IADSA Newsflash

June 2017

Global Food Supplement Regulation on Track

An IADSA survey presented at the Annual Meeting in Seoul has shown that the majority of respondents from associations (71%) believe that regulation in their country is moving in the right direction. While problematic legislation or elements of legislation exists in many countries, this result is a good indicator that on balance the sector is being heard and regulators are responding across the world.

The extent to which the sector feels it is being fairly treated showed huge variations across the world with those countries that have a close working relationship with their government coming at the top of the list. Both Australia and Singapore have long-established and open relationships with their governments which, in general, are supportive of establishing a viable and workable regulatory framework for supplements.

In contrast, only 54% of respondents consider that government policy on supplementation is moving in the right direction. Today, too many governments look negatively on the potential role of supplements to help achieve public health goals. This highlights the need to boost activities and investment across the world in this area. This was addressed in breakout sessions of national associations in Seoul to allow ideas to be shared and to help IADSA develop its policy programme for the coming years.

However, while there is more work to be done with policy makers, 55% of respondents consider that the attitude of policy makers towards supplements has become more positive over the last two years and only 14% believe it has become more negative. This illustrates that the work that is being done is starting to gain traction.

The two issues that worry the supplement sector most are adulteration and the anti-supplement media top the list with many associations also highlighting the frequent changes in decision makers in government as a major obstacle to making progress on both regulation and policy.

This IADSA survey "What is the supplement sector worried about?" is the first in a series of surveys to help the global supplement sector define priorities and benchmark regulatory and policy progress.

IADSA
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Food Supplement Associations

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What is the supplement sector worried about?

Generally speaking, would you say that regulation for the supplement sector is heading in the right direction in your country?

Generally speaking, would you say that policy for the supplement sector is heading in the right direction in your country?

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Regulatory news

ASEAN

TMHS PWG aims to finalise the agreement by end August

The ASEAN Traditional Medicine Health Supplement Product Working Group met in Da Nang, Vietnan in May to address the remaining issues before the finalisation/endorsement of the agreement foreseen for the end of August.

The major outcomes include a very important consensus on the name of the Agreement "ASEAN Agreement on Regulatory Framework for Health Supplements'. This issue had been holding up progress for over a year and Agreement that a Question and Answer document will be developed out of the safety substantiation training that IADSA supported earlier this year.

Indonesia

BPOM revises its position on claims for omega 3 supplements

The circular letter No. HK. 04.4.42.421.12.16.2451 -year 2016 prohibiting the use of maintenance health claims for supplements containing more than 300 mg/day of omega 3 is no longer valid.

The new provisions specify that health supplements with functional and disease risk reduction claims will be based on supporting data/evidence submitted by industry. The following warning will however apply for supplements containing EPA at a higher level than DHA:

Be careful in consuming a product with high EPA content together with anti-coagulants which may cause blood thinning effect

Inform your doctor that you are consuming omega 3 health supplements before having an operation.

China

Survey for Implementation of National Food Standards

The National Health and Family Planning Commission NHFPC has recently launched a survey on the assessment of the national food safety standards.

List of Key Standards covered

1《食品安全国家栃准 食品中致病菌限量》（GB 29921-2013）National Food Safety Standard-Limit of Pathogen in Foods
2《食品安全国家栃准 預包装食品栃笠通則》（GB 7718-2011）National Food Safety Standard-General Standard for the Labeling of Prepackaged Foods
3《食品安全国家栃准 預包装食品菅界栃笠通則》（GB 28050-2011）National Food Safety Standard on Nutrition Labelling of Prepackaged Foods
4《食品安全国家栃准 預包装特殊膳食用食品栃笠》（GB13432-2013）General Standard for the Labeling of Prepackaged Foods for Special Dietary Uses
5《食品安全国家栃准 食品経菅近程JJ生規危》（GB 31621-2014）General Hygiene Standard for Food Business Process
6《食品安全国家栃准 食品生戸通用JJ生規危》（GB14881-2013）General Hygiene Standard for Food Production
7 乳和乳制品相美栃准. Standards for milk and milk products
8 各哭検翰方法栃准 Food standards of testing methods

New Regulation on Imported Foods

From 1 October, all foods exported to China should be accompanied by a certificate issued by the competent authority in the country/district of origin.

