Emerging Issues

Part of the success of IADSA is its ability, through the global network of information from associations and companies, to see trends in opportunities and challenges that we need to focus on.

At present we are seeing three which are all rising up the list of priorities:

1. An increasing awareness among regulators of the role of adverse event reporting systems in providing the data that they require to feel comfortable about the placing of botanicals and combination products on the market.

2. A drive to introduce maximum levels of vitamins and minerals for vulnerable population groups, particularly children

For these 2 issues, discussions have been initiated both by the Technical Group and Scientific Council in order to provide guidance to governments through new publications expected in the course of next year.

3. Shifts from registration to notification systems for bringing products to market.

The term 'notification' is enjoying an increased usage among regulators across the world looking for a way to move away from burdensome registration systems. The application of a notification system is most commonly associated with the EU where for food supplements and some other product categories, Member States can request that companies submit

a copy of the label to the authority at the time of marketing so that the authority can use this information for market surveillance purposes.

However, increasingly notification has taken on a broader concept of something which requires the submission of data but which does not require pre-market approval as registration would. It is for this reason that the concept of introducing notification for at least some products is gaining traction in

China (where the registration system is one of the world's most challenging), in some parts of Latin America and in some countries of SE Asia.

In addition, a recent Court judgment in India which challenged the current registration process has opened up an opportunity for a debate to be held on a more workable system than the current registration model, potentially opening the door to a notification system for at least some products.

IADSA is working hard on building approaches which can work in a variety of market situations, which can speed market entry while still providing confidence to regulators. We are fully aware that many companies face many hurdles at the pre-market approval stage, some of them requiring retesting of products which delivers no value to either the regulators, companies or consumers. Our goal is to help improve this situation.

Block the dates
2015 Annual Week, Singapore

Tuesday 14 April

- Morning: Board/ Scientific Council/Training
- Afternoon: Political event ASEAN HS Harmonization

Wednesday 15 April

- General Assembly
- Dinner

Thursday 16 April

- Company Council
- Technical Group

IADSA
International Alliance of Dietary/ Food Supplement Associations

International Alliance of Dietary/Food Supplement Associations
International Non-Profit Organisation
50 Rue de l'Association, B-1000 Brussels - Belgium

Regulatory news

ASEAN

ACCSQ TMHS PWG Inter-sessional meeting to be held 25-29 August

The next meeting for the scientific committee, Framework Task Force and GMP Task force, will be held from 25 to 29 August 2014 in Bangkok, Thailand. There will be also a joint GMP-Regulatory Framework Task Force meeting to address the concerns raised by industry on the flexibility to be allowed on the implementation of the Guidelines.

China

Draft Food Safety Law including new Health Food Regulatory Framework being reviewed by National People's Congress

The National Peoples' Congress Standing Committee on 23 June had the first reading of the Draft Food Safety Law, which was then published for comments ended 31 July. A second reading of the draft Law after revision is expected later this year, and the aim if to finalize the Law by March 2015.
The current draft Law has made several new provisions on health food. The key change is the introduction of a new notification framework, which is expected to lower the market entrance barrier and make the health food market in China more open. IADSA has been working since 2004 to secure a move in this direction.

China publishes Draft Administration on Food Recall and Halt of Market Circulation

China Food & Drug Administration (CFDA) on 6 August published Draft Administration on Food Recall and Halt of Market Circulation for public consultation until 5 September.
The 11-page draft regulation sets detailed requirements on the criteria, process, and timeline on food recall activities, halt of market circulation, and dealing with recalled products. The draft regulation categorizes food recall.

Korea

Korea notifies WTO of draft amendment to functional health foods

The Ministry of Food and Drug Safety has notified WTO (G/SPS/N/KOR/483) of its intention to modify two pieces of legislations related to health functional foods Act.
The proposed amendments seek to strengthen the penalty for businesses that use materials not permitted in foods and delete the provision that restricts the reporting of the import of functional health food within five days prior to its arrival.

