IADSA Newsflash

May 2016

Prague Annual Week

It is hard not to come away from the Annual Meeting of IADSA in Prague without being highly optimistic for the sector.

It was not just the presence of so many trade association and company leaders from across the world, all working to ensure that the regulation in their country or region reflects the specific requirements for supplements.

It was not just the sheer size of the Annual Meeting, the largest we have ever had, and the presence of so many highly influential decisions makers from government.

But it was the feeling that the breath and depth of the work of the IADSA Alliance worldwide, from science to technical, from regulation to policy, puts food supplements in a unique space and that working together something special can be and is being achieved.

Moving away from the regulatory theme that is core to IADSA's work, members were fortunate to hear a powerful 3-hour session on potential value of supplementation. Facilitated by Andrew Shao, Chair of IADSA's Scientific Council, Dr. Manfred Eggersdorfer, Dr. Keith Randolph and Dr. Adam Drewnowski made the most compelling scientific case for supplements than has ever been made at an IADSA event. With an additional presentation by Christopher Shanahan from Frost & Sullivan on the global savings to society from higher intakes of some nutrients and highly supportive messages from Dr. Oran Kwon from Korea, there was no doubt about the key role that supplements could and should play at the heart of nutrition and health policy.

The Annual Meeting in 2017 will be held in Korea, a country with one of the highest consumptions per capita of supplements on the planet. It is also a country that is investing heavily in understanding how increased intake of certain ingredients could keep people healthier for longer, and has managed to not lose its traditional knowledge in developing its modern regulatory framework. As plans are being made, we will be seeing how we can build on what has been achieved in Prague to help take the food supplement sector forward.

IADSA

International Alliance of Dietary/ Food Supplement Associations

International Alliance of Dietary/Food Supplement Associations
Gridiron Building
One Pancras Square
London N1C 4AG
United Kingdom

From left to right
Dr. Oran Kwon, Dr. Manfred Eggersdorfer, Dr. Adam Drewnowski, Dr. Andrew Shao, Dr. Keith Randolph and Christopher Shanahan

Regulatory news

ASEAN

25th Meeting of the Traditional Medicines and Health Supplements Product Working Group

The TMHS PWG will have its 25th Meeting from 31 May to 3 June 2016 in Singapore. The key objective of the upcoming meeting is to finalise and endorse the ASEAN traditional medicine and health supplements agreements and its annexes. These documents are targeted for adoption and signing by ASEAN Economic Ministers (AEM) in February 2017. To prepare ASEAN countries for the actual implementation of the agreements, the scientific committee will be addressing technical capacity building activities for ASEAN Member States, which include good manufacturing practice (GMP), claims requirements, safety data requirements, and stability study.

China

New rules for naming health foods

China Food and Drug Administration (CFDA) announced new requirements for naming of health food. Health foods with a name indicative of physiological functions will be prohibited from being manufactured from 1 May 2016.
A grace period for non-compliant products has been given to companies during which dual brand names including the original product name and the new name can be permitted. The font size of the original name shall not be half larger than that of the new name. From 1 January 2017, the original product name will no longer be permitted.

Korea

Korea's Expansion of the Scope for Functional Food Ingredients

In March 2016, the Ministry of Food and Drug Safety (MFDS) of South Korea announced the revision of the "Code for Health Functional Food", which aims to expand the scope for functional ingredients of health functional food. Under the new regulation, specific standards and specifications have been established for each of the added 8 functional ingredients – raffinose, agar powder, creatine, hydrolysed milk protein, phellinus linteus, tomato extract, konjac potato extract, and jujube extract. Public consultation for the revised code ended in April, but the date of its implementation has yet to be determined.

Expansion of Genetically Modified Labelling Requirements to Any Food Products

In April 2016, the MFDS announced a draft amendment of Labelling Standard for Genetically Modified (GM) Foods. It aims to expand the GM labelling requirements to any food products (including processed food products, food additives and functional health foods) that contain genetically modified DNA or genetically modified proteins. The date of implementation of the new regulation has not yet been determined.

