

# IADSA Newsflash

February 2015

## The small issues that define market access

“Technical issues” are not famed for getting the pulse running of supplement companies! A new framework for legislation, a new system for claims used in claims, questions over ingredients often end up in the spotlight when we discuss supplement legislation worldwide. But very often it is these small technical issues which can hang on a change to one word in legislation that are even more important for the marketing of food supplements in the short-term.

Food supplements are complex products - composed of many ingredients compared to conventional foods - some of which do not naturally taste good and which require special coatings or flavors or intense sweeteners to give consumers a positive experience.

Educating officials on the real technical and manufacturing needs of supplements starts to become a major issue at this time as we see increasing numbers of initiatives being introduced in these areas.

The drive for change may come from a perception that it will increase product quality or safety. In addition there is a trend in the world towards setting or lowering level of contaminants (e.g. PAHs, heavy metals) or the additives used in the product.

Some of the key questions on which there is a growing need to educate officials in many countries are the following:

- Additives: why they are needed, at which levels and in which dosage forms.
- Tolerances: why the tolerance range for supplements should be broader than other foods, why measurement uncertainty should be excluded.
- Stability: Which parameters should be taken into account?
- Contaminants: Why accredited tests should be available before setting any limits.

As we see a stronger emphasis on conformity to GMP across the industry, it is very important that these the technical issues which lie at the heart of bringing a product to market are not forgotten. It is vital that education of authorities and invitations to visit companies to see and understand product formulation and manufacturing is increased.

Technical issues may not get the pulse running in many companies. But not being able to bring a product to market or having to recall a product from the market certainly do!

### Did you know ?

PACIFIC ALLIANCE	2014
CUSTOMS UNION	2013
ASEAN	2003
EUROPE	1989
CODEX	1988

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**IADSA**

International Alliance of Dietary/  
Food Supplement Associations

# Regulatory news



## ASEAN

### TMHS PWG Working Towards Finalization of Harmonized ASEAN Regulation

The ASEAN Traditional Medicines and Health Supplements Product Working Group (TMHS PWG) held the intercessional meetings on the regulatory framework, GMP and other technical requirements in the last week of January. The key outcome is the agreement to have separate agreements and annexes, which contains technical requirements for Traditional Medicines and Health Supplements. The TMHS PWG will need to have further discussion on the separated agreements at the next plenary meeting in June. The signing of the agreement is expected to now take place in early 2016.

## China

### CFDA to improve health food registration process

Efforts are being made by the China Food and Drug Administration (CFDA) to simplify and improve the registration process for health foods. CFDA in December issued proposed changes of the registration procedure for public consultation, which aims to simplify the registration process for health foods.

[www.sda.gov.cn/WS01/CL0780/111101.htm](http://www.sda.gov.cn/WS01/CL0780/111101.htm)

### NHFPC publishes 31 draft food safety standards

Last December, the China National Health and Family Planning Commission (NHFPC) published 31 draft food safety standards and including a Food safety national standard for the nutrient supplement Zinc Oxide

### China initiates national food safety insurance system pilot program

The China Insurance Regulatory Commission has recently issued Guidelines on Food Safety Insurance

Pilot Programs which mark the initial framework of the national food safety insurance system.

The guidelines indicate that implementation of the food safety insurance system will become part of the KPI (key performance indicator) of the local government as well as the credit record and grading of the food companies. This means both local governments and food companies would be encouraged, or even make it compulsory to participate in food safety insurance programs. The first batch of key sectors identified are: health food, meat, edible oil, wine, formula for infants and young children, liquid milk, soft drink, pastries; catering services, chained food restaurants, school canteens, online food sellers, etc. The guidelines have already been implemented in a few pilot regions in China such as Shanghai and Zhejiang Province, and will be further implemented in more regions nationwide.

<http://www.circ.gov.cn/web/site0/tab5168/info3949686.htm>

### China NHFPC Approved 37 China National Standards

China's National Health and Family Planning Commission (NHFPC) has recently published the finalized GB 2760-2014 National Food Safety Standard for Uses of Food Additives which will enter into force on 24 May 2015

The draft version had been under consultation for two years. The new regulation comes along with 37 national food safety standards including the GB16740-2014 standard assigned to health food.