India

Approval of dietary supplements on hold following Bombay HC's judgment

The Food Safety and Standards Authority of India (FSSAI) has put product approval on hold following the recent Bombay High Court judgment in favor of dietary and health supplement manufacturers.
The Court has held that the Food Authority - which requires all food products (not standardized under the Regulations) to get prior product approval - did not follow due procedure under the Food Safety and Standards Act and hence it does not have the power to issue it. The judgment deals only with the administrative part of the procedures but does not cover the methodology of product approvals. With the new government in place Industry is seeking Ministry support.

Europe

Gluten-free foods EU Regulation published

European Commission implementing Regulation (EU) No 828/2014 on the requirements for the provision of information to consumers on 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 41/2009 will be repealed.
The statement 'suitable for coeliacs' is now officially authorized as an alternative to 'suitable for people intolerant to gluten'. The same for the statement 'specifically formulated for coeliacs' as an alternative to the statement 'specifically formulated for people intolerant to gluten'.

Generic descriptor application for 'probiotico' submitted by Italy

The Italian Ministry of Health (following application of two Italian associations including AIIPA) has submitted to the European Commission an official dossier to request authorization for the term 'probiotico' (probiotic) as a generic descriptor.
Generic descriptors are denominations that have traditionally been used for more than 20 years and which could imply an effect on human.
Denominations which will grant this generic descriptor status will be exempt form the application of the EU Nutrition and Health Claims Regulation. The conclusion is eagerly awaited by the food supplement sector. The term probiotics has disappeared from the European market since no health claims for these microorganisms have been authorized so far.
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:251:0007:0009:EN:PDF

Red Rice in the focus of French Academy of Pharmacy

Following the recommendation of ANSES the French Agency for Food, Environmental and Occupational Health & Safety, it is now the turn of the French Academy of Pharmacy to focus on the safety of red rice and more specifically on its content of monacolin K (a compound similar to statins) and citrinin (a potentially toxic compound).
The Academy voted against the marketing of supplements containing this ingredient claiming that the daily doses available on the French market were highly variable, from traces of monacolin K to 10 mg, a dose that

could be achievable with a statin drug in France.
The Academy requested that the use of monacolin K should be prohibited or restricted: 'All food supplements containing red yeast rice are prohibited unless they contain only traces of monacolin and citrinin and provided that the labeling mentions the assay method and sensitivity.'
The use of this ingredient, like melatonin, is often a subject of controversy. If the decision to prohibit the use of red yeast in supplements would be endorsed by the French Authorities, this may have consequences in other Member States and on the use the EU permitted claim related to monacolin K and maintenance of normal blood LDL cholesterol concentrations for which a daily dose of 10 mg of monacolin K is required.

France publishes its permitted list of botanicals for supplements

The French Decree establishing a permitted list of botanicals for supplements, notified to the Commission in December 2012, has finally been published.
Initiated in 2006, the Decree has faced a number of obstacles - most of them related to administrative issues e.g. in March the resignation of the government that rendered the Decree signed at that period invalid.
The publication of this text will play a key role to secure the botanical supplement category in France and to hopefully enable the DGCCRF to move toward the Belfrit list in a more official way. In the meantime, the Belfrit substances not on the French list will continue to be permitted via the mutual recognition procedure.

Food supplements on the Czech market in the hands of the Ministry of Agriculture

All competences concerning food supplements - including the notification procedure - have now moved from the Ministry of Health to the Ministry of Agriculture.
With this reorganization, the notification procedure is expected to be simplified and more effective with a system that will allow companies to notify their products electronically.
The current database will nevertheless disappear.

Extension of use for *Schizochytrium*

The European Commission has authorized an extension of the conditions of use of the novel food ingredient oil from micro-algae *Schizochytrium* sp. The following limits now apply to supplements: 250 mg DHA per day for normal population and 450 mg for pregnant.

Citicoline wins Novel Food approval

On 1 July, Citocoline gained EU clearance as a Novel Food. The new substance is intended to be used in food supplements in Europe aimed at the adult population at a maximum level of 500 mg/day, and in foods for particular nutritional uses, specifically foods for special medical purposes, at a maximum level of 250 mg/serving, and with a maximum daily intake from these types of foods of 1.000 mg/day. The novel food ingredient shall not be used in foods intended to be consumed by children.