Philippines

FDA & DoH call supplement companies to refrain from unscrupulous promotions and advertisements

In response to the increasing number of unscrupulous promotions and advertisements of food supplements in the media, the Philippines FDA has recently issued a Circular (No. 2016-001) to reinforce the February 2015 Memorandum of Guidelines on the Placement of Advertisements in all Forms of Mass and Social Media, Billboards and Public Transport with the objective to discourage companies from promoting supplements with dubious, false or misleading claims.

http://www.fda.gov.ph/attachments/article/302951/FDA%20Circular%202016-001.pdf

Thailand

New Food Labeling Laws

Starting 2 December 2016, manufacturers and importers in Thailand are required to comply with the new food labelling requirements as contained in Thai Ministry of Public Health Notification No.367 (2014). It may be recalled that the said regulation has increased the labelling requirements for pre-packaged foods, which includes the following, among others:
Label text of pre-packaged food must be in Thai language.
Labels must display the words "should consume by" accompanied by the day, month and year if shelf life is not longer than 90 days, or display the day, month and year if shelf life is longer than 90 days.
Presence of 8 types of allergens or hypersensitivity substances (i.e. cereals containing gluten; crustaceans; eggs; fish; peanut, soybean and their products; milk and dairy products containing lactose; tree nuts; sulfite of 10mg/kg or more) in food products must be declared.

Taiwan

TFDA reviewed health food fee charges

In Taiwan no health food can be manufactured or imported unless it has been registered and received a permit valid for a period of 5 years after the payment of a fee.

Taiwan has recently revised its Regulations for Application of Health Food Permit setting more detailed instructions regarding the fee system and the Authority responsible for the registration. The name of the Authority has been changed from "Health Food Advisory Council" to "Health Food Review Panel."

http://www.fda.gov.tw/TC/newsContent.aspx?id=19517&chk=27525b6b-05ce-48f2-9672-8950c8b91ebb&param=pn&cid=3&cchk=46552e96-810a-42c3-83e1-bd5e42344633#.Vy2OWmNXVki

European Union

Possible veto for cranberry products marketed as medical device

Following the non-authorisation of health claims made on proanthocyanidins from cranberry and the increasing number of medical devices containing cranberry marketed in small dosage forms flourishing on their market, the French national Security Agency of Medicines and

Health Products have questioned the European Commission on whether such products meet the definition of a medical device. To answer this question, the European Commission is currently working on a draft law implying that such cranberry products would not fall within the definition of medical device set in Article 1(2)a of Council Directive 93/42/EEC: A new warning for companies looking at new routes for communicating on the benefits of their products.

EFSA draft guidance documents for novel foods/traditional food from third countries discussed with industry

Last April, the European Food Safety Authority (EFSA) held a stakeholder meeting in Brussels on the draft guidance documents for Novel Foods and traditional foods from third countries. The objective of the meeting was to exchange views with interested parties on the two documents that will be then considered by the EFSA experts for the issuance of the final guidance documents. An EFSA webinar on the new procedure for Novel Food applications is also foreseen by the end of this year.

EFSA releases draft opinion on DRV for Vitamin D for public consultation

By keeping the DRV for vitamin D at 15 mcg for adults, EFSA seems not to follow the trend for increasing the reference intake that was apparent in literature recently. At this intake level, EFSA considers that most of the adult population will achieve a serum 25(OH)D concentration near or above the target of 50 nmol/L.

The opinion is open for consultation until 16 May.

Hygiene Rules/ Provisions applicable to food supplements

The European Commission has revised Annex III of Regulation 853/2004 laying down specific hygiene rules for foods of animal origin. This Regulation is applicable to food supplements containing gelatine, collagen but also highly refined ingredients such as: Chondroitin sulphate, Hyaluronic acid, other hydrolysed cartilage products, Chitosan, Glucosamine, Amino acid. Supplements containing the above ingredients should ensure that the treatment used eliminates any public health risk.

