IADSA Newsflash

October 2014

Recent Developments

Latin America has in the past month been the focus of some intense and very productive discussions among regulatory bodies. In meetings organized by IADSA and the regional grouping ALANUR, regulators and leading scientists from 13 countries came together to share information and knowledge and potential solutions to regulatory issues related to food supplements.

Many barriers to marketing products exist across the region, from the levels of vitamins and minerals and ingredients that can be used to the claims that are approved. Fortunately, partially due to international pressure a substantial number of countries are considering changes to their regulatory systems.

The events in Buenos Aires permitted some open and very significant debate around issues such as the creation of maximum levels of vitamins and minerals based on safety (Brazil and Mexico are two of the remaining countries in the world with RDA based maximum levels in force); the creation of a positives lists of claims and approaches to including botanical ingredients and other bioactive ingredients in supplements.

This discussion was a significant step on the road to a better regulatory environment across Latin America.

In China discussions have been taking place with the authorities and IADSA on the process of implementing the future notification system for supplements. In a country as large and diverse as China, implementation of any regulation is a challenge and once the law permitting notification for supplements is adopted by the National People's Congress, it is clear that the process of implementing it will need to be developed fast. Experience is being provided from across the world on many aspects of such a system with a view to helping the officials achieve the best possible result.

Two countries also figure highly at present due to the challenging regulatory environment. Both in South Africa and Turkey legislation has been agreed which presents major challenges for many products. Significant work is underway by the industry in both countries, but it seems likely that the positive experience of international systems may be critical in helping open minds in government to alternatives. Work is underway to communicate alternative approaches to those who need to know in government.

New IADSA Scientific Publications

Vitamin and Mineral Safety handbook - 3rd Edition – Joint CRN IADSA publication

Nutritional risk analysis approaches for establishing maximum levels of vitamins and minerals in food (dietary) supplements

IADSA

International Alliance of Dietary/ Food Supplement Associations

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Regulatory news

ASEAN

The ASEAN Health Supplement Government meeting

The scientific committee, Framework Task Force and GMP Task force met in Bangkok on 25 to 29 August 2014. The major outcomes of this meeting were the agreement to address the concerns raised by industry on the flexibility to be allowed on the implementation of the Guidelines. Other outcomes include the agreement to adopt of the guideline Limits of Contaminants and Safety Data Substantiation requirements. These adopted guidelines will be presented for endorsement at the 22nd government meeting, which will be held from 10-14 November in Vientiane, Lao PDR.

China

Draft standard on sports nutrition food issued

A draft national food safety standard on Sports Nutrition Food was issued for public consultation in September.
It has consolidated and will substitute five related national and industry standards that have existed and will add consistency and technical and safety requirements.
The draft standard categorizes sports nutrition food into the following 4 categories:

- products to replenish energy
- products for energy control
- products for supplementing protein
- products for supplementing nutrients for specific sports (4 sub-categories)
- products for supplementing multi-nutrients

Besides complying to the general safety requirements such as the microbiological and chemical contaminants as set in the draft standard, each product category also has specific nutrient content requirements and the permitted levels of each functional nutrient.

Japan

New Health/Functional Claims System agreed

Japan has announced a new health food regulation, which is expected to be implemented next year. The new regulations will permit foods to make health claims.
Food companies will be responsible for safety assessment and scientific substantiation of the health/functional claims, similar to structure/function claims of dietary supplement system applying in the US.
Basic concepts for this new health/functional claims are:

- Assurance of the safety of the product
- Requirements for scientific substantiation of claimed health functions
- Labeling regulations/limitations to prevent misleading consumers
- Possibility of claims for parts of body
- Pre-notification (approximately 60 days before launching) and open publication system using home page.

The detailed guideline is under discussion including industry groups and is expected to be finalized at the end of this year.

The New Food Labeling Act expected in June 2015

There have been a number of notifications under the following three Acts. Food Sanitation Act, Japan Agricultural Standard Act and Health Promotion Act. In 14 June 2013, the creation of a new Regulation was announced.
The new Regulation foresees:

- Mandatory Nutrition Labeling
- Revision of Nutrient Function Claims
- Self- determine health/functional claims system.

This new Food Labeling Standard will be effective from June 2015.

