IADSA NEWSFLASH

February 2019

The Priority of Claims

It is a task of government to ensure that only fair and truthful claims for supplements reach the market. Creating legislation to achieve this is far from easy. And many governments across the world are faced with just this challenge at present.

In Turkey, claims have since December become a new responsibility of the Ministry of Health who have the task of developing new regulation. In India, having collected many examples of claims from the market, the FSSAI must now work out which claims should be permitted and which not. The European Commission's report on claims for botanicals is expected in June. ASEAN is considering how to ensure consistent application across the region of their Claims Guideline that was adopted in 2014. These are just a few examples of the many developments in this area across the world.

The issues governments face as they begin this work can vary widely:

- The borderline between claims for supplements and claims for medicines
- What level of substantiation is required for claims or different types of claims.
- How to evaluate the substantiation data and whether to establish a scientific committee to do this work
- What procedure to establish for the approval of new claims
- Whether to permit claims per ingredient or per product

And in the background, there is the ever present challenge for many governments and industry of how to stop those who insist on abusing any regulations with outrageous and often drug-like claims.

Finding the right balance that 1) allows fair claims 2) that are informative for the consumer 3) that are based on achievable levels of evidence and 4) still stimulate innovation in the field of nutrition requires common sense, pragmatism and a good understanding of the category.

IADSA

International Alliance of Dietary/ Food Supplement Associations

IADSA Annual Week 2019

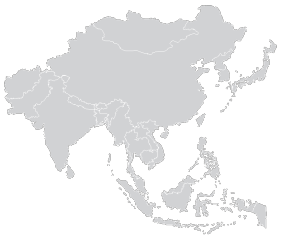
10 Apr - 12 Apr 2019, Sydney Australia

Members can register by **28 February 2019** via *http://events.iadsa.org/event/7*

CMA Innovation Day

Our Australian member association, CMA, is organising their Innovation Seminar on Tuesday 9 April in Sydney for which IADSA Members will receive a discount. Please follow this link for more information and to register: http://www.cmaustralia.org.au/event-3232144

Regulatory news



China

100-day campaign of action to clean up the market

China has recently started a 100-day campaign of action to 'clean up' the healthcare industry, including health foods. This follows the escalation of a case surrounding the death of a child suffering from cancer who was taken out of hospital by her father, but who subsequently died after taking herbal products. It is alleged that the company marketing the product was making claims relating to cancer. This campaign has the backing of both President Xi and Premier Li and is expected to focus on the product category, excessive claims and direct selling. The government has also stopped issuing health food approvals, having only just restarted them in December.

Transfer of responsibility to SAMR

The Chinese SAMR (the State Administration for Market Regulation - former FDA) has released this month its draft Food Safety Sampling Inspection Management Method for public consultation. Changes include the transfer of responsibility for this from CFDA to SAMR. SAMR will have the role to set up a food safety inspection supervision system for China.

http://www.cfda.com.cn/newsdetail.aspx?id=118868

Draconian labelling proposals for heath foods

China SAMR is consulting on new labelling requirements for health foods. One of the main changes is the inclusion of a disclaimer "Health food does not have a disease prevention and treatment function. This product is not a replacement for a drug". The draft provisions specify that the disclaimer should not be less than 30% of the surface area of the side of the label. It is worth noting that such requirements are equivalent to the size of the warning on tobacco packs in many countries.

The draft also requires the inclusion of information on the label of the complaints' hotline. Records of the complaints will need to be kept for at least two years.

India

Food Officers to reinforce controls

The Food Safety and Standards Authority of India (FSSAI) has recently asked its food control officers to launch a strong enforcement drive on non-compliant products and to initiate appropriate action against defaulting food businesses.

The FSSAI pointed out that it has received reports that labels of nutraceutical/health supplement products that have gelatine shells or contain ingredients of animal origin were bearing the green dot identifying them as vegetarian food. The FSSAI states that this is contravenes the Food Safety and Standards (Packaging and Labelling) Regulations 2011 which mandates the applicability of vegetarian and non-vegetarian logo on the labels of pre-packed foods products.