In response to concerns raised in February 2014 in the European Union, the revision also clarifies that human hair may not be used as a source for the manufacture of amino acids.

European Member States warn about the use of monacolin K

After France and Belgium, it is now the turn of Germany to warn about the use of monacolin K/ red yeast rice.
The joint Commission of Experts of BVL (The Federal Office of Consumer Protection and Food Safety) and BfArM (The Federal Institute for Drugs and Medical Devices) have recently come to the conclusion that products with a daily dose exceeding 5 mg Monacolin K should be classified as medicinal products. Consequently health claims for red yeast rice that have been approved for a daily dose of 10 mg Monacolin K should no longer be permitted in Germany.

It is to be noted that in June 2015,the European Commission suggested that food containing Monacolin K should be taken out of the Regulation on health claims. The use of warning statement on product labels was proposed instead. An expert group should be convened to amend the labelling legislation by a delegated act.

Communication to healthcare professionals: within or outside the health Claims regulation scope?

A request for a preliminary ruling from the Regional Court of Munich was recently referred to the European Court of Justice seeking clarification as to whether the Nutrition & Health Claims legislation excludes indirect commercial communication from its scope of application, such as those aimed at healthcare professionals.
The industry is anxiously awaiting the conclusions of the Court, which could have a major impact on current B2B commercial practices.

European Commission authorises two new novel foods for use in children's supplements

The European Commission has approved lacto-N-neotetraose and 2'-O-fucosyllactose as novel food ingredients for use in food supplements, particularly destined for young children.

Decisions can be found at the following links: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL_2016_070_R_0008
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL_2016_070_R_0007

Consensus reached on caffeine

After several months of debate, four caffeine claims on-hold have finally been agreed by the Standing Committee of food law in April.
The proposed authorisations take account of the EFSA Opinion on the amount of caffeine that consumers can take. The draft text needs now to be agreed by the European Parliament and Council. If no objection is raised the claims could be permitted for use around October.

Roadmap priorities set out for food additives

The European Commission has prioritised a series of food additives - *including sorbic acid (E 200), potassium sorbate (E202), calcium sorbate (E203); chlorophyllins (E140ii), cu-cuhlorophylls (E141i), cuchchlorophyllins (E141ii) and Iron oxides* - for re-evaluation after EFSA raised concerns either over lack of safety data or the exposure levels.
A dedicated website will be launched by the Commission at the end of May on the new data needed to complete the risk assessment. Companies will be requested to communicate within 6 weeks whether they are interested that the additive remains permitted and whether they are interested in providing the new data. The list of companies interested in submitting data will be public in order to facilitate interactions among them and possibly coordination in the data submission.

Request for scientific opinion on new sources of Calcium

EFSA has recently received requests from the European Commission for a Scientific Opinion on the safety and bioavailability of Silver hydrosol as a source of Silver and Calcium di-malate as new source of calcium. The conclusions of the Food Safety Authority are expected in the coming months.

Belgium

Belgium revises its decree on heavy metals

Belgium has notified the European Commission and EU Member States of its draft Royal Decree amending current law setting down maximum levels for heavy metals in food supplements. The revision proposes that the arsenic level, for which a limit of 1 mg/ kg is current in place, should be understood as the total arsenic

level from which the arsenobetaine species level is deducted. The draft amendment follows the recommendation of the Belgian Superior Health Council who questioned in 2015 the national maximum level in supplements. The end of the standstill period is 1 July 2016.

Belgium consults on the revision of limits for vitamins and minerals

Following new nutritional recommendations of the Belgium Superior Health Council, the Public Health authorities are currently working on a revision of the Royal Decree of 3 March 1992 on nutrients and foods to which nutrients have been added. In short: The maintenance or an increase of the maximum limits for most of the nutrients is proposed with the exception of manganese. Setting of MSL seems no longer required for vitamins B1, B2, B5, B12 and Biotin.