Philipppines

First health and nutrition summit of the supplement sector

A move to boost awareness of health lifestyles and supplementation was made in July with the launch of the first health and nutrition summit. Organized by HADSAP (Health and Dietary Supplement Association of the Philippines) the summit not only addressed the many issues around the value of supplementation but also helped companies become better equipped to deal with ASEAN harmonization in health supplements which is due for completion in 2015.

Vietnam

Vietnam notifies WTO of a guidance document on the labeling of foods containing GMOs and products of genetically modified organisms

The Ministries of Agricultural and Rural Development, and Science and Technology have issued a joint circular on the labeling of foods contained genetically modified organisms and products derived from genetically modified organisms. This Circular will apply to organizations and individuals engaged in production, trading, imports of goods and processed foods, food additives and food supplements. All foods containing genetically modified organisms and products of genetically modified organisms at a rate higher than 5% of each component shall, in addition to complying with the law on labeling, have to display the information relating to genetically modified organisms on the labels. 3 years from the effective date of the circular, the production, processing, packaging, import and processing for export of genetically modified food will not be permitted if food labels do not comply with the new provisions. The products already on the market will be permitted to be marketed but no longer than 12 months.

Taiwan

Taiwan notifies WHO of draft food additive amendment

On 23 October Taiwan notified the WTO of a draft food additive amendment on the use of various sweeteners in foods, including food supplements. The following maximum levels are proposed:

Saccharin/ sodium saccharin: 1.2 g/kg for food in capsules and tablets. And 0.08g/ for supplements in liquid form. Levels calculated as saccharin.

Sodium cyclamate/ calcium cyclamate 1.25 g/kg for food in capsules and tablets. And 0.4g/L for supplements in liquid form. Levels calculated as cyclamate.

Europe

EFSA publishes scientific opinions on DRVs for zinc, selenium and chromium

EFSA Scientific Opinions are part of EFSA's ongoing review of existing advice on DRVs for energy, macronutrients and micronutrients. The opinions are available here for zinc, selenium and chromium

EFSA introduces electronic submissions for regulated product applications

The European Food Safety Authority Applications Helpdesk has recently introduced E-submissions, 'the first step in developing a complete IT tool for the electronic management of applications' as part of EFSA's ongoing customer-oriented approach to strengthen the support it provides to applicants, reduce the administrative burden and deliver efficiency gains by streamlining the risk assessment process. Applications, updates to applications and responses to requests for additional information, for regulated products (e.g. additives, enzymes, health claims) should therefore now be submitted to the EFSA by electronic means such as a CD ROM, DVD or USB key. All technical dossiers submitted either by an applicant, Member State or the European Commission, should include the original of a signed cover letter listing annexes, their tables of content and the mandate. EFSA has clarified that while it is still possible to also send full paper copies of technical dossiers, the submission of an electronic copy is now regarded as the formal submission. Further information can be found here

New regulation on gluten free foods

Commission implementing Regulation on the requirements for the absence or reduced presence of gluten in food has been published. The Regulation will apply from 20 July 2016 at which time the previous Regulation will be repealed. The statement 'suitable for coeliacs' is now officially authorised as an alternative to 'suitable for people intolerant to gluten' (Article 3(2)). The same for the statement 'specifically formulated for coeliacs' as an alternative to the statement 'specifically formulated for people intolerant to gluten' (Article 3(3)).

EFSA publishes Administrative Guidance document on food enzymes applications

Pursuant to the so-called 'Framework Regulation' on Food Enzymes and Regulations on the Common Authorization Procedure for Food Improvement Agents, EFSA has recently published an Administrative Guidance document on applications for authorization of food enzymes in the EU.

Ethanol solubility specifications of polyvinyl alcohol (PVA) discussed

"Practically insoluble or insoluble" this is the term suggested by EFSA to describe the technical solubility of PVA in Ethanol. Following a request of the EU Commission for a modification of the ethanol solubility specifications of polyvinyl alcohol (PVA) (E 1203), EFSA came to the conclusion that the description of the solubility of the compound in ethanol (> 99.8 %) should be modified from "sparingly soluble" to "practically insoluble or insoluble". Given that the new solubility tests were conducted with a sample provided by the owner of the toxicological studies evaluated by the EFSA AFC Panel in 2005, it was also confirmed that the modification of the specification should have no safety impact.
The use of Polyvinyl alcohol (PVA) (E 1203) is currently authorized as a coating agent in food supplement capsules and tablets at a level of 18,000 ppm.