EFSA confirms the current ADI for Indigo Carmine

Part of the re-evaluation program, EFSA has now released his opinion on the safety of the food additive Indigo Carmine (E 132).
The ANS Panel confirms the current ADI of 5 mg/kg bw/day but stressed that this limit is only applicable to materials with the same purity and manufacturing process as material used in studies without adverse effects on testis, namely 93% pure coloring and 7% volatile matter. A revision of the current specifications is therefore proposed in order to restrict the additive to that for which the ADI is applicable. Extension of this ADI to compounds of lower purity and/or manufactured using a different process could be considered but new data would be required to address the adverse effect.
Indigo Carmine is currently authorized at the level of 100 ppm for supplements in liquid forms and 300 ppm for solid forms.

EFSA proposes a new ADI for Sunset Yellow FCF

Following a request by the European Commission, EFSA was asked to assess newly submitted data from a study conducted as a result of the recommendations contained in a 2009 opinion. The new information assessed comprised an evaluation of the 28-day study report, the data considered by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in its latest evaluation from 2011, and any additional toxicological information that had become available since the completion of the previous evaluation by the ANS Panel.
Based on the data assessed, EFSA concluded that an increase a new ADI from 2,5 to 4 mg/kg bw/day for all population groups can be established in agreement with the latest evaluation by JECFA.
A limit of 10 ppm currently applies for supplements in liquid and solid forms.

Iron oxide

Following a Rapid Alert System for Food and Feed (RASFF) notification concerning the use of an unauthorized irradiated coloring agent (brown iron oxide) as coatings of food supplements sold by a supplier based in Italy, in depth discussions took place in Europe to define measures to handle this issue. A important number of companies in Europe were affected some with a highly significant. Given the economic consequences that a withdrawal would have had,
Member States agreed to adopt the pragmatic and harmonized approach not to withdraw products containing irradiated iron oxide as colorant from the market.

Brazil

Public Consultation on Allergen Labeling

On June 16 ANVISA launched a public consultation on a document containing provisions for the labeling of food allergens. The proposal, which was drafted for ANVISA through international references, scientific papers, surveys and meetings with various agencies and sectors of society, provides a list of major food allergens and standards for the labeling of processed foods, including the font size, information position and background color. The rule applies not only to food but also to food ingredients, additives, processing aids and raw materials that are packaged in the absence of consumers, including those specifically designed for industrial process.
The text will remain in public consultation to send comments and suggestions for 60 days on the website of ANVISA. After this period and once

approved, the proposal provides for a 12-month period for industries to comply with the new labeling.

Costa Rica

New temporary registration process for Food Supplements

Through Executive Order No. 38498, the Vice President of Costa Rica, in exercise of the Presidency of the Republic, and the Minister of Health have decided to establish a 'voluntary transition process' for registration or renewal of registration of food supplements, which is valid from June 10 to September 19, 2014.
Among the reasons for the measure they mention an 'excessive backlog of applications for registration and renewal in products of sanitary interest, affecting the legitimate interests of the companies to obtain such registries or renewals within a reasonable time'.
Through this Executive Order, companies interested in registering food supplements have the opportunity to present their request in a more flexible way.

Argentina

New bill to regulate advertising of Food Supplements

On July 10, members of the ruling party 'Frente para la Victoria' (FPV) resented in the National Congress, a draft law to regulate the advertising of Drugs, Food and Supplements.

The bill mentions 'the advertising of food supplements which contain elements that far from being harmless, are disrupting the physiological mechanism of the human body, including vitamins, minerals, energizing and anabolic substances, without measuring health consequences, should be banned'.
If approved, the Federal Authority for Audiovisual Communication Services (AFSCA), which supports Argentina's National Administration of Drugs, Food and Medical Technology (ANMAT) in controlling the advertising of foods and dietary supplements, will be responsible to regulate advertising that is present on these products. AFSCA will ban any mention of improving performance in certain types of activities and the advertising associated with clinical effects, among others.
The project has been forwarded to the Commissions for Social Action and Public Health, Trade and Communications and Information Technology before being presented in the Chamber of Deputies for voting.