France

France launches Teleicare, an online notification system for supplements

The awaited e-procedure to notify through the Internet food supplements in France is now available. With 700 requests per month, the French Authorities DGCCRF hopes to simplify, speed up and make more transparent the notification procedure for companies. The new system Teleicare, launched on 26 April, should also help the authorities better understand the market and update the positive lists of plants and substances.
More information can be found at the following links (only available in French):
http://www.economie.gouv.fr/dgccrf/teleicare-teleprocedure
https://teleicare.dgccrf.finances.gouv.fr

Turkey

Permitted lists of substances for supplements updated.

MINFAL has recently published its updated list of other substances that may be used in supplements based on the recommendations of its Committee. The list is expected to be updated continuously based on the request from the sector submitted via the market access procedure.

Brazil

Brazil updates regulation on health claims

On 14 March, ANVISA updated the regulation on health claims and established new conditions of use and new specifications. Among the main updates, changes in the conditions of use of health claims for probiotics, Omega 3, dietary fibre, soy protein, are highlighted.

Programme for controlling food allergens

In view of the regulation on food allergens labelling coming into force next July, ANVISA has issued guidelines with the best practices for controlling food allergens in the establishments that manufacture or store food products, including food supplements. ANVISA will receive comments and suggestions until 8 April 2017.
Link to the guidelines:
http://portal.anvisa.gov.br/wps/wcm/connect/cfa0fd004c3c3aef90bed3feb6b50033/Programa+de+Controle+de+Alergênicos.pdf?MOD=AJPERES

New electronic application for import in place

As of 2 May applications for import (which includes foods and food supplements) can be made on line via a new system: called Vicomex. Non-electronic applications will still be permitted until 31 May 2016.

Chile

Chile closes public consultation on the update of the regulation for the use of claims in foods

The Ministry of Health has closed on April 14 the public consultation referring to the proposal for updating the regulation for the use of nutritional and health claims. One of the most highlighted proposals aims to forbid the use of health claims in food supplements.

Costa Rica

Costa Rica simplifies electronic registration of foods

The Ministry of Health from Costa Rica approved changes on the electronic registration process for foods with the objective of reducing its timing. For the moment, these changes apply only to those foods classified as “low risk”, reducing the process time from 22 to 5 days.

Ecuador

Ecuador to withdraw safeguard import tariffs by June

The Minister of Industry has announced that the safeguard import tariffs imposed last year, which impacted imported food supplements, would be withdrawn by June. However, it has been announced that new measures to restrict imported products could be applied after June.

Panama

New sanitary requirements for importing raw material

The sanitary authority (AUPSA) issued an update for the raw material import regulation, including food additives, used for the elaboration of food products in Panama. This new regulation entered into force in April.

Paraguay

Electronic registration of imported food products comes into force

As from 16 May all imported food products, including food supplements will have to be registered only using the the electronic platform VUI (“Ventanilla Unica del Importador”).

USA

FDA Recognises Canada as Having a Comparable Food Safety System to the U.S.

FDA Recognizes Canadian Food Safety System as Comparable to US (FDA)
FDA has signed an agreement with the Canadian Food Inspection Agency and

Health Canada formally recognizing that their food safety systems are comparable. This is the second time that the FDA has recognized a foreign food safety system as comparable, the first being New Zealand in 2012. A similar system recognition process is underway between FDA and Australia and the European Commission.
Such recognition should benefit food importers, subject to the Food Safety and Modernization Act (FSMA) rule on Foreign Supplier Verification Programs (FSVP)

