

# IADSA Newsflash

September 2017

## The Challenge of Implementation

Developing a good regulatory model is often hard for governments. Implementing it even harder. In many countries of the world, the systems of control and enforcement are not adequately resourced for the job at hand. There is often a shortage of staff, training and the technical and legal support to make the regulation work the way it was intended.

Governments are increasingly realising that only by partnering with the private sector is it possible to ensure that there is a workable path to constantly increasing compliance.

In July, IADSA signed a cooperation agreement to establish a Resource Centre on Health Supplements with the Confederation of Indian Industry, on the request of the Food Safety Standards Authority of India (FSSAI). For over a decade the FSSAI has been looking at introducing new regulation and on 1 January this will take effect.

While there are a few outstanding challenges in the regulation, it broadly provides an excellent and secure basis for the food supplement sector to invest.

However, regulation can only go so far. India is a huge and complex federation of states, each with powers regarding legislation and enforcement. The country therefore faces significant challenges in the consistent implementation of legislation.

And this is where the Resource Centre can be so important. Its primary goal will be to produce guidance and support for both government bodies and companies engaged in the market on how to implement the regulation according to best practice.

The first target - establishing guidance on Good Manufacturing Practice - will shortly be underway. Other activities focussing on an Indian Food Safety Management System for Supplements will follow.

What is clear is that such an initiative can only really work if there is government support. But this government support can only be sustained if the quality of such an initiative remains high.

We look forward to our investment in India. We also trust that this will create a new reference point for engagement with government globally.

Registration now Open  
Annual Week London  
19 Jun - 21 Jun 2018



IADSA will be holding its 20th Anniversary in June 2018 in London, the city where the Alliance was originally founded and is based today.

We look forward to seeing our member representatives at the Annual Week, to reflect both on the progress made over the past twenty years and to look forward to the future.

The meetings will be held at the Hilton Tower Bridge. Please see the Venue section for a range of hotel recommendations (<http://events.iadsa.org>). We strongly advise you to book soon since London gets very busy in June.

**IADSA**

International Alliance of Dietary/  
Food Supplement Associations

# Regulatory news



## Indonesia

### Indonesia consults on revised procedures for Health Supplement Registration

Indonesia has launched a public consultation on draft regulations on criteria and administration of health supplements registration, which is a revision of the current Regulation No. HK 00.05.41.1381.

The proposed provisions include, among others, the definition of health supplements, the introduction of an electronic registration system, the registration stages, documentation required and timelines, detailed labelling information, stability requirements, rules on umbrella names.

Health supplement registration in Indonesia is under the responsibility of the National Agency for Drug and Food, known as BPOM.

## Thailand

### Thailand to expand its list of botanicals for supplement use

Thai FDA is revising its positive list of botanicals that can be used in health supplements. The current list containing around 80 plants will be expanded to approximately 250 raw plants by the end of year.

## China

### China announces revised draft Implementing Rules

CFDA has recently notified its 3rd version of the new Draft Regulations on the Implementation of Food Safety Law to WTO. This new proposal containing 98 articles compared to the 208 articles in the second draft appears to contain challenging provisions for health food companies.

The draft text covers among others, general principles, risk monitoring and assessment for food safety, food safety standards, food inspection, food

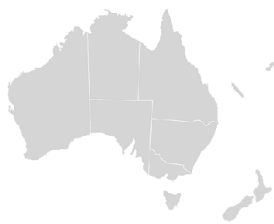
import and export and legal responsibility provisions. The final date for comments is 1 October 2017

### Information management System for Registration of Health Food

CFDA has recently published its new system of information management for the registration of health food covering new product registration, registration for the extension of certificates, registration for changes, registration for technology transfer, and for document supplementation for registration based upon the all new regulations. The new system came into effect on 1st August 2017. More information: <http://bjzc.zybh.gov.cn>

### Work plan to crack down on fraud and illegal claims

In a report recently released by China Consumers' Rights Association, the number of complaint reports from local consumers to the Association reached more than 250 000 in the first half this year, among these, 26 % of the cases were related to health food and mainly to the quality of the products and false claims. To address this issue, nine central government departments including Ministry of Commerce, CFDA, State Cyberspace Office and Ministry of Public Security co-released a work programme to tackle fraud and false claims in food including health food.