### 2nd draft of China Food Safety launched for public consultation

China National People's Congress (NPC) Standing Committee met December 2014 to review the 2nd draft of China Food Safety Law. The draft has been published for consultation. The main achievement for supplements is the inclusion in Article 71 of the sentence:

'Health foods that use new materials or health food that is imported for the first time shall get registered with the CFDA; however, first time import of health foods that are nutritious substances, such as vitamin supplements or mineral supplements, shall be filed for record with the CFDA. Other health foods, before launched into the markets, shall be filed for record with the food and drug regulatory department of the

provincial government.'

Other changes includes:

GMO labeling: A new article (Article 64) that requires that labels indicate whether foods contain genetically modified organisms.

Catalogue of health food ingredients CFDA must issue a catalogue of ingredients that may be used in health foods and include information on the permitted amounts of those ingredients. The catalogue will be published jointly by the CFDA, NHFPC and the National traditional medicine administrative departments

## India

### India consults on revision of Food Safety & Standard Act

Due to the difficulties encountered by companies to comply with the provisions of the Food Safety and Standards Act, India has decided to set up a Committee for a comprehensive review of the provisions of the act. This reflection is a key opportunity for the supplement sector to address the need for revision of the approach on maximum levels for vitamins and minerals which are currently based on RDA.

## Indonesia

### Indonesia publishes sweeteners regulation

The National Agency for Drug and Food Control (NADFC) has recently notified to the WTO of a regulation specifying the maximum limits of sweeteners as food additives including in various foods including food supplements. The regulation took effect 25 April 2014.

[https://docs.wto.org/dol2fe/Pages/FE\\_Searc/DDFDocuments/129490/2014/SPS/IDN/14\\_5592\\_00\\_x.pdf](https://docs.wto.org/dol2fe/Pages/FE_Searc/DDFDocuments/129490/2014/SPS/IDN/14_5592_00_x.pdf)

## Japan

### 4 additives proposed for designation

The Food Additive Designation Consultation Center (FADCC) established by the Ministry of Health, Labor and Welfare (MHLW) is now in operation. The following additives will be proposed for designation.

Canthaxanthin (CAS NO. 514-78-3) ;  
Colorant  
Zinc Gluconate (CAS NO. 4468-02-4) ;  
Fortificant

Triethyl Citrate (CAS NO. 4468-02-4) ;  
Emulifier, Stabilizer, Flavour  
Sodium Selenite (CAS NO. 26970-82-1) ;  
Fortificant

### Enforcement of the The Food Labelling Standards Acts and New Health/Functional Claims System

The 2 pieces of legislation will be enforced in April 2015.  
On health claims a detailed guideline is under discussion including with industry groups and will be finalized at the end of February 2015.

### Malaysia

#### Europe questions the limitation of health claims on omega 3 fatty acids to infant formulae products

In its comments on the proposed new provisions for added nutrients in Malaysian food regulations (WTO notification G/TBT/N/MYS/52), the European Commission has invited the Malaysian authorities to reconsider the restriction to infant formulae products on the use of nutrition claim related to DHA and ARA.

Europe pointed out that the World Health Organization (WHO) found convincing scientific evidence on the intake of long chain omega-3 fatty acids and the reduction of the risk of cardiovascular diseases. It is to emphasize that several claims on omega-3 fatty acids have been authorized in Europe.

### Taiwan

#### Taiwan extends the use of several sweeteners to liquid dietary supplements

Taiwan FDA has revised and expanded the use of several sweeteners to liquid dietary supplements under "Standards for Specification, Scope, Application and Limitation of Food Additives":

Saccharin 0.08g/L by saccharin  
Sodium Saccharin 0.08g/L by saccharin

Sodium Cyclamate 0.4g/L by cyclamate  
Calcium Cyclamate 0.4g/L by cyclamate

#### Taiwan sets requirement for importers of food additive combinations

Taiwan notified the WTO of a document requirement for importers of food additive combinations. This document specifies certificates that must be obtained for examination by authorities in order to prevent non-

food grade additives from being use for food purpose.