In early June, the China AQSIQ notified WTO of the "Measures for the Administration of Certificates Attached to Foods Exported to China".

The new regulation stresses that foods imported to China should come with a certificate from the competent authority of the exporting country so as to prove that foods are from a company under the supervision of the exporting country's authority.

China releases its detailed rules for the notification of health foods

CFDA has recently published the detailed regulations for the notification of health foods which clarifies in particular that 1) products will need to comply with the requirements of list of auxiliary ingredients; 2) stability testing and hygiene testing can be performed by the applicant in their own laboratory, but test reports on three batches of samples for testing on all items required in the technical documents are still requested from a qualified government laboratory; 3) foreign companies can notify products produced by another company.

New Zealand

Recall of iron supplements not compliant with New Zealand law

Companies not compliant with the legal amount of iron allowed in a tablet/capsule supplement and around the amount in a pack are being asked to recall stock.

The requirement for iron in general sale per Medsafe Medicine Classification is –

for oral use in medicines containing 24 milligrams or less per recommended daily dose either in medicines containing not more than 5 milligrams per dose unit or in medicines containing more than 5 milligrams per dose unit and in packs containing not more than 750 milligrams of iron; in parenteral nutrition replacement preparations

More information at: http://www.naturalproducts.nz/alert-iron-supplements-check-your-products-please/

European Union

Cranberry products are not medical devices

The Regulatory Committee on Medical Devices voted last May in favour of a European Commission decision clarifying that proanthocyanidins (PAC) in cranberry extracts to prevent or treat cystitis are not medical devices. The decision was based on an European Medicines Agency opinion saying that a pharmacological mode of action was most probable and a mechanical mode of action of PAC was highly unlikely. Food supplements marketed under this medical device status to escape the EU claims Regulation will therefore no longer be permitted on the market. Following the non-authorisation of health claims made on proanthocyanidins from cranberry, some countries like France have seen a number of medical devices containing these ingredients marketed in small dosage forms on their market.

The formal adoption and publication of the decision are foreseen during the summer.

EFSA opens public consultation on draft opinion for setting a DRV for riboflavin

The European Food Safety Authority has launched an open consultation on its draft scientific opinion on dietary reference values for riboflavin. This document proposes dietary reference values for riboflavin for adults (the Average Requirements (ARs) and Population Reference Intakes (PRIs of 1.3 and 1.6 mg/day), infants and children (ARs range between 0.5 and 24 1.4 mg/day, and PRIs between 0.6 and 1.6 mg/day for both sexes aged 1-17 years), pregnant and lactating women (PRIs of 1.9 and 2.0 mg/day).

Average Requirements (ARs) and Population Reference Intakes (PRIs) were determined from the weighted mean of riboflavin intake associated with the inflection point in the urinary riboflavin excretion curve reported in four intervention studies.

State of play of the re-evaluation of food additives

Under EU law (Reg. 1333/2008), the safety of all food additives authorised for use in the EU prior to 20 January 2009 must be re-evaluated by 2020. The programme was adopted setting priorities and deadlines for the re-evaluation of each additive.

To date EFSA has published opinions for approximately one third of the 316 additives that are subject to this re-evaluation. The evaluation started with colours in 2010 which generally have the oldest evaluations and should end with sweeteners which have the most recent.

A summery table of permitted food additives and status of their re-evaluation by EFSA is available on the Commission website.

https://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation_en

Call for scientific and technical data on the permitted food additives propyl gallate (E 310), octyl gallate (E 311) and dodecyl gallate (E 312)

The European Commission has launched a call for data for propyl gallate (E 310), octyl gallate (E 311) and dodecyl gallate (E 312).

Data is requested on the identity and levels of chlorinated organic compounds to assess their toxicological significance for E310, E311 and E312.

Data on the lowest achievable limits for the impurities of toxic elements (arsenic, lead, and mercury) for E310, E311 and E312.

Toxicological data to carry out an adequate assessment of the safety of octyl gallate as a food additive in all its currently permitted uses f or E311 and E312.

More information can be found at: https://ec.europa.eu/food/sites/food/files/safety/docs/fs-improv-additive-20170530-call_sci-tech-data-e310-e311-e312.pdf

EFSA gives positive verdict on Acacia Gum

There is no need for a numerical ADI for acacia gum (E 414) and the exposure levels to the food additive pose no safety concern for the general population.