## New Zealand

### Manufacturers call for a stop to misinformation about natural health products bill

A group of manufacturers say they are frustrated with the amount of misinformation circulating about the Natural Health Products Bill. Most of the Bill's detractors are fighting against it because they claim that its regulations would prevent traditional and trained health practitioners from prescribing or making certain natural health products available. This is refuted by the manufacturers.

A survey in 2014 showed that the natural products industry makes an

estimated \$1.4 billion per annum contribution to the New Zealand's economy (up from an estimated \$1 billion five years ago). Around 85% of natural health product companies export and this is the primary area of growth for the industry.

[http://www.naturalhealthproducts.nz/wp-content/uploads/2016/05/NHP-Bill-call-for-informed-debate\\_June-2017.pdf](http://www.naturalhealthproducts.nz/wp-content/uploads/2016/05/NHP-Bill-call-for-informed-debate_June-2017.pdf)

### Update to Natural Health Product Bill draft Permitted Substances List published with Preferred Name for Substances

The updated draft list also includes substances that are not proposed to be included in a permitted substances list (marked with a 'No'), and those substances to be referred to an Expert Advisory Committee (marked as 'Pending'). The period for free submission of requests for substances not on this list closed on 31 March 2017.

## New Zealand & Australia

### Hemp seeds to be legalised as food

An agreement reached between New Zealand and Australian food safety authorities will see hemp seed legalised as food in Australia and New Zealand. In April 2017 ministers responsible for food regulation considered FSANZ's approval of a proposal to permit the sale of low-THC hemp seed foods. Ministers did not seek a review of the decision. This means the Food Standards Code has been amended to permit the sale of low THC hemp seed foods. The change will come into effect on 12 November 2017. Until then the sale of low-THC hemp products is not permitted in Australia and New Zealand. Hemp or industrial hemp is a cannabis plant species (*Cannabis sativa*). Hemp is cultivated in Australia and New Zealand (under strict licensing arrangements).

<https://www.beehive.govt.nz/release/hemp-seeds-be-legalised-food>  
<http://www.foodstandards.gov.au/consumer/generalissues/hemp/Pages/default.aspx>

## Australia

### TGA consults on the exposure draft Bills

The TGA is seeking comments from interested parties on the exposure draft Bills amending the Therapeutic Goods Act 1989 and the Therapeutic Goods (Charges) Act 1989. The amendments will primarily establish a scheme for the provisional approval of

new medicines, streamline and simplify the framework for advertising therapeutic goods to the public, enhance the regulation of complementary medicines; and strengthen monitoring and compliance provisions. The Charges Bill will enable annual charges to be levied for Australian conformity assessment bodies and for provisionally registered goods.

The final Bills are anticipated to be introduced to Parliament on 13 September 2017.

<https://www.tga.gov.au/consultation/consultation-exposure-drafts-2017>



## European Union

### No safety concern for tara gum, Kjonjac gum & konjac glucomannane

EFSA has published its opinions on the re-evaluations of Tara gum (E417), Konjac gum (E 425(i)) and Konjac glucomannane (E 425(ii)) in which it is confirmed that there no need for a numerical ADI for any of these additives. For both E417 and E425, the Authority has recommended the revision of the current limits for the toxic elements and the harmonisation of the microbiological specifications for polysaccharidic thickening agents.

### EFSA launches consultation on its updated draft guidance on health claims related to antioxidants, oxidative damage and cardiovascular health

The European Food Safety Authority has recently published its public consultation on the draft update of its guidance for the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health (revision 1).

The draft guidance is available here: <http://www.efsa.europa.eu/sites/default/files/engage/170712.pdf>

EFSA recalls that the 'document is intended to assist applicants in preparing applications for the authorisation of health claims related to the antioxidants, oxidative damage and cardiovascular health'.

Interested parties are invited to submit written comments to EFSA by 3 September 2017.

### Online supplement sales under the spotlight

The European Commission has issued a draft recommendation calling on control authorities to search and report on websites for offers of food supplements that claim to prevent, treat or cure bone and/ or joint diseases and those containing certain novel foods. Article 53 of Regulation (EC) No 882/2004 on official controls empowers the Commission to recommend coordinated plans on an ad hoc basis, in particular with a view to establishing the prevalence of hazards in feed, food or animals. This proposal sets the scene for the first time for an EU coordinated Control plan (CCP) for online food supplements sales. This CCP would take place during a defined timeframe, the current draft indicates 4-29 September 2017

### Two new minerals permitted for use in supplements

The European Commission has recently authorised two new mineral substances for use in the food supplements:

- organic silicon (monomethylsilanetriol), as source of silicium
- calcium phosphoryl oligosaccharides, as source of calcium

They can be used in supplements since the end of July.