Action level for Dioxin like PCBs in clays sold as supplements increased

In order to align the action level for dioxin-like PCBs in clays as food supplement to the action level applicable to the same clays intended for animal feed, a recommendation was published in September.
Action levels are set to reduce the dioxin intake of the European population and should be used as a tool for authorities and companies to highlight those cases where it is appropriate to identify a source of contamination and to take measures to reduce or eliminate it.
The following action levels apply to clays sold as supplements:

- Dioxins + furans: 0.50 pg/g wet weight
- Dioxin-like PCBs: 0.50 pg/g wet weight.

Germany launches list with permitted, prohibited and restricted plants

The German Federal Office for Consumer Protection and Food Safety (BVL) launched in September the 2014 version of the German plant list ("Stoffliste"), which has been updated on the basis of the previous 2010 BVL list. The purpose of this list is to facilitate the classification of plants and plant parts in food, in cases where their classification is "not clear" or "controversial". The list, which contains approximately 600 plants is not legally binding and is intended to be used by companies and enforcement authorities as guidance. It will be updated regularly.
Further information can be found at the following address:
http://www.bvl.bund.de/SharedDocs/Downloads/01_Lebensmittel/stoffliste/stoffliste_pflanzen_pflanzenteile_EN.pdf?__blob=publicationFile&v=4

Pyrrolizidine alkaloids in botanicals and honey under scrutiny

The French Authority DGCCRF has recently launched a survey to collect data on the presence of pyrrolizidine alkaloids in honey and food supplements containing some botanical ingredients and pollen.
79 institutions were targeted, from which 84 samples (53 honeys and 31 food supplements) were taken for laboratory analysis for 21 toxic alkaloids. Results showed that one third of the samples of food supplements contained pyrrolizidine alkaloids (PAs) at levels between 2.3 and 225 mcg/kg. However according to the Authority, those levels would not lead, by sole consumption of these products, to a consumer exceeding the exposure level inducing a long-term toxic effect. This level was identified by EFSA as being 15 µg/kg of body weight per day.
PAs are toxins exclusively biosynthesised by plants. It has been estimated that approximately 6000 plant species world wide, representing 3 % of all flowering plants, may contain pyrrolizidine alkaloids. They are mainly found in the distantly related angiosperm families of the Boraginaceae (all genera), Asteraceae (tribes Senecioneae and Eupatorieae) and Fabaceae (genus Crotalaria).

Violation of the health claims regulation severely punished in Italy

The Italian Competition Authority AGCM has recently imposed a fine of

250,000 Euro on a company for its

misleading advertising campaign on a product "Immun'Âge" (in printed material, radio, TV and on internet, including a dedicated internet webpage). The health claims made for the papaya ingredient product were judged as misleading and non-authorized. The promotional material made extensive reference to claims on serious diseases (Alzheimer's, Parkinson's disease, etc.) or other diseases/physiological properties such as cellular aging, flu and colds, vaccinations and states of debilitation. The decision on the final fine took in particular into account the turnover of the company, the fact that multiple misleading health claims were used in several fields of health, targeting several consumer health profiles/population groups, across a wide range of channels.

Europe approves health claim on supplemental folic acid and reduced risk of neural tube defects

On 28 October the European Commission published the authorization of the health claim on supplemental folic acid and reduced risk of neural tube defects.
The authorization of this claim is a major step forward for the sector that will undoubtedly contribute to demonstrate the importance of supplements for public health. Thanks to David Richardson advisor to CRN UK and of the IADSA Scientific Council for his involvement in this great achievement.

Argentina

Public consultation on food supplements

During August, the National Food Commission (CONAL) published in Public Consultation a new Draft Resolution on Food Supplements.
The main change relates to an increase from 20% to 30% the minimum RDA of vitamins and minerals that must be used in food supplements.
Additionally, the proposal mentions the inclusion in the Argentine Food Code of those plant species that may be used in the manufacture of food supplements. The consultation ended in September and it is expected that the CONAL publish the results before end of year.