[https://docs.wto.org/dol2fe/Pages/FE\\_Search/DDFDocuments/129667/2015/TBT/CHT/15\\_0017\\_00\\_x.PDF](https://docs.wto.org/dol2fe/Pages/FE_Search/DDFDocuments/129667/2015/TBT/CHT/15_0017_00_x.PDF)



### Europe

#### Daily intakes of caffeine up to 400mg do not raise safety concerns

The long awaited draft EFSA Opinion on the safety of Caffeine concludes that single doses of caffeine up to 200mg and daily intakes of up to 400mg do not raise safety concerns for adults in Europe. Other key provisional conclusions were made, and the draft is now open for consultation until 15 March 2015.

<http://www.efsa.europa.eu/en/press/news/150115.htm>

#### EU monitors the use of lycopene on the market

EFSA has published a Scientific Opinion on the post-marketing monitoring of the use of lycopene in the EU, taking into consideration its total intake from different dietary sources (as natural source, active ingredients as well as food additives). The general conclusion was that intakes of naturally occurring lycopene do not lead to intakes above the Acceptable Daily Intake (ADI) of 0.5 mg/kg bw/day.

<http://www.efsa.europa.eu/en/efsajournal/doc/3955.pdf>

#### EFSA announces 2nd Scientific Conference for October 2015

The EFSA 2nd Scientific Conference is set to take place in Milan on 14-16 October 2015 (on the occasion of the World EXPO 2015 exhibition).

The conference 'Shaping the Future of Food safety, Together' will focus on 2 areas: Assessment Science & Science, Innovation and Society.

It will be organized in plenary and breakout sessions.

#### EFSA tweaks its guidance on gut and immune health claims

EFSA has published a revised draft guidance to assist companies in preparing their applications for health claims related to the gastrointestinal tract, the immune system and defence against pathogenic microorganisms. The revision takes into account the outcome of a public consultation on a discussion paper together with new scientific evidence available to the NDA Panel and the experience gained to date. The final date for comments is 23 March 2015.

#### European Commission calls for usage data on Polyoxyethylene sorbitans (E 432-436) in food supplements

Polysorbate 20 (E 432), polysorbate 80 (E 433), polysorbate 40 (E 434), polysorbate 60 (E 435) and polysorbate 65 (E 436) are authorized as food additives in the EU in accordance with Annex II to Regulation (EC) No 1333/2008 on food additives.

These Polyoxyethylene sorbitans (E 432-436) were evaluated by the Joint FAO/WHO Expert Committee on Food Additives in 1973 and the EU Scientific Committee for Food in 1983 and re-evaluated in 1993.

They are currently being re-evaluated by EFSA, who issued a public call for food additives usage data on polysorbates especially for those which are only limited by *quantum satis*.

The current re-evaluation contains an up-to-date exposure assessment. However, exposure due to authorization for food supplement categories could not be considered in that assessment as no usage levels were reported and no analytical data were available.

The food supplement sector is therefore requested to provide urgently input regarding the use (and usage levels) of polysorbates until end of February. There is a possible risk that the authorization for the use of these substances could be removed.

#### Norway releases risk assessment results for folic acid and beta-carotene in supplements

Pending establishment of common maximum limits in the EU, the Norwegian Food Safety Authority is evaluating the national maximum limits for vitamins and minerals in food supplements. Recently the levels of Vitamin D and vitamin A were reviewed. The focus is now on beta-carotene and folic acid for which the Norwegian Scientific Committee for Foods Safety (VKM) has been requested to provide its opinions.

The conclusions of the risk assessment carried out by the Norway can be summarised as follows:

#### *Beta-carotene*

- No UL for beta-carotene can be derived.
- A tentative upper level (TUL) of 4 mg/day is proposed based on a LOAEL of 20 mg and the uncertainty factor of 5.
- Smokers and anyone else in the population with vulnerable lungs (e.g. asthmatics, COPD patients) should be discouraged from taking beta-carotene containing supplements all together.

#### *Folic acid*

- There is no need to amend the current UL for folic acid (i.e. 1000 µg per day).
- Increasing the maximum limits in food supplements to 400 or 600 micrograms will not imply exceedance of UL among adults.

About 26% of women and 18% of men aged 18-70 years who participated in the nationwide dietary survey Norkost 3, reported that they take folic acid supplements. The mean intake of folic acid among users was 149 microgram per day among women and 172 microgram among men.