FSSAI issues its verdict for 14 supplement ingredients

Last December, the FSSAI clarified its decision regarding 14 ingredients used in supplements. While a positive verdict was issued for vitamin D3 from lichen (*Cladonia rangiferina*) as a vegetarian source, the authorisation to use raspberry ketone, silica, *Angelica sinensis*, chlorella growth factor, chaga extract, tea tree oil (*Melaleuca alternifolia*) and *oxalobacter formigenes* was discontinued. The same decision was made in relation to *Paullinia cupana* (Guarana), saw palmetto, notoginseng, pine bark extract from *Pinus radiata*, pine bark extract from *Pinus pinaster* due to lack of adequate data such as history of safe usage in India for 15 years.

Talking to consumers

Many countries have labelling systems that consumers do not understand. This is also true in India where the supplement market is

flourishing since the entry into force last year of a legislative framework for supplements. In order to educate consumers, the Food Safety and Standards Authority of India has worked with ReCHaN, the resource centre created in partnership with IADSA and the Confederation of India industry, to launch the following video "Know your supplement". https://youtu.be/ed-XSkNHdlk

Indonesia

Halal label deadline pushed back

Indonesia is to postpone an October deadline for halal labels on foods, drugs and cosmetics, after industry raised fears it could bring chaos and impact supplies of vaccines and other products.

In 2014, the world's largest muslim-country adopted a new law imposing mandatory halal certification for all food, beverage, drugs, cosmetics, chemicals (used for human consumption), organic and genetically modified products sold in Indonesia as well as for the machinery and equipment involved in processing these products. The obligation of halal certification was aimed to start in October 2019, under the lead of the new Government Agency BPJPH (Badan Penyelenggara Jaminan Produk Halal). BPJPH was created in 2017.

Taiwan

Towards the recognition of the food supplement category

The Taiwan FDA presented at the end of last year a draft regulation on food additives introducing a definition for dietary supplements:
"Food products with recommended daily intake amount for the purpose of nutrition supplementation that include vitamins, minerals, herbs or other botanicals, amino acids/peptides, and other dietary ingredients. The product form includes capsules, tablet, powder or liquid form".

This development marks an important step forwards in a country where the category is not yet legally recognised.

New labelling rules on Health Food

The Ministry of Health and Welfare of Taiwan has announced the adoption of new regulations governing the labelling of heath food.

In particular, capsules must have precautionary statements regarding the recommended intake, namely:

"This product is not a drug for health care, and patients who are ill are still in need of medical treatment". "Please eat according to the recommended intake, do not overdo it." The statements should be distinguished from the background color.

https://www.fda.gov.tw/tc/includes/GetFile.ashx?id=f636832679301864662

Korean

New provisions for functional food

The Korean National Law Information Centre amended in early January the "Health Functional Foods Act" defining health functional foods as "foods that are manufactured (including processing) by using raw materials or ingredients having useful functions in the human body" and establishes policies to ensure improved quality, distribution and sales of the subject matter. The new rules will enter into force mid-February 2019.

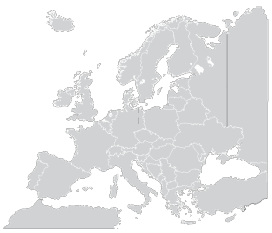
http://www.law.go.kr/법령/건강기능식품에관한법률/(16295,20190115)

New Zealand

Patience: the big virtue

Despite acknowledging the need for a new regulatory system for the supplement sector, the Government is not moving forward.

The New Zealand supplement industry is expected to go through another round of workshops, surveys and consultations on a new regulatory system that will unlikely be adopted this Parliamentary term.
The current regulation, which was set to expire in March 2019, was extended in February 2018 to March 2021.



European Union

EU bans yohimbe

The proposal to ban Yohimbe and its preparations, prohibiting their use in foods and supplements, was adopted by the Standing Committee of the European Commission in December due to the absence of new data to demonstrate its safety.

Yohimbe is derived from an African tree of the same name and its uses include weight loss and sexual performance. EFSA raised in 2013 the possibility of harmful effects on health associated with the use of the substance. Yohimbe was put under scrutiny in 2015 for a period of four year after which time a decision needed to be made on whether to allow it, ban it or impose restrictions.