These are the conclusions of the European Food Safety Authority on the re-evaluation of Acacia Gum (E 414) as a food additive. It also said that the daily intake of a large amount of acacia gum up to 30,000 mg acacia gum/person per day (approximately equivalent 430 mg acacia gum/kg bw per day) for up to 18 days was well tolerated in adults but some individuals were shown to experience flatulence which was not considered by the Panel as adverse effect.

Acacia Gum is used in food supplements at quantum satis (QS) level (group I). It is also authorised without specific limits in all nutrients and as food additive including carriers in all food flavourings.

EFSA requires usage data to confirm the safety of the existing uses of lecithins (E322)

EFSA has confirmed the safety of existing uses of lecithins (e322) in its re-evaluation of the additive based on the data reported by industry.

However, the Panel noted discrepancies between the data reported from industry and the Mintel Database. Data of usage and use levels of lecithins (E 322) will be requested to allow EFSA to perform a more realistic exposure assessment.

The ANS Panel in charge of the assessment has also called for the specifications to be updated with regard to the maximum levels for lead, mercury and arsenic and recommended that limits for cadmium be included.

It also said that the residual proteins should be reduced as much as possible to limit the risk of hypersensitivity.

The food additives are used at Quantum Satis in food supplements and as secondary additives including carriers for all food enzymes, all food flavourings and all nutrients.

EFSA publishes advice on vitamin K

EFSA has set dietary reference values for vitamin K as part of its review of scientific advice on nutrient intakes: 70 µg/day for all adults including pregnant and lactating women, at 10 µg/day for infants aged 7- 11 months, and between 12 µg/day for children aged 1- 3 years and 65 µg/day for children aged 15- 17 years.

The Panel on Dietetic Products, Nutrition and Allergies (NDA) decided to maintain the dietary reference values established by the Scientific Committee for Food in 1993.

Calcium sorbate E203 will be removed from the permitted list of food additives.

The reason for this decision is the lack of data submitted by the food /food supplements sector to permit the European Food Safety Authority to confirm the safety of the additive.

In 2015, EFSA indicated in its opinion that genotoxicity studies on calcium sorbate needed to be performed in order to consider including E 203 in the group ADI defined for sorbic acid (E200) and potassium sorbate (E202). Regrettably no information could be submitted in response to the second of call for data launched by the Commission on 10 June 2016. https://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation_en

Transition periods are being introduced for products already on the market.

The European Commission authorises two claims for lactitol and creatine

The European Commission has published Implementing Regulations (EU) 2017/676 and (EU) 2017/672 authorising two claims for lactitol and creatine.

Daily creatine consumption can enhance the effect of resistance training on muscle strength in adults over the age of 55. Information shall be provided to the consumer that: the claim is targeting adults over the age of 55, who are engaged in regular resistance training; the beneficial effect is obtained with a daily intake of 3 g of creatine in conjunction with resistance training, which allows an increase in the workload over time and which should be performed at least three times per week for several weeks, at an intensity of at least 65 %- 75 % of one repetition maximum load.

'Lactitol contributes to normal bowel function by increasing stool frequency' conditions of use: This claim may be used only for food supplements which contain 10 g of lactitol in a single daily quantified portion. In order to bear the claim, information must be given to the consumer that the beneficial effect is obtained by consuming 10g of lactitol in one daily dose. The claim shall not be used for foods targeting children.

Since lactitol is an authorised novel food for use in food supplements, additional regulatory conditions of use apply.

More information required for the safety assessment of Sorbate esters

In its opinion on the safety re-evaluation of the food additives sorbitan esters: sorbitan monostearate (E 491), sorbitan tristearate (E 492), sorbitan mono laureate (E 493), sorbitan monooleate (E 494) and sorbitan monopalmitate (E 495), EFSA has called for more information from industy, in particular relating to the use levels to complete its assessment.

The additives are used in several food categories including food supplements.

Calls for data regarding the safety assessment of green tea and hydroxyanthracene derivatives.

These calls are aimed to address the safety concerns raised on green tea and hydroxyanthracene derivatives in response to the decision of the European Commission to initiate the Article 8 procedure in Regulation 1925/2006. This so-called article 8 allows the Commission, on its own initiative or at the request of a Member State to prohibit, restrict or put under Union scrutiny a substance other than vitamins or minerals or an ingredient containing such a substance that is added to foods or used in the manufacture of foods.