#### **Refined exposure assessment for Brilliant black BN (E151) published**

Part of its re-evaluation work on food additives already on the market in the EU on 20 January 2009, EFSA has recently published its refined exposure assessment for Brilliant Black BN (E 151), taking into account new information on its use. Based on the data collected, EFSA noted that for both children and adults, the current mean exposure were of the same order of magnitude, whereas the 95th percentile exposure was lower, particularly in adults. In other words, when considering the refined scenarios, the mean and high-level exposure estimates of Brilliant Black BN appear to be below the ADI for all population groups. E151 is coloring agent belonging to Group III that covers colors with a combined maximum limit. It is permitted for use at a level of 300 mg/kg for solid food supplements and 100 mg/l for liquid.

#### **EFSA consults on DRV for Calcium**

EFSA has opened a consultation on its opinion relating to the setting of a DRV for Calcium. The population reference intakes for calcium have been increased for all groups as compared to the previous levels (PRIs, established

by the Scientific Committee in 1993). Deadline for comments is 28 February.

#### **EFSA publishes its refined exposure assessment for Allura Red AC**

Exposure estimates do not exceed the ADI of 7 mg/kg bw per day in any population group according to EFSA. The current exposure estimates for Allura Red AC (E 129) based on the MPLs scenario were in the same order of magnitude at the mean exposure level in all population groups, whereas high exposure levels (95th percentile) were lower for all populations except adults. In other words, exposure estimates.

Allura Red is permitted in supplements under Group III. Since 20 July 2010, products containing allura red should display the following warning message "may have an adverse effect on activity and attention in children."

#### **Italy publishes updates on clays, lipoic acid and niacin in food supplements**

Italy has recently informed the sector about decisions affecting supplements, namely: The obligation for food supplements containing lipoic acid to display the mandatory statement "If you are being treated with hypoglycemic medication, please consult your doctor before using this product. The new requirements apply to all new productions. The ban of clay in supplements produced from 1 March 2015 in order to limit the population to aluminum exposure.

Finally, it has been announced that the increase of maximum daily level of niacin from 36 to 48 mg.



#### **Venezuela**

#### **National Institute of Hygiene implements Electronic Registration**

The National Institute of Hygiene "Rafael Rangel" (INHRR) announced the implementation of a web service to receive all applications for registration and evaluation of products for human use and consumption. In this way, the respective company or product representative, via the Internet, will

quickly receive both the application and the assessment from such requests.

The system will simplify procedures conducted by the National Institute of Hygiene, improving quality and reducing response times, providing a faster market access without diminishing the quality of the assessment and, therefore, the products safety.

For the moment, the only products with electronic registration are Pharmaceutical and biological products. However it is expected that all other products of public health importance such as food supplements, will also use this procedure.

The operating manual for the submission of registrations is available on the website of the INHRR ([www.inhrr.gob.ve](http://www.inhrr.gob.ve)).

#### **Nicaragua**

#### **New Regulation Department for Food Supplements**

In January 2015 the authorities of the Ministry of Health of Nicaragua announced the creation of a new Department of Regulation for Food Supplements with the purpose of responding requests for registration of this product category.

The decision is largely related to the work done by the Latin American Alliance for Responsible Nutrition (ALANUR) through the meetings and events held with the authorities of the Ministry of Health of Nicaragua in 2014.

The new Department will begin operations during February 2015, and will be responsible for developing a food supplements regulation

#### **Brazil**

#### **Public Consultation for ANVISA's Regulatory Agenda 2015/2016**

The authorities of the National Health Surveillance Agency (ANVISA) in Brazil have published for public consultation the definition of priority issues that will be part of the institution's regulatory agenda for the period 2015-2016. Contributions may be made by both citizens and public and private entities with the purpose of determining the activities that ANVISA will focus on over the next two years.

Among the issues proposed in 2015-2016 regulatory agenda, the development of a Food Supplements Technical Regulation is included. This work had been included in the

regulatory agenda for the period 2013-2014 but has not been finalized yet. The proposal will be on public consultation until next March 1st through the website of ANVISA (<http://portal.anvisa.gov.br>)



## Uganda

### East African Standard on the Use of nutrition and health claims standards published

Uganda has notified WTO of its final draft Uganda Standard specifying requirements for the use of nutrition and health claims in food labeling and in advertising. This standard applies to all foods for which nutrition and health claims are made without prejudice to specific provisions under other standards or guidelines relating to foods for special dietary uses and foods for special medical purposes.