EU consults on levels for pyrrolizidine alkaloids in botanical supplements

The European Commission is consulting on possible regulatory measures as regards the presence of pyrrolizidine alkaloids in tea, herbal infusions, food supplements and honey. It clarified that the levels should be based on the sum of 21 pyrrolizidine alkaloids. For tea, herbal infusions, herbs, food supplements containing herbal ingredients, pollen-based supplements, pollen and pollen products, a maximum level of Limit of 400 µg/kg is proposed with a Limit of Quantification set at 5 mcg/kg for the individual pyrrolizidine alkaloids (or co-eluted pyrrolizidine alkaloids).

Food supplements suspected of microplastic pollution

The European Chemicals Agency (ECHA) has submitted a proposal to restrict intentionally added microplastic particles.The proposal targets several sectors including food supplements which, according to the report, contain microplastics, essentially used for their controlled release and taste masking functions, through a film forming function. Some microplastics are authorised as food additives for use in solid food supplements. These include E1205 (Basic methacrylate copolymer), E1206 (Neutral Methacrylate Copolymer), E1207 (Anionic Methacrylate C opolymer), and E1208 (Polyvinylpyrrolidone-vinyl acetate copolymer).

https://echa.europa.eu/-/echa-proposes-to-restrict-intentionally-added-microplastics

Levels of citrinin in red yeast rice supplements may be lowered

The European Commission is considering a reduction of the level of citrinin (a nephrotoxic mycotoxin) in food supplements which can be produced by some some strains of *Monascus purpureus*. The level is proposed to be reduced from 2000 to 100 µg/kg in supplements containing this red yeast. This is based on analyses from a Member State showing that levels in such products are generally low.

The question mark on CBD products

"Without prejudice to the information provided in the novel food catalogue for the entry relating to Cannabis sativa L., extracts of Cannabis sativa L. and derived products containing cannabinoids are considered novel foods as a history of consumption has not been demonstrated. This applies to both the extracts themselves and any products to which they are added as an ingredient (such as hemp seed oil). This also applies to extracts of other plants containing cannabinoids. Synthetically obtained cannabinoids are considered as novel"

This is the explanation included in the Novel Food Catalogue regarding Cannabis sativa, CBD and cannabinoids. This entry leaves traditional products derived from Hemp seed untouched. However, the status of products such as the use of leaves and flowers for infusions still remains unclear.

Hemp is a traditional non-novel food commodity, but views on cannabinoids and in particularly on cannabidiols are widely diverging across the EU: Some Member States considering these substances as narcotics, others classifying them as medicine and still others having a wide range of products already on their market.

EU vows more openness and transparency

The Council and Parliament have recently reached a provisional agreement on the revision of the General Food Law Regulation promising more openness and transparency to consumers.

This amendment of the General Food Law Regulation, backbone of EU food law, was aimed to address concerns expressed by a European Citizens' Initiative asking for a ban on glyphosate and better protection of people and the environment from toxic pesticides.

The provisional agreement notably sets out that supporting data and information linked to an application for authorisation will be made public by EFSA after the assessment of the validity of the application, unless the applicant proves that this could significantly harm its interests and requests confidential treatment by EFSA. EFSA could also be requested to commission its own verification studies in exceptional, controversial cases of high importance for society.

https://www.consilium.europa.eu/en/press/press-releases/2019/02/12/safe-and-transparent-food-chain-provisional-agreement-on-availability-and-independence-of-scientific-studies/

Claims authorisation on monacolin K from red yeast rice suspended

The European Commission has announced the suspension of the health claim authorisation procedure on a disease risk reduction claim for a product containing monacolin K until the they have taken a decision on the safety of the ingredient.

In 2018, EFSA indicated in its opinion that Monacolin K could pose a significant health concern with adverse effects similar to those of lovastin.

Estonia

Flagging non-compliance

The Estonian authorities have recently announced their aim to now 'name and shame' illegal products by listing them on the web portal: https://vet.agri.ee/?op=body&id=1349

Illegal products include those that have not been notified as required by law, that bear medicinal or prohibited health claims, do not include mandatory food information or for which business operator details are missing.

Among those listed products, many are for weight loss, sports, detox or stimulants.