The request on green tea was linked to concerns from Sweden and Denmark and Norway over the liver toxicity of epigallocatechin-3-gallate in green tea.

For hydroxyanthracene derivatives, the decision was connected to discussions on a favourable opinion on a health claim on bowel function for the substance, where EFSA raised the alarm over the use of laxatives.

EFSA conclusions are expected by the end of the year.

EU revises model veterinary certificates for import

The European Commission has published a new Implementing Regulation (EU) 2017/731 amending the model veterinary certificates for imports of certain products. The impact for food supplements is on the paperwork that may be required for import when these are composite products. This new Regulation amends the certificate that was required in accordance with Annex I to Regulation (EU) No 28/2012 for imports into the European Union of composite products intended for human consumption.

The new requirements in this regard are laid down in Annex III of Implementing Regulation (EU) 2017/731, and simplify the certificate with a 'declaration'. This new requirement shall apply from 1 July 2017.

Article 4 provides a transition period until 31 December 2017 for consignments of certain composite products intended for human consumption accompanied by a model certificate issued in accordance with current rules, provided that the certificate was issued no later than 30 November 2017.

Call for data for chlorophylls and chlorophyllins

In response to the EFSA opinions of 2015 where it was said that the data was inadequate or insufficient to complete the safety evaluation of the additives E 140(i) chlorophylls, E 140(ii) chlorophyllins, E 141(i) copper complexes of chlorophylls and E 141(ii) copper complexes of chlorophyllins, the Commission has launched a new call for data as part of its re-evaluation process to collect the missing information.

Information required includes:
Data on the definition and identity of the food additive. Data on the lowest achievable limits for the impurities of toxic elements. Toxicological data for E 140(ii)), E 141(i), E 141(ii). Data on actual levels of ethanol and methanol in E 140 (i). Data on the lowest achievable limits for the impurities of toxic elements (arsenic, lead, mercury and cadmium):

Stakeholders had until 10 June to express their interest to submit data.

Belgium

Belgium to set conditions of use for four food supplement substances

Belgium has notified to the European Commission and Member States a draft Ministerial decree amending the Ministerial Decree of 19 February 2009 regarding the manufacture and marketing of food supplements that contain substances other than nutrients and plants or plant preparations (notification number 2017/182/B).

The draft proposes to add 4 new substances to the Annex of the Ministerial Decree, stipulating the conditions for their use in food supplements following the recommendations of the Belgian

Superior Health Council opinions / guidelines thereon. Namely:

- caffeine: maximum 80 mg/day and compulsory warning: 'Unsuitable for children or pregnant or lactating women'
- lutein: between 2 and 10 mg/day
- lycopene: between 2.5 and 15 mg/day
- red yeast rice or any other source of monacolin K: maximum 10 mg/day of monacolin K and compulsory warning: 'This product is unsuitable for pregnant or lactating women, children and adolescents, those over 70 years of age, those with liver, kidney or muscular problems, those taking medicinal products liable to interact (e.g.: cholesterol-lowering drugs) or those intolerant to statins. If in doubt, please seek advice from your doctor or pharmacist.'

France

European Court rules against France on maximum vitamin levels

European Member States cannot set individual maximum levels for vitamins and minerals unless they are based on international safety data and risk assessments.

This is the view of the European Court of Justice that was consulted on a French court hearing about a case against a supplements company marketing products that exceeded maximum vitamin levels stipulated in French law.

It is particularly timely considering that Sweden and Germany are reflecting on the setting of their own levels in the absence of EU harmonised rules.

France raises concerning about the intake of supplements during pregnancy

The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) warns against combining multiple sources of vitamins and minerals during pregnancy, in the absence of an identified need.

ANSES recommends pregnant women not to consume food supplements without seeking prior advice of a Healthcare Professional (HCP) and furthermore recommends HCPs further investigate and take appropriate measures in cases of hypercalcemia where supplementation to the pregnant woman may be causal, ensure simultaneous exposure to various sources of iodine (medicines, food supplements) is avoided, and recalls the importance of not cumulating sources of vitamins and minerals without regular biological monitoring and reporting undesirable effects via the "nutrivigilance" system.