### GCC regulation on additives notified to WTO

Kuwait notified the WTO of a draft GCC Standardization Organization (GSO) technical regulation for "Additives Permitted for Use in Food Stuffs," including food additives for supplements. The draft Regulation should enter into force 6 months after its publication in official Gazette.

[https://docs.wto.org/dol2fe/Pages/FE\\_Search/DDFDocuments/129258/2014/TBT/KWT/14\\_5452\\_00\\_e.pdf](https://docs.wto.org/dol2fe/Pages/FE_Search/DDFDocuments/129258/2014/TBT/KWT/14_5452_00_e.pdf)

## Saudi Arabia

### SFDA new Guideline for Baseline eCTD Submission Requirements

The drug sector in the SFDA has published on 10 February a new guideline for baseline eCTD submission requirements. So far, both the non-eCTD Electronic Submission (NeeS) or the eCTD formats were accepted by the SFDA for the registration and marketing of food supplements in Saudi Arabia. Since January 3rd 2015, only the eCTD format will be accepted.

The guideline covers the rules

regarding the Technical baseline applications, Baseline eCTD submission, Baseline starting a sequence 0000, and Components of a Baseline eCTD Submission.

[http://www.sfda.gov.sa/en/drug/drug\\_reg/Regulations/SFDA\\_Baseline\\_eCTD\\_Submission\\_Requirements\\_Feb\\_2015.pdf](http://www.sfda.gov.sa/en/drug/drug_reg/Regulations/SFDA_Baseline_eCTD_Submission_Requirements_Feb_2015.pdf)

### SFDA new guideline on requirement for formal meeting between SFDA and applicants

The drug sector of the SFDA has published new Guidelines on January 4 on the requirement for formal meetings between SFDA and applicants, in order to assist applicants in the preparation and submission of meeting requests. Formal meetings include any meeting that is requested by a sponsor or applicant following the procedures provided in the guidance. The guideline which also applies to supplements, covers recommendations on: Meeting requests by applicants, Assessment of the meeting request (e.g. accepting or denying the meeting request), Meeting rescheduling or cancelling, Meeting procedure.

[http://www.sfda.gov.sa/en/drug/drug\\_reg/Regulations/Requirements%20for%20Formal%20Meeting%20between%20SFDA%20and%20applicants.pdf](http://www.sfda.gov.sa/en/drug/drug_reg/Regulations/Requirements%20for%20Formal%20Meeting%20between%20SFDA%20and%20applicants.pdf)



## United States

### New trends in Americans' use of supplement

A nationally representative survey shows that natural product use in the United States has shifted since 2007, with some products becoming more popular and some falling out of favor. Overall, natural products (dietary supplements other than vitamins and minerals) remain the most common complementary health approach.

Survey highlights:

- Fish oil was the top natural product among adults.

- Adults' use of fish oil, probiotics or prebiotics, and melatonin increased between 2007 and 2012.
- Adults' use of glucosamine/chondroitin, echinacea, and garlic decreased between 2007 and 2012.
- Fish oil was the top natural product among children. This is a change from 2007, when Echinacea was first.
- Melatonin was the second most used natural product by children in 2012. Its use increased substantially from 2007 to 2012

[www.nih.gov/news/health/feb2015/nccih-10.htm](http://www.nih.gov/news/health/feb2015/nccih-10.htm)

### Senators urge FDA to ban pure caffeine

Following the death of a high school student, a group of six senators urged last January the Food and Drug Administration (FDA) to immediately ban the retail sale and marketing of pure caffeine.

According to the FDA, a single teaspoon of pure caffeine is roughly equivalent to the amount in 25 cups of coffee - more than six times the recommended daily amount of caffeine for an adult.

<http://www.brown.senate.gov/newsroom/press/release/following-tragic-death-of-lorain-county-teen-brown-calls-for-ban-on-powdered-caffeine>

### FDA seeks \$4.9 billion for FY 2016 to implement the FDA Food Safety Modernization Act

The U.S. Food and Drug Administration is requesting a budget of \$4.9 billion to protect and promote the public health as part of the President's fiscal year (FY) 2016 budget - a nine percent increase over the enacted budget for FY 2015. The overall request includes \$147.7 million in budget authority for initiatives tied to several key areas, including the implementation of the FDA Food Safety Modernization Act and the building of a more modern FSA. As the agency's mandate expands, more scientists, doctors, analysts and inspectors are needed. 'A 7% increase of FDA staffing is foreseen by 2016' said FDA.