### EFSA seeks data on sweeteners authorised as food additives in the EU

EFSA is looking for technical and toxicological information on sweeteners which includes information on the presence of impurities, microbiological specifications, nature and the range of percentage of the different components of the food additive. Toxicokinetics, studies on subchronic and chronic toxicity and carcinogenicity, reproductive and developmental toxicity and any other relevant studies are also required. This re-evaluation is based on a programme set up by Commission Regulation (EU) No 257/2010 for all food additives approved before 2009. EFSA has until 31 December 2020 to finalise this task.

<https://www.efsa.europa.eu/en/data/call/170621>

### Pectin & Amidated Pectin raise no safety concerns

While more information would be required to address the discrepancies between the data reported from industry and the Mintel database, EFSA has re-confirmed the safety of Pectin E 440i and Amidated Pectin E 440ii.

The conclusions of the Food Safety Authority have recently been published as part of the re-evaluation process of food additives. In its opinion, the Authority highlighted the need to lower the maximum limits for the impurities of toxic elements (arsenic, lead, mercury and cadmium) and set limits for Aluminium. Harmonising the microbiological specifications for polysaccharidic thickening agents, such as pectins, and including criteria for the absence of Salmonella spp. and Escherichia coli in the EU specifications for pectin (E 440i) and amidated pectin (E 440ii) was also recommended. Pectin and amidated pectin are allowed at *Quantum Satis* in food supplements in the EU.

### EFSA examines Pyrrolizidine alkaloid safety in supplements

Exposure to pyrrolizidine alkaloids (PA) in food, in particular for frequent and high consumers of tea and herbal infusions, is a possible long-term concern for human health due to their potential carcinogenicity, say EFSA's experts. According to EFSA, the consumption of food supplements based on pyrrolizidine alkaloid-producing plants could also result in exposure levels causing short-term toxicity resulting in adverse health effects. These conclusions will be taken into account by the Commission who is considering specific limits of PA for the supplement category.

### Xanthan Gum: No safety concern says EFSA

EFSA has confirmed the absence of safety concerns for Xanthan Gum (E 415). However, due to the discrepancies observed between the data reported from industry and the Mintel database, where xanthan gum is labelled in more products than in food categories for which data were reported from industry, more data on use levels will be needed to perform a more realistic exposure assessment. Xanthan gum is permitted for use in supplements at *Quantum Satis* with the restriction that the food additive may not be used to produce dehydrated foods intended to rehydrate on ingestion.

## Green light for prolyl oligopeptidase in food supplements

The Commission has cleared an enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger* for use in supplements. The novel food is authorised at a maximum dose of 120 Prolyl Peptidase Units or Proline Protease Units/day (2,7 g of enzyme preparation/day) ( $2 \times 10^6$  Protease Picomole International/day) for the general adult population.

## Novel Food: EFSA call for Member States collaboration on preparatory work

EFSA has launched a call for proposals for Member State collaboration on preparatory work related to the assessment of novel food (NF) ('GP/EFSA/NUTRI/2017/01 - Entrusting preparatory work for the safety assessment on Novel Foods and Traditional Foods from third countries').

This consultation is the result of discussions between Member States and EFSA to keep countries involved in novel food assessments, given the expertise they have built up over the years. EFSA has opened this call to select a number of Member States that will help EFSA in the preparatory phase of the assessments. The call is limited to those organisations that have been designated by the Member States for assisting EFSA with its mission (see <http://www.efsa.europa.eu/sites/default/files/assets/art36listg.pdf>).

The new NF regulation, which was adopted in November 2015, comes into effect in January 2018. It will introduce a centralised authorisation and assessment procedure with the European Food Safety Agency in charge of conducting the scientific risk assessment for the novel food applications received.