Brazil

New bill regarding Food Supplements presented in the Senate

Senator Cicero Lucena, member of the Brazilian Social Democracy Party (PSDB), introduced last month a new bill in the Brazilian Senate regarding Food Supplements (PL No. 233).
The bill provides in Article 1 a ban on the import of food supplements that are not registered in Brazil as well as the need to comply with laboratory analysis to market these products.
Additionally, the bill clarifies that all food supplements are subject to pre-market registration, which would impact those vitamin and mineral supplements currently "notified" in Brazil. The project has been sent to the Environment, Consumer Protection and Control Commission and is currently awaiting the Rapporteur's opinion.

Ecuador

Substitute Regulation for Natural Products Registration

On 11 August, the Ministry of Public Health of Ecuador published in the Official Gazette a Substitute Regulations for the Registration and Control of Processed Natural Products for Medicinal Use. Since there is no specific regulation for Food Supplements in Ecuador, several products with botanicals and other ingredients are registered as Natural Products by the authority even if they do not have therapeutic effects.
Among the new provisions mentioned in the regulation is a pharmacovigilance plan.

GCC (Gulf Cooperation Council)

UEA and Oman notify general requirements for Halal food

The AE and Oman notified a Gulf draft regulation on General requirements for Halal Food (GSO 05/FDS/2055-1:2013) which has a very broad scope without specificity as to which products will be impacted. There is a potential risk on requirement for halal certificates for all products (even where the company does not declare halal) and for factories. The proposed certification process to be followed in all stages of the food chain and could create a technical and economic burden for companies as well as trade barriers.

GSO draft standard on food additives under discussion

Saudi Arabia and the UAE are currently revising the GSO draft standard on food additives permitted in foodstuffs and the comments received. In addition, the UAE has unilaterally decided to adopt the Codex GSFA list of permitted additives (2013) in a new UAE standard on additives. However, it is still unclear whether warning statements will be required for Sunset Yellow E 110 and Allura Red E129.
The Dubai Municipality and ADFCA are considering to add an annex that would permit, on a case by case basis, the food additives that are not listed in the Codex GSFA, and that are permitted in the EU / US.

Canada

Health Canada consults on proposed pre market submission process for food additives.

On 7 October Health Canada launched a consultation on the Food Directorate's Proposed Pre-Market Submission Process for Food Additives, Infant Formula and Novel Foods. With this consultation, the food Directorate intends to improve the timelines, predictability and transparency of the submission process. Comments are accepted until 5 December.
www.hc-sc.gc.ca/fn-an/consult/2014-foods-aliments/index-eng.php

United States

FDA warned about supplement claim to treat concussions

The U.S. Food and Drug Administration is warning consumers about dietary supplements that falsely claim to prevent or cure concussions or other traumatic brain injuries.
FDA said it identified two companies selling multiple products claiming to prevent and treat concussions and other TBIs. The agency sent both companies warning letters in 2012 and both companies changed their websites and labeling. In December 2013, FDA issued a warning letter to another company for marketing its product with claims to treat TBIs.

The FDA will continues to monitor the marketplace for products with similar fraudulent claims, and will take appropriate regulatory action to protect the public health.

Dietetics and nutrition webinar organized by FDA

FDA's Center for Food Safety and Applied Nutrition (CFSAN) and the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) sponsored a Dietetics and Nutrition webinar held on 22-23 September. The Webinar was designed for dietetic interns, students and faculty in dietetics and nutrition, and practitioners in dietetics, nutrition and related professional areas. Its purpose was to communicate FDA's nutrition and regulatory activities that are relevant to the practice of nutrition and dietetics.

FDA announces public meeting on FSMA proposed rules

On 29 September, FDA published supplemental proposed rules for four of is foundational FSMA (Food Safety Modernization Act) proposed rules:

- Produce Safety
- Preventive Controls for Human Food
- Preventive Controls for Animal Food
- Foreign Supplier Verification Programs.

Russia

Embargo lifted for dietary supplements

Following pressure from the food supplement sector, the government amended on 20 August the import ban list published on 7 August in reaction to the economic sanctions introduced by a number of countries against Russia (as a consequence of the crisis and war in Ukraine). Starting from 29 August 2014, the sanctions no longer affect selected types of agricultural produce, raw materials and foods, including dietary supplements, vitamin-mineral complexes, flavour additives, animal and plant protein concentrates and mixes thereof, dietary fibres and food additives (complex additives inclusive).