<http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm432600.html>

## FDA Commissioner Margaret A. Hamburg Stepping Down

Margaret Hamburg, M.D., FDA commissioner of Food and Drugs for almost six years, is stepping down. FDA's chief scientist, Stephen Ostroff, will fill the position until a new commissioner is named.



## Russia

### Russia adopts GMP standard for supplements based on IADSA GMP

The supplement industry in Russia adopts state standard that harmonizes national manufacturing requirements with the best international practices. The new GOST introduces a comprehensive set of requirements for manufacturing, storage and transportation of dietary supplements in accordance with the General Manufacturing Practice (GMP). This is the first successful attempt in recent history to standardize supplement manufacturing in Russia, which allows international and local producers alike to apply the same efficient approach in ensuring product safety, quality and efficacy.

Scientists of Russia's Institute of Nutrition authored the document, which won positive reception from the industry experts and the regulators. The backbone of the new standard was the GMP guide developed by IADSA in 2011.

### Law to fight falsified dietary supplements came into force in Russia

Federal Law No 532-FZ of 31 December 2014 "On amendments of several legislative acts for the purpose of counteracting the illegal trafficking and distribution of falsified, counterfeit, defective and unregistered medicines, medical products and dietary supplements" came into force from 23 January 2015. The bill specifies the notion of falsified foods contained in Federal Law 29-FZ "On the quality and safety of foods" of 2 January 2000: "falsified food products (including dietary supplements), materials and articles are food products (including dietary supplements), materials and articles which are deliberately changed (forged) and/or possess hidden qualities and properties on which the

information provided by the manufacturer is designedly incomplete or misleading". The bill introduces administrative and criminal liability for

the distribution of falsified dietary supplements.

The bill states that a discrepancy between the amount of a dietary supplement ingredient and the amount stated on the label may qualify as the distribution of falsified dietary supplements if the label statement is proved to be incomplete or misleading, and may incur a fine of between 70,000 and 5 million roubles (\$1,230 to \$88,080 at the current exchange rate).

The bill proposes the following administrative and criminal penalties: Administrative liability will arise from:

- Activity related to the distribution of falsified dietary supplements which do not contain pharmaceutical substances not declared during the process of the state registration procedure, irrespective of the value of the batch;
- Activity related to the distribution of falsified dietary supplements which contain pharmaceutical substances not declared during the process of the state registration procedure, provided that the value of the batch does not exceed 100,000 roubles (\$1,515).

Criminal liability will arise from activity related to the distribution of falsified dietary supplements which contain pharmaceutical substances not declared during the process of the state registration procedure, provided that the value of the batch exceeds 100,000 roubles (\$1,515).

### Russian antimonopoly watchdog to propose one-stop-shop registration of food supplement and medicine names

The Russian antimonopoly watchdog (FAS) is going to propose a one-stop-shop registration of food supplement and medicine names to exclude chances of coincidence in their names. The move was reported by deputy head of FAS. The initiative aims at avoiding the risk of circulation of a medicine with potential side effects under the name of a food supplement, without an instruction for medicinal use.

## Fines for violating GMO food labeling requirements introduced

Federal Law No 521-FZ of 31 December 2014 on Introducing amendments to the Russian Code of Administrative Violations had been developed under the president's instructions and aimed at introducing a harsher punishment for violations of the mandatory requirements to the labeling of foods manufactured with the use of or containing genetically modified or genetically engineered organisms. Under the Law the Russian Consumer Rights watchdog (Rospotrebnadzor) shall be entitled to initiate proceeding with respect to such violations whereas the court shall have the authority to impose administrative punishment. The Law came into force on 11 January 2015.

According to the new act, the government is effectively authorized to ban import of GMO-containing products to Russia. The act was introduced by the Ministry for education and science and will be read at the coming session of the government.

## Ukraine

### Ukraine harmonizes national GMO legislation with EU laws

The bill, tabled in the parliament, is aimed at harmonizing the text of the law on the state system of biological safety to be observed during the creation, testing, transportation and use of genetically modified organisms with the provisions of Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed.