## Cranberry not to be considered as Medical Device

The European Commission has now officially confirmed that products containing proanthocyanidins (PAC) present in cranberry (*Vaccinium macrocarpon*) and presented to prevent or treat cystitis, cannot be registered as medical devices any longer. This follows an opinion of the European Medicines Agency on 22 July 2016 to the effect that the principal intended action of this group of products is achieved probably by pharmacological means since metabolites of PAC and other constituents of cranberry exhibit most probably a pharmacological activity

not a mechanical mode of action of PAC.

Cranberry food supplements can continue to be placed on the EU market, but unfortunately so far, no health claim has been approved.

## EU to address the safety of glutamic acid and glutamates

EFSA has published its opinion, in the framework of the additives re-evaluation safety assessments, on glutamic acid (E 620), sodium glutamate (E 621), potassium glutamate (E 622), calcium glutamate (E 623), ammonium glutamate (E 624) and magnesium glutamate (E 625) as food additives.

Based on the NOAEL of 3,200 mg monosodium glutamate/kg bw per day and applying the default uncertainty factor of 100, EFSA derived a group acceptable daily intake (ADI) of 30 mg/kg bw per day, expressed as glutamic acid, for glutamic acid and glutamates (E 620- 625).

EFSA noted that the exposure to glutamic acid and glutamates (E 620-625) exceeded not only the proposed ADI, but also doses associated with adverse effects in humans for some population groups.

The European Commission has therefore been asked to consider the revision of the maximum permitted levels, in particular, in food categories contributing the most to the overall exposure to glutamic acid and its salts: fine bakery wares, soups and broths, sauces, meat and meat products, seasoning and condiments and food supplements.

## EFSA publishes its scientific opinion on setting a DRV for Riboflavin

The document proposes dietary reference values for riboflavin for adults, infants and children, pregnant and lactating women.

For adults, the Average Requirement (AR) and Population Reference Intake (PRI) are set at 1.3 and 1.6 mg/day. For infants aged 7-11 months, an adequate intake of 0.4 mg/day is set by upward extrapolation from the riboflavin intake of exclusively breastfed infants aged 0-6 months. For children of both sexes aged 1-17 years, ARs range between 0.5 and 1.4 mg/day, and PRIs between 0.6 and 1.6 mg/day. For pregnant or lactating women, additional requirements are considered, to account for fetal uptake and riboflavin accretion in the placenta during pregnancy or the losses through

breast milk, and PRIs of 1.9 and 2.0 mg/day, respectively, are derived.

## EU to address occurrence of T2 & HT2 in food supplements

The EFSA Evidence Management (DATA) Unit has recently published a scientific report on human and animal dietary exposure to T-2 and HT-2 toxin. These toxins are trichothecenes, which form part of the group of fusarium mycotoxins. The background of this report is a European Commission request for EFSA to provide a chronic and acute animal and human exposure assessment of T-2 and HT-2 toxin. While Exposure comes mainly from cereal containing foods, very high levels were unexpectedly found in a small number of data related to specific plant extract food supplements. Most of these products were food supplements based on milk thistle reported only by the Czech Republic. In the elderly and very elderly, food supplements were also found to make an important contribution to exposure from these toxins. In addition to further collection of data and use of appropriate analytical methods, further research for the occurrence of T2 and HT2 in food supplements should be encouraged in order to evaluate a possible important exposure source from these products said EFSA.

## EFSA releases its guidance on weight of evidence and biological relevance

EFSA has recently published two cross-cutting guidance documents (one on weight of evidence and one on biological relevance). As reported by the Authority, 'these guidance have been developed as key methodological frameworks to improve the robustness, quality and transparency of the scientific assessments performed by EFSA's 10 sectoral scientific panels'.

## Italy

### Last step before the formal adoption of the BELFRIT list

Italy has notified its new plants decree to the European Commission. This is the last step in the formal adoption of the BELFRIT list (combined list from Belgium France and Italy) by the Italian Ministry of health.

In 2014, Italy modified its plants decree by including the BELFRIT list plants next to the Italian list in two annexes. The proposed decree is aiming at merging the two lists into one single permitted list. The proposed list will also include new provisions to

facilitate the proper use of botanicals in supplements.

## Poland

### Poland sets minimum levels for vitamin/mineral supplement

Poland has established minimum quantities of vitamins and minerals in food supplements.