JRC Tips for nanomaterial definition

The Joint Research Centre (JRC) of the European Commission has recently published their 'overview of concepts and terms used in the European Commission's definition of nanomaterial'. The report aims to assist the implementation of the European recommendation on a definition of nanomaterial, on which the European Commission is working on, by providing abroad scope of the definition which can be applied across all relevant legislative areas including food/ supplement regulation.

https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/overview-concepts-and-terms-used-european-commissions-definition-nanomaterial

France

Titanium dioxide in danger

France reaffirmed in January its willingness to ban the use of TiO2. In order to obtain the necessary legal conditions for this prohibition, the French ministry in charge indicated that the French Food Safety Agency (ANSES) would be asked to update its opinion on nanoparticles in relation to TiO2 by 15 April. This assessment should be based on any new studies available. On the basis of this ANSES report, the Government will refer the matter to the European Commission. The Minister is expected to exercise his right of 'safeguard' by taking a unilateral decision prohibiting TiO2.

While EFSA stated in its 2016 opinion that the additive TiO2 poses no health concerns, a 2017 French scientific study from the French National Institute for Agricultural Research (INRA) highlighted potential carcinogen risks of nanoparticles of TiO2. This led the French National Assembly to pass an amendment to the Farm and Food Bill signed in October 2018 (so called EGALIM Law) aiming to ban the use, import and marketing of TiO2 and any food containing it.

In February, ANSES launched a call for information on the use of manufactured nanomaterials in food related to a number of food additives. This list includes TiO2, magnesium salts of fatty acids (E470b), silicon dioxide (E551) and many other additives.

Control Authorities post new guidelines for vitamin and mineral supplements

The French Food Control Authorities (DGCCRF) have updated their guidelines on indicative safety maximum levels for vitamins and minerals in food supplements. As with the Irish model, the 95th percentile intake as the "mean highest intake" was used for the calculation of the maximum levels in supplements.

https://www.economie.gouv.fr/files/files/directions_services/dgccrf/securite/produits_alimentaires/Complement_alimentaire/CA_Internet_RS_Nutriments.pdf

Food supplement containing rhubarb on the radar of French authorities

The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) has recently investigated a case of severe hypokalaemia following misuse of a food supplement containing liquorice: Approx. 30 tablets per day over several months, whereas the recommended daily dose was set at maximum 3 per day over 10 days.

The food supplement, designed to assist with the transit, was used for weight loss purposes.

ANSES concluded that, without excluding an effect of the other substances contained in the product, licorice and rhubarb could, respectively, be the cause of potassium loss by the body through a direct and indirect mechanism. In this regard, ANSES stated that:

- Hypokalemia has been reported in the literature following the consumption of liquorice.
- Rhubarb, by its laxative properties, can also indirectly cause hypokalemia.
- The severity of the adverse effect observed in this report can be attributed to the association of these two plants, consumed in excess.

It remains to be seen how this case could impact current EU discussions on hydroxyanthracine derivatives.

Italy

Confirmed benefits for botanicals

To ensure the continued use of previously permitted mandatory indications/ descriptions for botanicals in Italy, the Italian Ministry of Health has recently adopted an additional Ministerial Decree to amend the previous 'Decree on permitted plant substances and preparations used in food supplements of 10 August 2018. ' This now includes the beneficial effect for botanicals in its Annex.

http://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?anno=2019&codLeg=67517&parte=2&serie=

Ireland

Good bye to VAT exemption

Ireland is to remove the VAT exemption on vitamins, minerals and fish-oil supplements. From 1 March 2019, all supplements will be subject to the Standard VAT rate of 23%.

Since 1972, a zero-rate tax was applied to vitamins, minerals and fish-oil supplements. The Irish Revenue decided early this year to impose the same VAT treatment to all food supplements marketed in Ireland.

United Kingdom

Brexit: What to expect on day one of a 'no deal' scenario?