South Africa

Amendments to the CAM Regulations challenged by industry

On 15 November 2013, without prior comment period or prior consultation the Minister of Health published amendments to the general regulations in terms of the Medicines and Related Substances Act 101 of 1965 pertaining to Complementary Medicines [CAMS].
The regulations contain clauses which effectively exclude an estimated 65% of CAMS products currently on the market. These are likely to impact a wide range of products from milk thistle to melatonin. Retailers have begun to delist products that do not comply with the law. A legal action has therefore been taken against the Minister of Health to challenge the amended regulations. Discussion between the government and industry is now down to the attorneys from both sides on whether a moratorium can be agreed on the implementation of the law to permit discussions to restart on the right approach to regulation.

GCC (Gulf Cooperation Council)

GSO New Draft standard on food additives

While the GCC Member States are still reviewing the comments received in order to proceed with the revision of this draft standard, the UAE has unilaterally decided to adopt the Codex GSFA list of permitted additives in a new standard on Additives Permitted for Use In Food Stuffs (UAE.S /FDS/ CAC 192:2014). It is still unclear whether the warning statements will be required for Sunset Yellow E 110 and Allura Red E129.
The Dubai Municipality and the Abu Dhabi Food control Authority are still discussing whether to permit certain food additives that are not listed in the Codex GSFA and that are considered safe by food safety authorities globally (e.g. EFSA) on a case by case basis.

Amendment to the GSO 2233 on Requirements of nutritional labelling

The GSO has circulated a new draft standard on Requirements of nutritional labeling. The main changes in the draft are in the list of NRVs for labeling purposes where the draft introduces a new NRV for Vitamin K: 60 µg, Biotin: 30 µg, Pantothenic acid: 5 mg, Biotin: 30 µg. The draft also introduces a number of additional changes to NRVs for other vitamins.

Dubai (United Arab Emirates)

Updated Healthy/ Dietary Supplements Guideline

The Dubai Municipality is developing an updated guideline for Food Supplements. The guideline contains a definition for supplements and botanicals, the procedure for notification (characteristics for the Healthy/Dietary supplement, labeling requirements, requirements, conditions for making certain claims). The new guideline, unlike the previous version, will contain more specifications for herbals or botanicals based products. The guideline also contain in the annexes a positive list of vitamins and minerals which may be used in the manufacture of Healthy/Dietary supplement, a list of permitted concentration of Vitamin and mineral in Healthy/Dietary supplements, a list of permitted Additives in Healthy/Dietary supplements, a list of Herbs and Botanicals allowed in Healthy/Dietary supplements.

United States

FDA Issues nanomaterial safety guidance

The Food and Drug Administration (FDA) released two final guidance documents regarding the use of nanotechnology in the manufacture of FDA-regulated products. These papers aim at providing an overarching framework to the regulation of nanotechnology products and addressing factors that should be

considered when determining whether a significant change in manufacturing process for a food substance already in the market affects the identity of the food substance; its safety or its regulatory status.
While the guidance documents do not establish regulatory definitions of 'nanotechnology', 'nanomaterial', 'nanoscale', FDA recalls that these terms are commonly used in relation to the engineering (i.e., deliberate manipulation, manufacture or selection) of materials that have at least one dimension in the size range of approximately 1 nanometers (nm) to 100 nm.

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM401695.pdf
http://www.fda.gov/downloads/Cosmetics/GuidanceRegulation/GuidanceDocuments/UCM300927.pdf

FDA Gluten fee Label Rules now effective

Since 5 August, food products labeled on or after that date must meet the new rule's requirements for the voluntary use of the claim 'gluten-free'. 'Gluten-free' food are defined as food that is either inherently gluten free; or does not contain an ingredient that is: 1) a gluten-containing grain (e.g., spelt wheat); 2) derived from a gluten-containing grain that has not been processed to remove gluten (e.g., wheat flour); or 3) derived from a gluten-containing grain that has been processed to remove gluten (e.g., wheat starch), if the use of that ingredient results in the presence of 20 parts per million (ppm) or more gluten in the food. The final rule applies to all regulated packaged foods, including dietary supplements.