FDA developing improved methodology for determining purity of probiotic products

"Scientists at the US Food and Drug Administration (FDA) provided "proof-of-concept" for a technique that identifies the presence of potentially harmful contaminants in probiotics" said FDA. The technique eliminates a product's beneficial bacteria and allows any potentially harmful contaminants in the product to grow unimpeded, allowing detection of potentially harmful contaminants using standard laboratory methods.
More information can be found at the following link: Development of Phage Lysin LysA2 for Use in Improved Purity Assays for Live Biotherapeutic Products, http://www.ncbi.nlm.nih.gov/pubmed/26694451

FDA issued warning letters regarding products containing Acacia rigidula sold as dietary ingredient

On 15 March, the FDA issued warning letters to six companies regarding a total of six products for which the product labeling lists A. rigidula as a dietary ingredient. The FDA considers these products to be adulterated because they contain a new dietary ingredient, A. rigidula, and because they have not satisfied the conditions described above regarding the use of A. rigidula as a new dietary ingredient. Under existing law, including the Dietary Supplement Health and Education Act, the FDA can take action to remove products from the market, but the agency must first establish that such products are adulterated or misbranded.

FDA publishes guidance on omega-3s nutrition content claims for small businesses

FDA recently issued guidance for industry—Nutrient Content Claims; Alpha-Linolenic Acid, Eicosapentaenoic Acid, and Docosahexaenoic Acid Omega-3 Fatty Acids; Small Entity Compliance Guide. The guidance is developed to assist small entities in complying with a rule published in April 2014 that prohibits certain nutrient content claims for foods, including conventional foods and dietary supplements, that contain omega-3 fatty acid.

http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm484250.htm

Russia

Nearly one half of Russians take dietary supplements

A survey conducted by Romira research company in late 2015 indicates that 45% of Russians take vitamins and dietary supplements, and 55% have a negative attitude towards them. Three years ago, in 2012, the figures stood at 32% and 67%, respectively. Over one half (51%) of those polled who take vitamins do so irregularly. A quarter of those taking both vitamins and dietary supplements do so regularly. A total of 27% respondents have taken vitamins only once, in a single course. These figures stay relatively unchanged from three years ago. A total of 41% of respondents who take dietary supplements have been doing this to replenish a deficit of vitamins and minerals, whereas 30% use vitamins to strengthen their immune system. Improving metabolism is the aim of 7% of those who take vitamins and dietary supplements; 6% do this to improve their appearance; 5%, for losing weight; and 4% are after building their muscle mass.
The survey polled 1,000 people aged between 18 and 60 across Russia.

Federation Council supports domestic production of sports foods and supplements

The Federation Council's (upper house of the Russian parliament) committee for social policy has held a working group meeting to discuss state regulation of measures to support domestic manufacture of sports foods and raising athletes' and coaches' awareness of sport nutrition as a means of preventing the use of doping. Attending experts concurred that the sports foods industry is suffering from three major problems whose resolution should be addressed. The absence of a uniform register of substances, foods and specialised foods; the dominating position of foreign foods and dietary supplements intended for athletes; and the low level of optimum nutrition awareness among athletes, coaches, and sports doctors.

The speakers also expressed their concern that the Russian sports foods market is currently oversaturated with products whose effectiveness is not validated and by outright ineffective or harmful products. Given that such products are only subject to a declaration procedure, not requiring manufacturers to disclose the composition of products, the market is overflowing with products of dubious quality and low effectiveness.