The UK authorities have recently published guidelines entitled: 'Partnership pack: preparing for changes at the UK border after a 'no deal' EU Exit' This document aims to provide assistance to companies in preparing their set up for continued import after 29 March in case the UK and the EU have been unable to reach a withdrawal agreement.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/777373/Partnership_pack_Feb_2019.pdf

Saudi Arabia

SFDA to set contaminant limits for supplements

The Saudi Food and Drug Authority (SFDA) has recently published its Draft Standard "Contaminants and toxins in food and feed" laying down specific provisions for food supplements. Interested parties can submit comments until 6 April 2019.

https://www.sfda.gov.sa/ar/food/about/administration/management_regulations/Documents/ContaminantsToxinsE.pdf

Norway

Impact of caffeine on children more data needed

The Royal Norwegian Ministry of Health and Care Services haver recently consulted the Norwegian Food Safety Authority (NFSA) to investigate and recommend measures to protect children and adolescents (8 to 18 y.o) from adverse health effects caused by high consumption of energy drink. The request focuses not only on potential adverse health effects of energy drinks but caffeine. Reason for this investigated was based on the observation that children and adolescents who drink energy drinks can get both sleep problems and experience anxiety, anxiety and heart issues if they drink a lot, especially over a short period of time. While the report highlights all the data gaps that would be required in order to have a better idea on the impact of caffeine on children including more specific estimations of caffeine from supplements, it was reported interesting that chocolate, beverages with cocoa, cakes with cocoa and tea were the main dietary sources of caffeine in the age groups 8-9 and 12-13 years (sodas was not included in this study).

Turkey

Back to square one on claims

The Parliament last December amended its "Bill of law on health"

with the implication that all food and food supplements bearing health claims must be granted approval by the Ministry of Health (Turkish Medicine and Medical Device Agency, TMMDA) before being placed on the market. This switch of responsibility from the Ministry of Agriculture (MINFAL) to the Ministry of Health brings complexity on the market: It is

not yet known whether claims that were allowed under the MINFAL Nutrition and Health Claims Regulation (an adaptation of the EU Regulation) will continue to be permitted.

USA

FDA announces the formation of Dietary Supplement Working Group

FDA Commissioner Scott Gottlieb, M.D. announced the creation of a working group within his agency to improve oversight of the dietary supplement industry.

The new FDA Dietary Supplement Working Group will notably examine FDA's current and existing powers of authority for regulating dietary supplements. The working group would also be examining the agency's own internal operating processes and structure as part of this effort.

Since passage of the Dietary Supplement Health and Education Act of 1994 (DSHEA), the industry has grown from US$4 billion to more than $40 billion, with more than 50,000 products on the market, Gottlieb noted.

More Transparency for Consumers on Bioengineered Food

The USDA has recently released its Final Rule implementing the National Bioengineered Food Disclosure Standard (NBFDS). The new Standard requires food manufacturers, importers, and other entities that label food for retail sale to disclose information about BE food and BE food ingredients.

This rule is intended to provide a mandatory uniform national standard for disclosure of information to consumers about the BE status of foods.

https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-27283.pdf

FDA promises new efforts to strengthen regulation of dietary supplements

FDA has announced a new plan for policy advancements with the goal of implementing a significant modernization of dietary supplement regulation. It includes communication to the public as soon as possible when there is a concern about a dietary supplement on the market, a flexible regulatory framework to adequately evaluate product safety, the development of new enforcement strategies, and continued engagement in a public dialogue with dietary supplement stakeholders.

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm631065.htm

Argentina

Argentina aligns with Mercosur regulation for materials in contact with foods

On 9 January 2019, Argentina adopted the Mercosur Harmonized Regulations GMC 40/15 and 41/15 related to materials and packaging in contact with food including food supplements. Although these regulations are a decade old, Argentina has never adopted them. Since the Mercosur Commission of Foods has initiated the process to update both regulations, Argentina recognised the need to implement them in national legislation. This will help harmonisation in the region in this area.

Registration fees to go up

The National Agency of Drugs and Foods (ANMAT) has increased its fees for the registration of food products, including food supplements, and the renewal of registrations. The new fee for the registration of food supplements is 8.000 ARS (approximately 210 USD) and to modify some information in the registry is 4.550 ARS (approximately 120 USD).