FDA warns about powdered pure caffeine sold over the Internet

The FDA is warning about powdered pure caffeine being marketed directly to consumers, and recommends avoiding these products.
'Pure caffeine is a powerful stimulant and very small amounts may cause accidental overdose' 'All consumers seeking caffeinated products should be aware of the potentially high potency of these powdered pure caffeine products' said FDA.
A single teaspoon of pure caffeine is roughly equivalent to the amount in 25 cups of coffee.
Consumers who have experienced adverse effects with powdered pure caffeine and other highly caffeinated products are invited contact the FDA.

Russia

Self-regulating organization of dietary supplement producers

Russia's self-regulating association of dietary supplement manufacturers is in cooperation talks with Belarusian and Kazakh companies.

Bill on falsified dietary supplements gets first reading approval

On 01 July 2014, the State Duma passed in first reading the draft law 'On introducing amendments into certain statutory instruments of the Russian Federation regarding prevention of circulation of falsified, counterfeit, unsafe or unregistered medicines, medical products or falsified dietary supplements' (draft law No. 392886-6, initiated in November, 2013).
The draft law is forwarded to the President of RF, to the Federation Council (upper chamber of parliament), Government of RF, committees and commissions of the State Duma and to the Supreme Court of RF. All amendments were due by 1 August 2014, after which the Duma Committee for Civil, Criminal, Arbitrage and Procedural legislation would be tasked to finalize the draft embracing the amendments and to bring it in for the second hearing.
The bill introduces the concept of falsified dietary supplement and associated penalties.

Ukraine

Attempts continue to regulate sales of dietary supplements as medicines

The Ukrainian Health Ministry has prepared a draft law on amending Art 21 of the law on advertising (the text is available for discussion on the ministry's website).
The bill seeks to prevent the 'marketing of dietary supplements as medicines through telephone call centers'.

The current wording of P.9 Art.21 of the law on advertising already contains restrictions on the advertising of food products. In particular, 'advertisements of food products for special dietary consumption, functional foods and dietary supplements must not contain statements as to their medicinal properties'.
The new bill introduces a ban on the use of telephone services in advertising dietary supplements:
'Advertisements of dietary supplements must not contain contact phone numbers.'
'Contact phone numbers must not be mentioned in printed publications, in news and news-and-analysis broadcasts and in health-related programs, for the exception of advertisements of medical institutions licensed to provide medical services'.
The Health Ministry believes the bill will empower the Interior Ministry to institute criminal proceedings over instances of dietary supplement marketing via telephone call centers.

