutrient and non-communicable disease risk, including validated biomarkers for the disease risk, for at least one major segment of the population (e.g., adults).

- Public health importance of the nutrient-non-communicable disease risk relationship(s) among Codex member countries.

- Relevant and peer-reviewed scientific evidence for quantitative reference values for daily intake should be available.

- Daily intake reference values from FAO/WHO or other recognized authoritative scientific bodies.
NRV-NCD for EPA DHA
The story

IADSA presented the proposal that CCNFSDU consider new work on the establishment of a new Codex NRV-NCD for omega-3 fatty acids based on EPA and DHA in order to achieve better public health and information to consumers. CCNFSDU supported new work to be co-chaired by Chile and the Russian Federation.

February 2015
Chile and The Russian Federation issued an invitation to join the 2015 eWG on February 6, 2015; 21 Codex members and 9 observers indicated their interest in participating in the 2015 eWG.

April 2015
First consultation on NRV-NCD for DHA & EPA.

October 2014

November 2014

December 2015
CCNFSDU will discuss the establishment of the NRV-NCD based on the recommendations of the eWG.

First consultation on NRV-NCD for EPA and DHA long chain omega-3 fatty acids adopted as new work by Codex Alimentarius Commission.

21 Codex members and 9 observers indicated their interest in participating in the 2015 eWG. In addition to IADSA, these include Argentina, Australia, Canada, China, Ecuador, Europe, Germany, Greece, Ireland, Japan, Mexico, New Zealand, Norway, Peru, Serbia, Singapore, Sweden, Switzerland, Thailand, USA, CRN US and GOED.