Brazil

ANVISA guide on regulation for the sector

ANVISA has issued the 4th version of the Q&A document on food supplements providing more clarity on how the agency is applying the provisions of the regulation. Although this is an informative tool, it is aimed to clarify questions and interpretations of the regulations. Compared with the previous version, this 4th edition provides more clarification on issues such as: permitted claims, sources of fish oil, combinations of amino acids, how to calculate the nutrients present in a product, denomination of the category, nutrition labelling, use of

the term “thermogenic”, and warning statements related to pregnant and lactating women.

http://portal.anvisa.gov.br/documents/33916/2810640/Suplementos+Alimentares/a6fd2839-6d80-496a-becb-8b2122eff409

Public meeting on the draft guide for the evaluation of probiotics

On 31 January ANVISA held a public meeting to introduce the new approach to the assessment of probiotics used in foods and food supplements. A document to help industry in this process, based on Resolution RDC 241/2018, was presented. This Guide sets out the requirements for the development of technical-scientific dossiers required for the approval of probiotics, including the identity of microorganisms, the evaluation of safety, and proof of health benefit. ANVISA has published the Guide on their website, providing stakeholders one year to provide comments. In the meantime, the document will serve as a reference.

http://portal.anvisa.gov.br/documents/219201/219401/Minuta+Guia+Instrução+Processual+Avaliação+Probióticos+em+Alimentos/7546c7c2-a698-4975-8a26-51d9e9e18d97

Lactose labelling regulation fully enforced

The regulation that requires the declaration of lactose on food labels that was approved in 2016 fully entered into force on 9 February 2019. The declaration shall be placed below the list of ingredients in bold capital letters following the specifications given in the regulation.

Proposal to adopt Mercosur regulation on additives permitted in the manufacture of plastic and polymer coatings in contact with foods

Brazil has opened for public consultation Mercosur's proposal of Resolution 05/18 which foresees a positive list of additives destined to the manufacture of plastic materials and polymer coatings in contact with foods and food supplements. The final date for comments is 1 April 2019.

Colombia

The Ministry of Health confirms current rules for food supplements

On 28 December, the Ministry of Health issued Decree No. 2474 which

confirms the continuation of the current regulation on food supplements (Decree No. 3249 of 2006, amended by Decrees No. 3863 of 2008 and No. 272 of 2009). This followed a consultation process in accordance with a review procedure that takes place every five years. However, this does not preclude future changes during the next five-year period.

https://www.opinionysalud.com/wp-content/uploads/2018/12/DECRETO-2474-DEL-28-DE-DICIEMBRE-DE-2018.pdf

Dominican republic

Dominican Republic levies tax on imported food supplements

On 4 January, the General Direction of Customs (DGA) clarified that as of 1 January a tax of 18% will be levied on food supplements (in pill, capsule and tablet form) in accordance with Law No. 11-92 Tax Code, which sets the Tax on the Transfer of Industrialized Goods and Services (ITBIS). However, due to misinterpretation of the law, DGA has now decided to suspend the measure and invite the involved sectors for discussions. This tax has been on hold since 2007 due to issues regarding legal interpretation.

Food supplement importers must update information at DGA

On 1 February, DGA announced to importers that its database for food supplements needs to be updated to include technical information on products prior to import.

Mexico

Regulation for food additives updated

COFEPRIS has updated the regulation for food additives, including for food supplements. Changes have been introduced for azorubine/carmoisine INS 122, which is now permitted for food supplements at a maximum level of 300 mg/kg. It applies to food supplements in solid form including capsules, tablets etc. It excludes chewable forms. This update is already in force.

Belarus

Belarus introduces rules for approving labelling claims for foods

The Belarusian cabinet's resolution of 15 January 2019 adopted the regulation on special and/or claimed properties of food raw materials and foods to be displayed on product labels. Claims include special nutritional properties, indications for use and contra-indications for individual age groups and for certain diseases, including those used for dietary supplements and foods for special dietary use. Claims and supporting materials are to be reviewed and approved by a special commission set up by the Health Ministry. Applications for the claim review are to be sent to Belarus' Centre for Hygiene, Epidemiology and Public Health. The regulation came into force on 29 January 2019.