Taking into consideration the definition of food supplements, which stipulates that they are foodstuff whose purpose is to supplement a normal diet and which are a concentrated source of vitamins or minerals or other substances with a nutritional or other physiological effect, the Polish authorities have decided to set a minimum quantity of 15% of reference intake values for vitamins and minerals.

Minimum quantities of vitamins and minerals have not been laid down by the European Union. In the absence of harmonised rules, national provisions apply.

## Norway

### Norway assesses copper and selenium supplement intakes

The Norwegian Scientific Committee for Food Safety (VKM) at the request of the Norwegian Food Safety Authority (Mattilsynet) has recently evaluated the intake of copper and Selenium in the Norwegian population.

Conclusions showed that adults and 13-year-olds with high copper intakes from regular foods (95th percentile) will exceed the ULs (5 mg/day) with supplemental copper at doses of 3 mg/day or higher. The existing maximum limit is 4 mg/day.

As for selenium, according to the scenario estimations in adults, a supplement intake of 150 mcg will be below the UL while a supplement intake of 200 mcg of selenium will imply that it exceeds the UL. In the assessment of selenium, VKM uses the tolerable upper intake level established by the SCF at 300 µg/day for adults. Today the maximum limit is 100 µg/day.

It remains to be seen how and by when the current Regulation on maximum levels could possibly be revised to reflect the latest conclusions of the Norwegian Scientific body.

### Isoflavones and L-aspartic acid raise potential safety concerns

In preparation for a possible regulation on the use of other substances in supplements, Norway has published three new opinions related to the safety of isoflavones from soy, L-aspartic acid and L-threonine.

Conclusions are concerning for the first two substances. According to the Norwegian Scientific Committee for Food Safety (VKM), isoflavones as supplements in doses of 40 or 80 mg/day taken for one to three months may represent a risk of negative effects on hormone levels in adolescents of both genders and/or menstrual function in adolescent women. These doses do not appear to have other significant negative effects on adolescents. With regard to L-aspartic acid, the intake of the amino acid in supplements at a minimum daily dose of 3000 mg may represent a risk of adverse health effects in adults, adolescents and children (from 10 years and above) said VKM. Favourable conclusions are however given for L-threonine in food supplements at doses between 1000 and 2400 mg/day. According to the authorities the intake of L-threonine at the specified levels are unlikely to cause adverse health effects.

41 other substances have already been assessed by Norway. The opinions can be found at the following link:

[http://www.english.vkm.no/eway/default.aspx?pid=278&trg=Content\\_6444&Main\\_6359=6582:0:31,2568&Content\\_6444=6393:2169160::0:6596:1:::0:0](http://www.english.vkm.no/eway/default.aspx?pid=278&trg=Content_6444&Main_6359=6582:0:31,2568&Content_6444=6393:2169160::0:6596:1:::0:0)



## Brazil

### Draft food supplement law triggers debate

The Brazilian Authorities ANVISA are currently discussing with the industry draft rules for the food supplement category for which there is no current dedicated legislation. The main objective is to provide greater certainty to both the authorities and companies.

While this development should be seen as a positive step, this draft may raise

a number of challenges if the proposal remains at it stands.

## Chile

### Restrictions to the use of health claims

Chile published its Technical Standard 191 on Guidance for the use of Health Claims in Foods through the Resolution N° 860, which modified the Resolution N° 764 of 2009. This new Resolution N° 860 restricts the use of health claims as follows:

- Bans the use of health claims in the category of food supplements and foods destined to children under 4 years old
- Bans the use of health claims in foods with medicinal presentations, such as powder, liquid, granulated, tablets, capsules, etc.

The Resolution will come into force in 6 months, meaning that by 26 January 2018 all the restrictions will be mandatory.

## Ecuador

### Proposal to update the labelling standards

INEN aims to update the INEN standards for general labelling (NTE INEN 1334-1) and nutritional labelling (NTE INEN 1334-2), and for that reason it has shared a draft which seeks to amend both standards:

- NTE INEN 1334-1 on General food labelling: the draft proposes to modify some wording
- NTE INEN 1334-1 on Nutritional labelling and claims. The draft proposes to group the specific requirements for each nutrient, modify some Nutrient Reference Values. For food supplements, only the amounts and the percentages of NRV-N according to Annex I of the proposal should be indicated. Requirements for the use of nutritional claims now included will impact those claims related to vitamins, minerals, proteins and fibre. Requirements for addition and fortification with vitamins and minerals were removed.