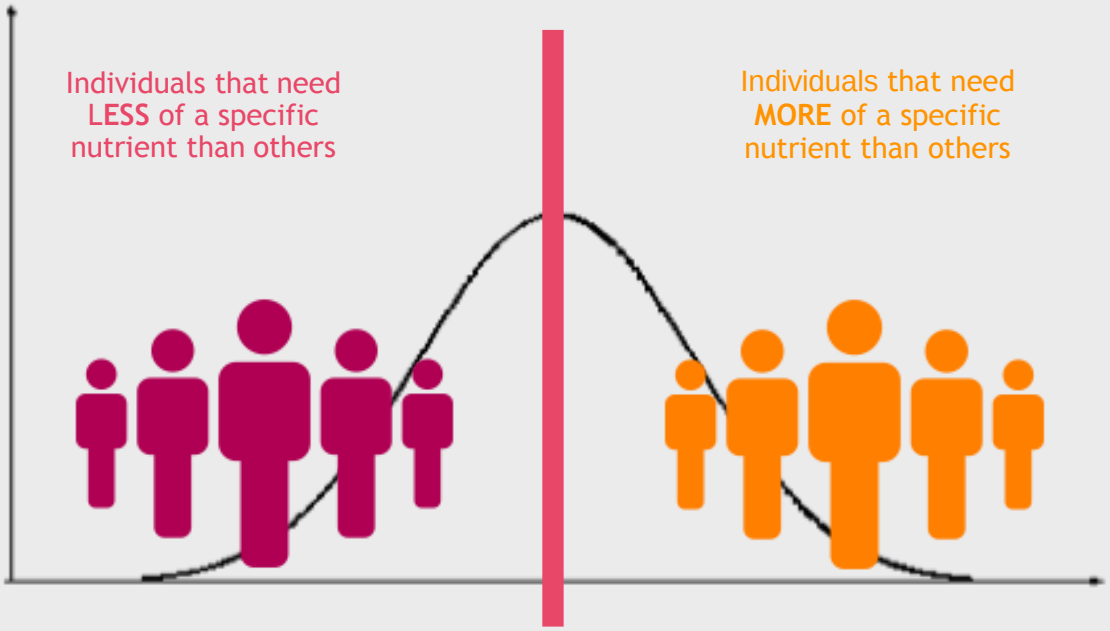
The meeting arrived at the conclusion that measures should be taken to create and develop a market for domestic sports foods. The experts noted that Russia had a good chance of taking up a significant portion of the sports foods market.

Federal anti-trust authority details requirements for 'not a medicine' warning in dietary supplement advertising

The Russian Federal Antimonopoly Service (FAS) issued an alert highlighting the rules for the warning statements in dietary supplement advertisements. In accordance with the law on advertising, a dietary supplement advertisement must be accompanied by a warning to the effect that the product is not a medicine. In radio advertisements, the duration of the warning must amount to at least three seconds; in advertisements shown on TV, in cinemas and in video materials, it must be at least five seconds long and take up at least 7% of the frame area; in other types of advertisements, the warning must take up at least 10% of the advertisement area or space.

The service also explains that in instances when an advertisement is up for several products, the size of the warning should be calculated based on the total advertising area, i.e. an advertisement mentioning several dietary supplements may be supplied with a single warning statement, provided that the latter takes up at least 10% of the advertising area.

THE EAR

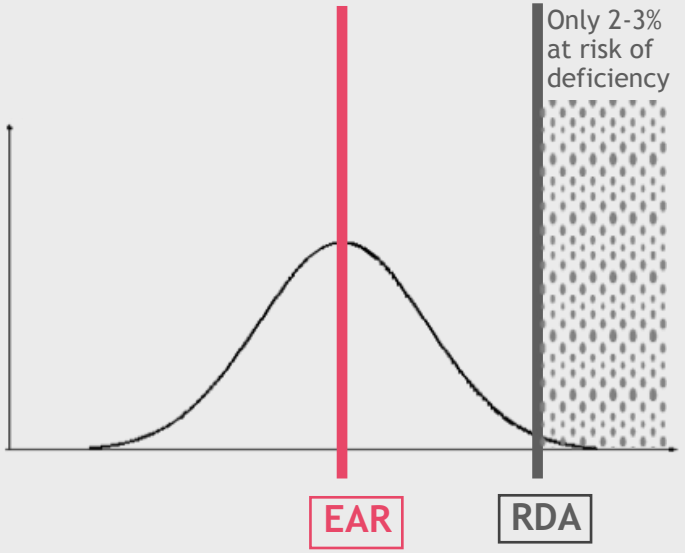


For a given nutrient, this population is not at risk of deficiencies if its intake equals the EAR

EAR

Average amount of a nutrient that is required by half of population / that meets the requirements of half the population

For a given nutrient, this population is at risk of deficiencies if its intake equals the EAR



The RDA

Recommendation to ensure that almost all the population (97-98%) is adequately nourished including individuals who need more than the average amount.