Each batch of dietary supplements to be tested for quality prior to release onto market

The Belarusian cabinet's adopted in January procedure and requirements for controlling the quality and safety of dietary supplements and foods for special use intended for athletes.
The resolution reads that legal entities and sole traders engaged in the manufacture and/or sales of foods will have to control quality of every batch of locally manufactured and/or imported dietary supplements and foods for special use intended for athletes. Quality control implies assessing:
• the content of biologically active substances;
• information on the packaging, labels and inserts of dietary supplements and foods for special use intended for athletes, as well as the information contained in the registration certificates and in the uniform register of state registration certificates.
The resolution also requires annual check of product safety, i.e. compliance with the requirements of Belarusian laws and EAEU technical regulations.
Quality and safety tests are to be performed in laboratories accredited by the national accreditation system, and their results are to be kept on file.
The resolution came into effect on 29 January 2019.

Russia

Dietary supplements subject to snap inspections

Based on the results of scheduled and snap inspections of dietary supplement manufacturers and vendors carried out by Rospotrebnadzor in the first nine months of 2018, Rospotrebnadzor's territorial offices have been instructed early this year to track down and withdraw from circulation any dietary supplements in circulation whose labelling does not contain information in Russian, as per CU TR 022/2011 on Labelling of foods.
The inspections will check for the conformity of dietary supplements to technical regulations in general, not just for the presence of information in Russian.

Amendments to technical regulations to introduce new requirements to food additives used in dietary supplements

In December 2018, the EAEU portal put up for public discussion Amendments to CU TR 029/2012 on safety requirements for food additives, flavouring agents and processing aids. The amendments are primarily aimed at harmonising the use of food aids, flavouring agents and processing aids with the Codex Alimentarius standards and EU regulations, and also at specifying certain provisions of the applicable EAEU technical regulation.

The amendments:
• modify existing terminology, such as flavouring agent, natural flavouring substance and complete preparation, as well as introduce the new terms: new food additive, carrier, processing aid, traditional production methods for foods, table sweetener and contrast enhancer;
• expand the list of requirements for the use of food additives, flavouring agents and processing aids in the manufacture of foods, as well as the labelling requirements for food additives in food labelling;
• take 16 food additives off the list of substances permitted for use within the EAE, including *Stevia rebaudiana Bertoni* sweetener in the form of leaf powders, leaf syrups and plant extracts;
• introduce six new food additives to the list of permitted substances.

The special requirements for dietary supplements include:

• restrictions on silicon dioxide (E551): not more than 10 g/kg (current edition – according to technical documents);
• new food additives permitted in the form of glazing agents (E1205, E1206, E1207, E1209) at maximum permissible levels;
• for the first time, steviol glycosides (E960) are permitted in manufacture as sweeteners, expressed as steviol equivalents (maximum levels of 200 and 670 mg/kg for liquid and solid state respectively, and 1,800 mg/kg for syrupy and chewy dietary supplements).
• Requirements to the use of sweeteners in the food industry.

The document are open for comment until the end of February.

1

2 STEPS to establish the harmonized maximum levels of vitamins and minerals based on scientific risk assessment

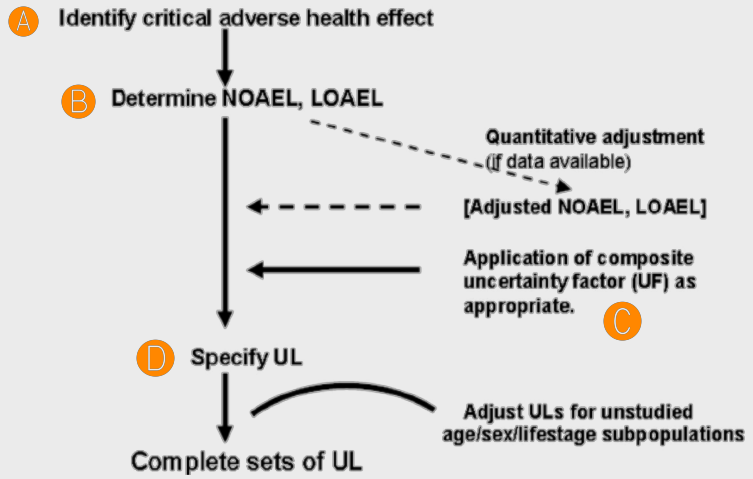
Derive tolerable upper levels (ULs) of vitamins and minerals from all sources of intake

Use the ULs to establish maximum levels of vitamins & minerals in health supplements