This investigation is linked to five cases of neonatal hypercalcemia and of two cases of congenital hypothyroidism related to the consumption of supplements intended for pregnant women containing vitamin D and iodine.

Italy

Italy authorises the use of Palmitoylethanolamide (PEA) and increases maximum levels for 3 vitamins

The Italian Ministry of Health has recently revised its two food supplement guidelines on permitted daily levels of vitamins and minerals and nutrients and other substances with a nutritional or physiological effect. These revisions set the maximum levels for the following vitamins increased for vitamin D (50 µg/ day), vitamin K (180 µg/day) and vitamin B12 (1000 µg/day). Palmitoylethanolamide (PEA) is also added to the list of substances for use in food supplements without defined maximum limits.

The Netherlands

Control action on libido/slimming/sports supplements

More than 60% of food supplements tested contained 1 or more (unauthorised) pharmacologically active substances. These are the conclusions of the Netherlands Food and Consumer Product Safety Authority (NVWA) who has recently published findings of an investigation on slimming/fat-burning, libido boosting and pre-workout supplements.

During this investigation conducted during 2015 and 2016, the NVWA tested a total of 160 samples of food supplements for the presence of pharmacologically active substances.

From 42 samples of libido enhancing food supplements, 32 samples proved positive; from 118 samples of slimming preparations, fat burners and pre-work-out products, 66 samples were positive.

The NVWA has taken action against many products, but has also acknowledged that the products tested were chosen as they were suspected to potentially contain pharmacologically active substances so did not necessarily reflect the broad offerings on the Dutch market.

Sweden

Sweden assesses the need to set maximum levels of vitamins and minerals

The Swedish National Food Agency (NFA) has been commissioned by the government to investigate and, if necessary, introduce national legislation on maximum levels for vitamins and minerals in food supplements. A pilot risk assessment is scheduled for 2019 on the nutrients vitamin A, iodine and selenium.

Israel

Israel updates its list of supplement ingredients

Israel has updated the list of ingredients that may be used in supplements. The government clarified that the quantities are daily amounts, as requested or discussed by the professional committee for nutritional supplements.

Turkey

Turkey extends the deadline to comply with food supplement law

The Turkish Ministry of Agriculture and Food MINFAL has extended the deadline to July 2017 for supplements not in line with the new Regulation. This extension only applies to supplements that were notified to MINFAL by end of last year and which are still awaiting an answer from the authorities.

South Africa

MCC consults on caffeine

The South African Medicines Control Council MCC has recently launched a consultation on its guidelines intended to provide recommendations to applicants wishing to submit applications for registration.

The draft guidelines underline that caffeine is not permitted as a single substance formulation. When used as an active ingredient, caffeine should not be responsible for the primary action of a product.
A maximum dose of up to 200 mg per single dose and total caffeine consumption of up to 300 mg is proposed. Products containing caffeine could promote the role of caffeine to promote alertness and the reduction of fatigue. Wordings proposed are: Assists (temporarily) to promote alertness and wakefulness; assists (temporarily) to relieve fatigue.

Brazil

Public-private cooperation to control the marketing of illegal food supplements

The sanitary authorities from ANVISA and the main e-trade platform, Mercadolivre, have renewed the agreement signed in 2015 to strengthen control over the marketing of "illegal" food supplements. Through this agreement, ANVISA can request Mercadolivre to remove those products that are not in compliance with the sanitary regulation.

Colombia

Changes in the internal process at INVIMA

The Columbian Ministry of Health has opened for public consultation a proposal to modify Article 4 of Resolution 719 of 2015, giving INVIMA the right to update, when necessary, the risk classification of foods process that currently is under the competence of the Specialized Commission of Foods and Beverages (SEABA).

Costa Rica

Costa Rica simplifies procedure to market food supplements

Companies marketed food supplements in countries having similar or a higher level of regulation to the Costa Rica law (e.g. Canada or EU) will see the formalities to enter Costa Rica simplified. The new provisions were introduced with the promulgation of Executive Decree 40233S. The list of eligible countries remains to be established by the Ministry of Health.

Costa Rica updates its food supplement law

Since mid-June, supplement companies have to comply with the new provisions set in Decree 20003-S which include: A broader definition for food supplements; the setting of maximum levels based on the risk management approach developed by Food Supplements Europe.