RDA = EAR + 2 SD

? What is the difference

EAR UL
ULS RDA
AI MLS

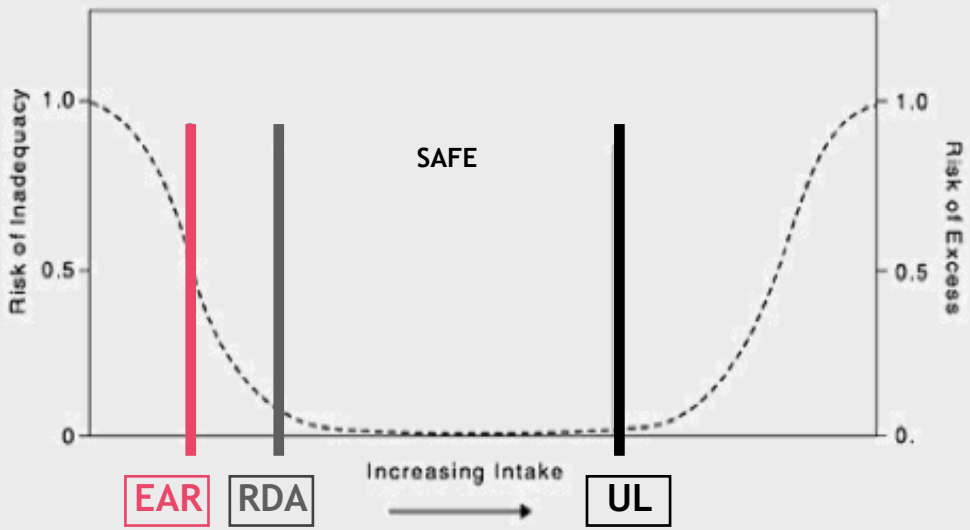
EAR	Estimated Average Requirement
RDA	Recommended Dietary Allowance
AI	Adequate Intake
UL	Tolerable Upper Intake Level
NRV	Nutrient Reference value
SD	Standard Deviation

The AI

For some nutrients, there is not enough data to set a precise RDA. In these cases, an **adequate Intake (AI)** from analysing the food records of a large group of healthy people is established so as to determine how much of a specific nutrient is consumed. Like the RDA, the AI can be used as a nutrient goal for individuals.

The UL

Nutrient intakes can sometimes be excessive and may lead to too many nutrients. Usual intake above this level may place an individual at risk of adverse effects. The UL is not a recommended level of intake. It is based on a risk assessment of nutrients that involves establishment of a No Adverse Effect Level (NOAEL) and/or a Lowest Adverse Effect Level (LOAEL) and application of an Uncertainty Factor (UF) related to the evidence base and severity of potential adverse effects.



The ULS

Tolerable upper intake from supplements (ULS) calculated as follows: ULS = UL – ICF (Usual intakes from conventional foods)

The MLS

Maximum level that balances the risk of deficiency with the risk of overconsumption for each nutrient in supplements. The MLS would not be expected to result in any adverse effects.

The NRV

Developed for labelling purposes.
In many cases, NRVs are closed to RDAs.

? What is the difference

EAR UL
ULS RDA
AI MLS

AI	Adequate Intake
UL	Tolerable Upper Intake Level
ULs	Tolerable Upper Intake Level for supplements
NRV	Nutrient Reference value
ICF	Intakes from Conventional Foods