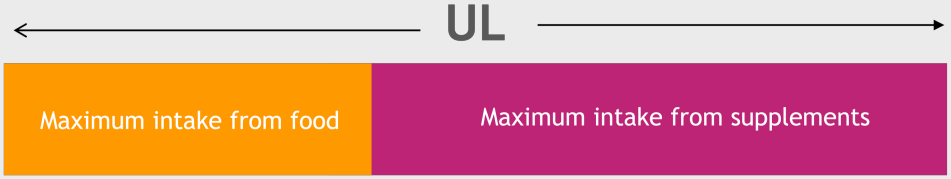
2

The basic approach to derive ULs

Report of a joint FAO/ WHO technical workshop on nutrient risk assessment. Geneva, Switzerland, 2-6 May 2005

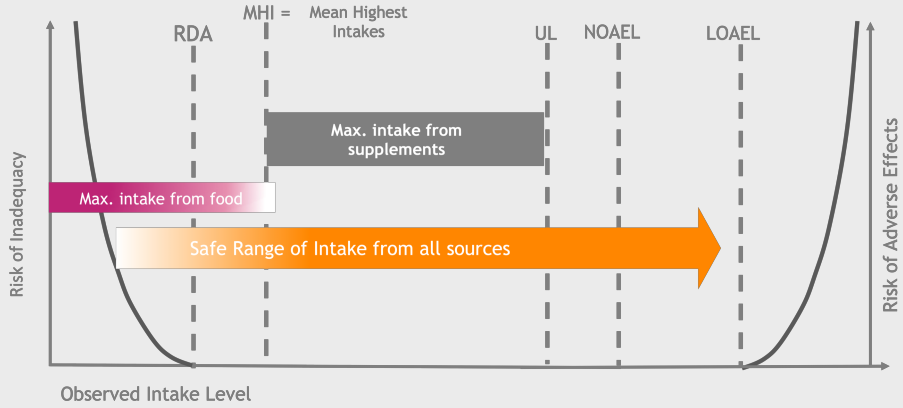


UL = NOAEL ÷ UF



MHI (Mean Highest Intake)

The maximum level of a vitamin or mineral in health supplements = UL - MHI



The model for setting maximum levels for vitamins & minerals in supplements

IADSA
International Alliance of Dietary/ Food Supplement Associations

CAC/GL 55-2005 Guidelines for Vitamin and Mineral Food supplements

The upper safe levels of vitamins and minerals should be established by scientific risk assessment and not be solely based on RDA

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The basic approach to derive Maximum Safe Levels

Calculate the Population Safety Index (PSI) for each nutrient taking into account the contribution to total nutrient intake from all sources including conventional foods, fortified foods and food supplements

Evaluate the risk management options for current and future intakes of nutrients from all sources

Categorise nutrients into three groups of risk using quantitative and qualitative information

Propose maximum safe levels (MSL) for each nutrient in food supplements

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$$PSI = \frac{UL - (MHI + IW)}{RDA}$$

- *IW Intake of minerals from water*
- *MHI Mean Highest Intake*
- *PSI Population Safety Index*
- *RDA Recommended Daily Allowance*

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Calculation of Maximum Safe Levels

1. No UL established - When there are no safety concerns about a nutrient and when a UL cannot be identified, a maximum value can be based on the HOI (Highest Observed Intake) risk assessment method* GROUP 1

2. Vit/Min with PSI>1.5: Max level = UL - MHI GROUP 2

3. Min with PSI<1.5: Max level = 1 x RDA GROUP 3

In some cases, a precautionary factor can be considered, In that case, maximum levels can be calculated as follows:

For vitamins: MLS = UL - (MHI x 150%)
For minerals: MLS = UL - [(MHI x 110%) + IW]

** FAO/WHO 2006; Hathcock and Kriengsinyos 2011*

Categorisation of nutrients into three groups of risk

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Group 1: Nutrients that do not represent a risk to human health: no UL established.

Group 2: Low risk of exceeding the UL: RDA< Max level < UL

Group 3: Potential risk at excessive intakes: Max level = 1 x RDA

The model for setting maximum levels for vitamins & minerals in supplements

IADSA
International Alliance of Dietary/ Food Supplement Associations

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