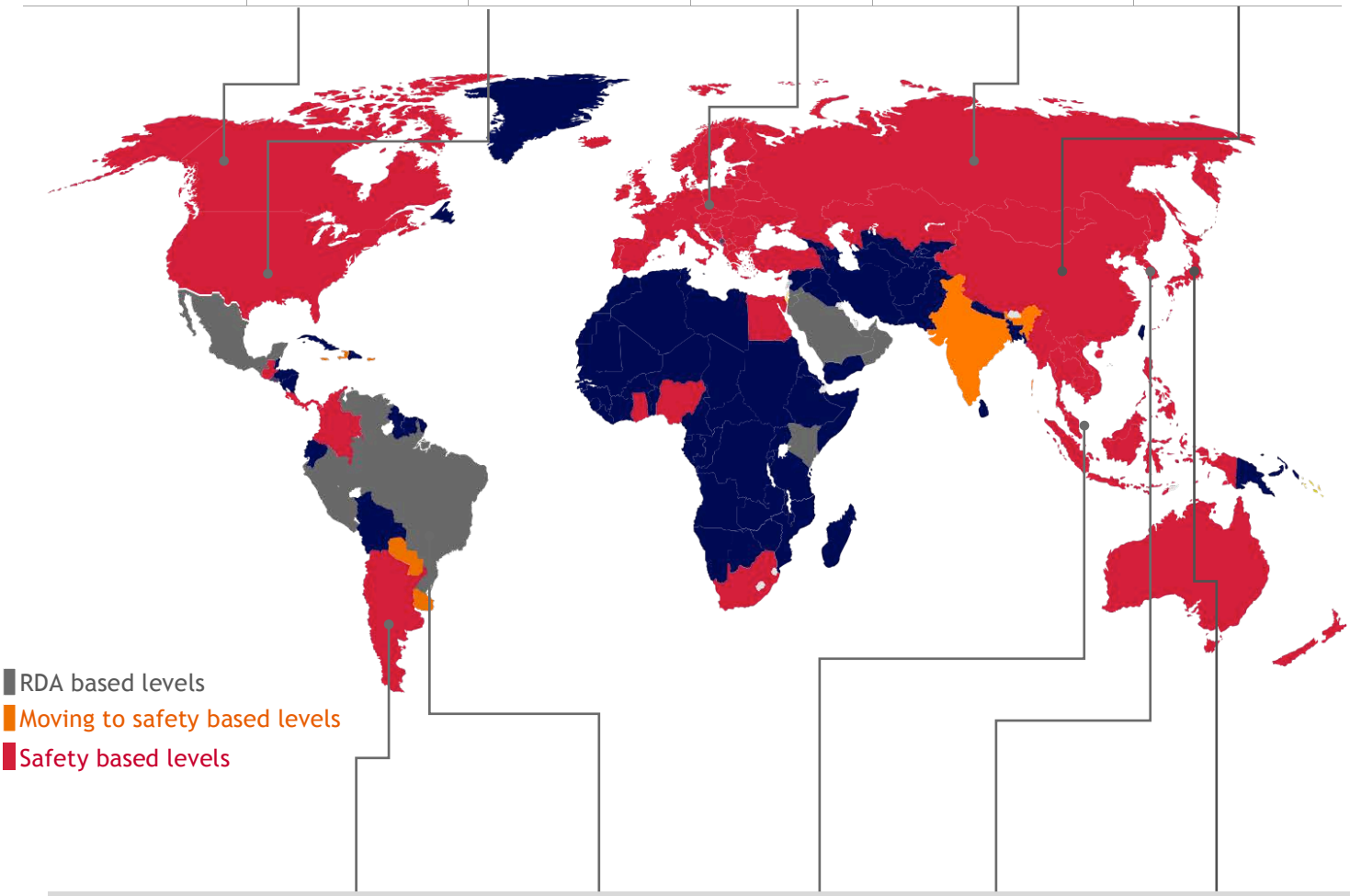
Customs Union

CU technical regulation for supplements underway

IADSA'S Customs Union working group has launched work on drafting a regional regulation for supplements.
The close partnership of IADSA WG with experts from Belarus, Kazakhstan and Russia made possible that in June 2014 the Kazakhstan Academy of Nutrition submitted to the Eurasian Economic Commission a formal proposal to adopt a single CU technical regulation for supplements.
The companies, members of the WG, hope that the proposal by Kazakhstan shall find support both with the Eurasian Commission and with the governments of CU member states. A significant step in the implementation of this project shall be the inclusion of the technical regulation for supplements into the plan of development of CU technical regulations for 2015.
At the same time IADSA WG members together with experts from Belarus, Kazakhstan and Russia upon approval of the key provisions of the technical regulation have started drafting the regulation text thereof. The discussion of the draft text is scheduled for September 2014.

Focus on supplement regulation worldwide

	Canada	USA	Europe	Russia	China
Category's name	Natural health product	Dietary supplement	Food supplement	Biological active food supplement	Health food
Premarketing Procedure for Finished product	✔	✗	✔	✔	✔ *Under discussion*
Claims	All	All	All	Nutrition claims	All



	Argentina	Brazil	ASEAN	South Korea	Japan
Category's name	Dietary supplement	Name relates to the composition	Health supplement	Health function supplement	No specific
Premarketing Procedure for Finished product	✔	✔	✔	✗	✗
Claims	All	Nutrition claims	All	All	All

All: Nutrition, functional and health claims

IADSA

Ensuring global markets are open, vibrant and successful

The Firsts!