Food supplements containing caffeine have also now to declare on their labels: "Consumption it is not recommended for individuals sensitive to caffeine"

Ecuador

Sanitary authority published a check-list for food supplements

In relation to the new regulation for food supplements approved in Ecuador at the beginning of 2017, the sanitary authorities from ARCSA published a check-list to provide guidance on the classification of a product under the food supplement definition.
http://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2017/04/TABLAS-DE-REFERENCIA-SUPLEMENTOS-ALIMENTICIOS.pdf

Peru

Modification of the market access requirements for food supplements

Peru has published an amendment of the Supreme Decree 016-2011-SA "Regulation for the Registration, Control and Sanitary Surveillance of Pharmaceutical Products, Medical Devices and Sanitary Products" simplifying the requirements for the placing of food supplements on the market. In particular, technical specifications on the packaging materials, technical analytical validation of the finished product, flowcharts and validation of the manufacturing process are no longer required. The time to expedite the sanitary registry is also reduced from 60 to 30 days.

Mexico

COFEPRIS partnership with third parties to control the advertising of food supplements

COFEPRIS has signed an agreement with third parties that will accelerate the issuing of authorizations for the advertising of food supplements, which are subjected to prior evaluation by the sanitary authorities. The Federal Commissioner of COFEPRIS mentioned that "the goal is to speed up this process and to reduce the issuing of authorizations from 40 to 5 days". The process would be done through a specialized electronic platform and will enter into force on 16 June 2017.

COFEPRIS and ANAISA agreed to educate consumers on food supplements

COFEPRIS signed an agreement with the food supplements' association ANAISA to launch a campaign to educate consumers on the consumption of food supplements.

Bill proposes to update the regulation for food supplements

The Mexican Congress has proposd to update Article 215 of the General Health Law to amend the definition of food supplements, including the permitted ingredients and the pharmaceutical forms allowed. Advertising requirements are also suggested.

USA

GAO makes recommendations on memory supplements

The U.S. Government Accountability Office (GAO) has recommended that FDA and FTC provide additional guidance to consumers clarifying the agencies' differing roles in their shared

oversight of memory supplements and other dietary supplement marketed on the Internet.

In its report released mid-June, GAO examines (1) how memory supplements are marketed and the extent marketing targets older adults and may violate federal requirements; (2) related enforcement and outreach actions taken by FDA and FTC; and (3) challenges to agency oversight

Memory supplements—dietary supplements claiming to improve memory—are a growing market, with sales estimated at $643 million in 2015, almost double 2006 sales. FDA and FTC share oversight of memory supplement marketing—labeling and advertising claims.

The report found that about 96% of the marketing of memory supplements they identified appeared on the internet. Of the 490 memory supplement products identified, 28 examples of advertisements linked supplement use to treatment or prevention of memory-related diseases, which is generally prohibited by federal law.

The FDA announces its intention to extend the compliance date for the Nutrition Facts Label final rules.

In May 2016, the U.S. Food and Drug Administration finalized the Nutrition Facts and Supplement Facts Label and Serving Size final rules and set the compliance date for 26 July 2018, with an additional year to comply for manufacturers with annual food sales of less than $10 million. After careful consideration of the industry and consumer group feedback regarding the compliance dates, the FDA has recently announced that additional time would be given to manufacturers to help them be able to complete and print updated nutrition facts panels for their products before they are expected to be in compliance.

Details of the extension will be provided through a Federal Register Notice.

https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm#dates

Ukraine

Ukraine harmonising hygienic requirements for dietary supplements with EU legislation

The Ukrainian Health Ministry has published for discussion a draft decree on adopting amendments to the hygienic requirements for dietary supplements (as adopted in December 2013).The new decree is aimed at harmonising the hygienic requirements with national law on the fundamental principles and requirements for the safety and quality of food products, and with the EU Food Supplements Directive 2002/46/EC.

In particular, the draft decree eliminates references to the following pieces of legislation and provisions:
- the national law on safety and quality of food products;
- the Ukrainian National Commission on Codex Alimentarius (dismantled in 2015);
- the registration requirements for dietary supplements.

The amendments call for any quality and nutrient daily intake criteria not otherwise established by national laws to meet the EU requirements.