WHO remote office to be opened in Moscow in January 2015

The Russian Ministry of Health (MOH) announced the date of the launch of a joint project of MOH and the World Health Organization. A geographically dispersed office (GDO) - a technical office integrated with the WHO European regional office - will be opened in Moscow in January 2015.

The Moscow office will be mainly focused on objectives of control and prevention of non-communicable diseases (NCDs). The decision to set up the office was taken at the 67th session of World Health Assembly held in Geneva in May, the key topic of which was the NCDs and promoting health through the life course. Russia has gained a considerable experience (including various health protection measures and regulative measures) in prevention of diseases for the last ten years. The realization of the project is an important step in the implementation of the WHO Global Action Plan for the prevention and Control of NCDs for 2013-2020.

Ukraine

Ukraine revises RDAs based on WTO recommendations

On 27 August, the Ukrainian Health Protection Ministry published a draft instruction on approving recommended nutritional norms for macronutrients and calories. The bill describes recommended daily intake norms for children, adults (men and women) and senior citizens as applied to proteins, fats, carbohydrates, calories, mineral substances and vitamins, based on the WHO recommendations.

The bill also introduces recommended daily intakes for micronutrients and biologically active substances with a proven physiological effect (for adults).

Better regulation for consumer rights protection

On 18 August, the Ukrainian Ministry of Economic Development and Trade published a draft law on amending a number of regulatory acts related to the protection of consumer rights.
The bill is aimed at improving the segment of legislation related to consumer rights protection.
In particular, it proposes:

- Eliminating the overlapping functions of the human rights regulators, market control agencies, food safety enforcement agencies and enforcement agencies in the field of safety of services;
- Introducing uniform food labeling requirements,
- Eliminating regulatory provisions which present technical barriers to trade;
- Simplifying procedure for consumer complaints and enforcing the protection of consumer rights.

In the meantime, the coordination centre for the introduction of economic reform, which reports to the Ukrainian president, and the Ukrainian Cabinet of Ministers have begun implementing reforms of the government. Among other things, the reforms are aimed at streamlining the structure of government controlling agencies.
Of the 1,032 controlling functions currently performed by various central executive bodies, only 680 should stay. Of the 56 central controlling agencies, only 27 will remain. The reforms are expected to improve the ineffective state control system and relieve pressure on business.

Risk Analysis for Nutrients

Why Risk Analysis ?

Vitamins and minerals are essential for life, and consequently adverse effects can result from suboptimal intakes and deficiencies as well as from excessive intakes.

For food regulators and policy makers, risk analysis provides a systematic and structured approach to assess public health and safety risks from food and food supplements, and a means to manage any characterized risk. Nutritional risk analysis addresses two key questions:

1. What is the nature and magnitude of the health risk?
2. How should the risk be managed and communicated to those affected?

Reference

Science-based approaches to nutritional risk analysis and the establishment of upper levels of intake for nutrients are based primarily on principles and guidelines from:

CODEX ALIMENTARIUS

Components of risk analysis based on FAO/WHO Report (2006)

Risk Assessment
Science based
- ULs

Risk Management
Policy based
- Maximum Levels

Risk Communication
Interactive exchange of information & judgement about risks

Characteristics of Upper Levels

ARE

Based on scientific risk assessment's assumptions and uncertainties. • Not only safe, but safe by a comfortable margin. • Defined and identified to reflect safety of chronic intakes. • Values that take account of identified sensitive populations.

ARE NOT

Thresholds for adverse effects. • "Safety limits". • Applicable to temporarily elevated intakes

Step 1

1

Nutrient Hazard Identification

Review literature to identify potential health problems (e.g. deficiency and excess endpoints).

Step 2

2

Nutrient Hazard Characterization / Quantitative Evaluation of Critical Effects

Identify, where possible, level at which a nutrient causes adverse effects (e.g. dose–response, clinical, epidemiological, metabolic data, case reports). Set acceptable range of oral intake (AROI) or tolerable upper intake level (UL) or safe upper limit (SUL).

Step 3

3

Dietary Intake Assessment

Evaluation of the average intake of various population groups from food, water, supplements. Assess variability of the magnitude of intake using intake percentiles.

Step 4

4

Nutrient Risk Characterization

Integrate intake information and AROI, UL, SUL data. Evaluate strength and weakness of each step and identify group of greatest concern.

Principles of Risk Assessment : 4 Steps