Comments will be received until 31 October of 2017



## United States

### Public meeting to discuss the development of a list of pre-DSHEA dietary ingredients

The FDA will hold a public meeting on 3 October to discuss the development of a list of pre-DSHEA dietary ingredients.

The purpose of the meeting is to give interested stakeholders an opportunity to discuss issues related to FDA's future development of such a list. In August 2016, FDA published a revised draft guidance for industry entitled, "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues." In this document, FDA stated their goal to compile an authoritative list of pre-October 15, 1994 dietary ingredients based on independent and verifiable data to be supplied by industry.

### FDA Releases Compliance Guide for Small Businesses under FSMA Intentional Adulteration Rule

The FDA announced the availability of a Small Entity Compliance Guide (SECGs) to help small businesses comply with the Final Rule on Mitigation Strategies to Protect Food Against Intentional Adulteration (or Intentional Adulteration Rule), mandated by FSMA. The SECG was prepared in accordance with the Small Business Regulatory Enforcement and Fairness Act. It provides nonbinding recommendations on such topics as developing a food defense plan and records management. The compliance date for small businesses under the Intentional Adulteration Rule is 27 July 2020.

### FDA Launches Food Safety Plan Builder to Help Businesses Comply with FSMA Requirement

To help businesses meet the requirements of the Food Safety Modernization Act (FSMA) Final Rule for Preventive Controls for Human

Food, the U.S. Food and Drug Administration is releasing a new software tool to help owners and operators of food facilities create a food safety plan specific to their facilities. The Food Safety Plan Builder (FSPB) is a free and optional software application, developed by FDA, that businesses can download from the FDA's website to guide them, step-by-step, through the creation of a food safety plan, as required by FSMA.

[https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm539791.htm?source=govdelivery&utm\\_medium=email&utm\\_source=govdelivery](https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm539791.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery)

### New qualified health claim Macadamia Nuts and the Risk of Coronary Heart Disease

After conducting a systematic review of the available scientific data, the U.S. Food and Drug Administration has confirmed that:

"Supportive but not conclusive research shows that eating 1.5 ounces per day of macadamia nuts, as part of a diet low in saturated fat and cholesterol and not resulting in increased intake of saturated fat or calories may reduce the risk of coronary heart disease. See nutrition information for fat [and calorie] content."

The qualified health claim is supported by scientific evidence, but does not meet the more rigorous "significant scientific agreement" standard required for an authorized FDA health claim. As such, the claim must be accompanied by a disclaimer or other qualifying language so that the level of scientific evidence supporting the claim is accurately communicated.

<https://www.fda.gov/food/newsevents/constentupdates/ucm568052.htm>

## Canada

### Health Canada Updates Site License Holders List

Health Canada has recently updated its lists of manufacturers and importers of natural health products. The lists are updated on a periodic basis and can be found at the following link:

<https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/applications-submissions/site-licensing/list-site-licence-holders.html>



## Kazakhstan

### Kazakhstan to introduce new advertising rules

The Kazakh parliament in June approved in the first hearing a draft law on amending certain legislative acts with regard to advertising. For the first time in the country's history, the bill identifies the National Economics Ministry as the authorised agency and the ministries of information and communications, investment and development, interior, and of healthcare as the regulatory agencies for the advertising market.

The authorised agency will be responsible for overseeing and coordinating advertising issues among relevant industries, and also for adopting standards for outdoor advertisements. The regulatory agencies will be supervising individual industries involved in the advertising process (including medicines, dietary supplements, and medical equipment).

The document introduces the notion of ambient media, which includes all structures and other media that can be used for the placing and distribution of advertisements. The bill differentiates between ambient media and advertising itself. Outdoor advertisements will be regulated by the law on advertising and by the rules governing the placing of such advertisements. Ambient media will be regulated by the Land Code and by the laws on urban development, architectural and construction activities, on motorways and on road safety.

The bill introduces administrative penalties for breaching the legislation on advertising, including for stating prices other than in the national currency.

**IADSA**

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# Focus on nutrient values on supplement labels

NRV-R

? What does NRV-R stand for

NRVs-R refer to Nutrient Reference Values (NRVs) that are based on levels of nutrients associated with nutrient requirements. The NRVs-R are based on Individual Nutrient Level 98 (INL 98 - see below). NRVs - R set by the Codex Alimentarius Commission are based on the widest applicable age range for adult males and females. The values for pregnant and lactating women are excluded.