Bill restricting dietary supplement advertisements submitted to Ukrainian parliament

In 2014, the Ukrainian Health Ministry drafted a law on amending national law on advertising. The bill was aimed at preventing dietary supplements from being advertised and sold via call centres in the guise of medicines. Two years on, the bill has finally been approved by the relevant ministries, adopted by the cabinet, and submitted to parliament.

The bill proposes the following:
- banning any mention of contact telephone numbers in advertisements for dietary supplements;
- banning any mention of contact telephone numbers in print publications, in televised news and analysis programmes, and also in televised programmes devoted to medical topics, for the exception of advertisements for health care establishments licensed to market their services.

If passed into law, the bill will come into force on the day following the day of its official publication.

Russia

Federal Antimonopoly Service will not amend dietary supplement distribution rules

The head of the Russian Federal Antimonopoly Service (FAS) has stated that in the current situation of regulatory ambiguity, antimonopoly agencies should not inspect pharmacies for compliance with Federal Law on commerce, including the sales and purchases of dietary supplements. Sales of dietary supplements through pharmacies are in full compliance with law on the circulation of medicines. The FAS believes the right approach to eliminate the ambiguity is in excluding pharmacies from the scope of Law on Commerce.

In November 2016, the FAS was working to draft clarifications for the Law on commerce. The clarifications indicated that provisions of the law would be extended to cover sales of dietary supplements both through retail networks and through pharmacies.

Azerbaijan

Azerbaijan to introduce fines for sales of improperly labelled dietary supplements

The amendments to the Code of Administrative Violations, which introduce fines for the manufacture, importation and sales of dietary supplements whose labels and package leaflets do not contain the phrase “not a medicine”, were proposed for discussion at a meeting of the parliamentary committee on healthcare of Azerbaijan.

The draft document introduces fines of between $294 and $470 for officials and between $882 and $1176 for legal entities. The fines for putting dietary supplements on medical prescriptions are proposed at $29-$58 for officials and $87-$116 for legal entities.

Regulation on the import, manufacture, processing and marketing of food supplements

IADSA
International Alliance of Dietary/ Food Supplement Associations

Authorities in charge: Ministry of Food, Agriculture and Livestock (MINFAL)

Food supplement definition: Concentrated sources or extracts of nutrients such as vitamins, minerals, proteins, carbohydrates, fibers, oil acids, amino acids or other substances with a nutritional or physiological effect whose purpose is to supplement the normal diet, either from herbal or animal origins, bioactive materials and similar materials, solely or in mixtures, with the defined daily intake dosage prepared in capsule, tablets, pastilles, single use powder package, liquid ampoule, dropping bottle and other similar liquid or dust forms.

Food Supplement Committee Role (redefined in 2015)
Composition: representatives of MINFAL and Ministry of Health

- Evaluate vitamins, minerals and other substances with nutrition or physiological effects used in food supplements and submit evaluation results to the Ministry,
- Evaluate applications for approval of food supplements for 2-4 age group and submit evaluation results to the Ministry.

The Communiqué

Technical requirements

Implementing Order

Information for the notification of supplements Deadline for non-compliant products extended to 31/12/2016 (extended in March 2017 to July for products awaiting authorization but notified before 31 Dec. 2016)

The Claims Regulation

Similar to the EU list + pro/prebiotics claims

The Communiqué
Technical requirements

- Establishes the forms of vitamins/minerals that can be used - in line with Annex of EU Food Supplement Directive
- Establishes minimum levels (15%) and maximum levels for vitamins and minerals.
- Establishes that ingredients permitted for use should comply with the conditions of use set in the permitted lists (The list of botanicals and other ingredients are updated on a regular basis and posted on the website of the authorities)
- Prohibits the use of substances/botanicals included in the prohibited list
- Sets labelling requirements (mandatory statements, net weight etc)
- Prohibits the marketing of supplements for children under 2
- Sets specific labelling requirements and provisions for supplements for 2-4 and 4-10 y.o

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Implementing Order
Information for the notification of supplements

- Information about the company (name, address, URL etc)
- trade name and product name
- Information about the presentation /dosage form
- Information about the composition name of ingredients and quantity
- Company statement regarding commitment to comply or not with HACCP or GMP principles
- Information about whether the food supplement is promoted on the declared URL*

* If illegal advertising and promotion is found on internet, companies should commit in writing to take legal actions for
the removal of any promotion and advertising on domain names and URL address(es) which do not belong to themselves