97 First global meeting of food supplement associations in Brussels

00 First publication 'Dietary Supplements Policy: The Guide to Global Decision-Making Bodies'

01 First African Conference on Food Supplements: 'Towards a Global Regulatory Model', Cape Town, South Africa

02 First Asia conference on food supplements Bangkok, Thailand

02 First scientific publication Nutrition in Transition: the role of micronutrients

03 First Latin American Conference on Food Supplements, Rio de Janeiro, Brazil

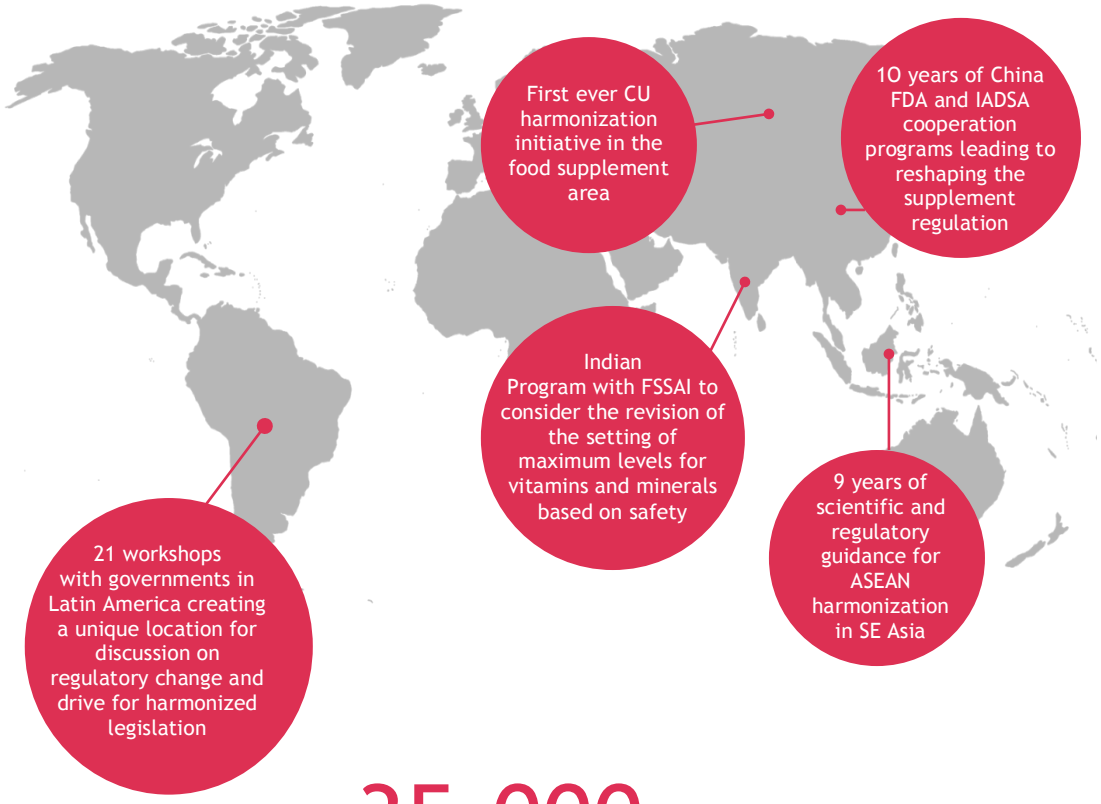
07 First Russian conference on dietary supplements

08 First IADSA Global Scientific Forum in Verona

11 First Global Guide to Good Manufacturing Practice for Supplements

14 First IADSA Expert Roundtable on botanicals supplements with governments

How IADSA influences key decisions?



35.000 copies of IADSA scientific & policy publications circulated across the world

What We Do

- Defending and promoting dietary supplements in law
- Shaping legislation worldwide
- Opening new markets and easing access to markets through eradication of barriers to trade
- Guiding government officials in the development of regulation and policy
- Sharing information and developing tools for the industry and governments