The bill provides for the creation of a GMO product labeling procedure, for improving controls over the circulation of biotechnologically modified plants, for the establishment of a government system for the control, registration and circulation of biotechnologically modified seeds, etc.

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# Focus on European (EU) Legislation

503 million people

EU is the world's 4th largest population after China, ASEAN and India



## Objectives

Establish a common market with a high level of protection of public health, safety and consumer protection

## BASIC PRINCIPLES



Safety is responsibility of industry



Consumers must be provided with essential and accurate information

## The legal process in Europe

**Scientific Advice**  
Provided by EFSA to underpin the legislative process.



**Proposal**  
All EU legislative acts adopted on the basis of a proposal of the European Commission.



**Control & enforcement**  
under the responsibility of the 28 Member States.

**Consultation & Adoption**  
Involving the Council and the European Parliament.



## REGULATORY APPROACH

**Horizontal measures** lay down general rules applicable to foodstuffs: food hygiene, additives, contaminants solvents, materials in contact with food and novel foods. Priority is in general given to horizontal measures.

**Vertical measures** lay down specific rules for a particular sector which has sometimes considered necessary notably in the case of food Supplements.

Focus today on combining into one piece of legislation as many texts as possible - vertical and horizontal - in order implementation of the legislation for industry and Member States.

## European Institutions: What do they do?

EFSA



Assesses and communicates on all risks associated with the food chain.

EU Commission



Proposes new laws to Parliament & the Council, manages the EU's budget and allocates funding, enforces EU law (together with the Court of Justice). Represents the EU internationally.

EU Court of Justice



Interprets EU law to make sure it is applied in the same way in all EU countries.

EU Parliament



Debates and passes European laws, with the Council. Scrutinizes other EU institutions, debates and adopts the EU's budget, with the Council.

EU Council



Passes EU laws. Coordinates economic policies of EU Member States. Signs agreements between the EU and other countries. Approves the annual EU budget. Develops the EU's foreign and defence policies.

# The EU food supplement Legislation

- Fastest growing distribution channel for VDS: Internet
- Degree of maturity: mature market
- Key categories: Digestive, General, Immune



## THE 3 HOT TECHNICAL CHALLENGES DISCUSSED TODAY IN EUROPE

**Legislation**  
Directive 2002/46/EC

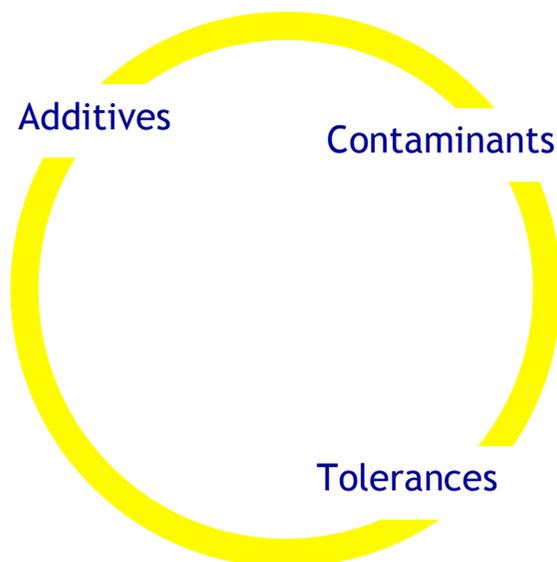
**Aim**  
Establishes harmonized rules for the labeling of food supplements and introduces specific rules on vitamins and minerals in food supplements

**Definition**  
Food supplements' means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities

- How to define syrup-type supplements?
- Reasons to include tablets to 'crunch' supplements in chewable forms?
- Limits of additives in dilutable supplements. Can limits apply to the forms ready for consumption as it was laid down in the old directives?

### Industry views:

- Responses to the above questions will determine the levels of additives permitted in supplements and potentially impact products currently on the market.



- Should limits of PAHs be set for supplements? If so, which levels? Should they apply to all supplements?

### Industry views:

- Potential contamination has been found in a relatively small proportion of the ingredients used in supplements.
- There are serious concerns about the methodology being used for the analysis of PAHs in the various food supplement matrices.

- Commission published guidelines on the tolerances for nutrition labeling purposes. Member States have the power to implement the new requirements and challenge products that would not be compliant.

### Industry views:

- Guidance very complex.
- The tolerance ranges proposed are too tight and do not exclude measurement uncertainty.