? How does INL98 mean

The Individual Nutrient Level (INL98) is designed to meet the nutrient requirements of most of (98 percent) the apparently healthy individuals in a specific life stage and gender group. It is generally based on the Average Nutrient Requirements (ANR) plus 2-Standard Deviations (SD) of the ANR if the distribution of requirements is a normal distribution.

? What are the other terminologies for INL98 & ANR

Individual Nutrient Level (INL98) is used as the generic term. Different countries may use other terminologies : for example, Recommended Dietary Allowance (RDA), Reference Nutrient Intake (RNI), Population Reference Intake (PRI).

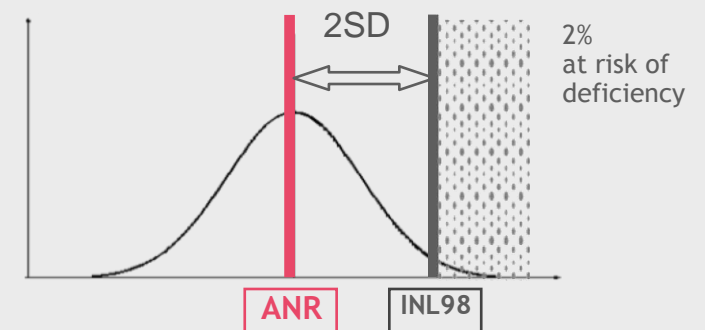
Average Nutrient Requirement (ANR) is also used as the generic term. Different countries may use other terminologies, for example, Estimated Average Requirement (EAR), Average Requirement (AR).

?

Why NRVs-R are important

NRVs are designed to provide a quantitative basis for comparing the nutritive values of foods/ food supplements, helping to illustrate how specific foods fit into the overall diet.

NRVs-R are used in nutrition labelling. Current NRVs-R are also included in the Codex Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55-2005) and the Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23- 1997, Rev. 1-2004) as a basis for criteria for nutrition and health claims.



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

$$\text{INL98} = \text{ANR} + 2 \text{SD}$$

### Development of Codex NRVs

**1985** | Adoption of Codex Guidelines on Nutrition Labelling. Numerical information on nutrients may be expressed as a proportion of “Reference RDAs”. The Reference RDAs were described as being based primarily on a single group of consumers.

**1988** | Joint FAO/WHO Expert Consultation in Helsinki. Codex Reference RDAs replaced by “Nutrient Reference Values (NRVs)”. NRVs set for 9 vitamins (A, D, C, thiamin, riboflavin, niacin, B6, folic acid, and B12), 5 minerals (Calcium, Magnesium, Iron, Zinc, Iodine) and protein.

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### Setting Codex NRV-R: Progress so far and revisions

#### Minerals

- Calcium (mg) 800 [1993] to 1,000 [2013]
- Magnesium (mg) 300 [1993] 310 [2016]
- Iron (mg) 14 [1993] to 14 (15% dietary absorption) & 22 (10% dietary absorption) [2016]
- Zinc (mg) 15 [1993] to 11 (30% dietary absorption) & 14 (22% dietary absorption) [2015]
- Iodine (µg) 150 [2013]
- Copper (µg) 900 [2016]
- Selenium (µg) 60 [2015]
- Manganese (mg) 3 [2015]
- Molybdenum (µg) 45 [2015]
- Phosphorus (mg) 700 [2016]
- Fluoride: Agreed to be established [2015]
- Chromium /Chloride: not foreseen due to limited scientific information [2016]

#### Vitamins

- Vitamin A (µg) 800 [1993]
- Vitamin D (µg) 5 [1993] to 5-15 [2017]\*
- Vitamin C (µg) 60 [1993] to 100 [2015]
- Vitamin K (µg) 60 [2013]
- Thiamin (mg) 1.4 [1993] to 1.2 [2013]
- Riboflavin (mg) 1.6 [1993] to 1.2 [2013]
- Niacin (mg NE) 18 [1993] to 15 [2013]
- Vitamin B6 (mg) 2 [1993] to 1.3 [2013]
- Folate (µg DFE) 200 [1993] to 400 [2013]
- Folic acid (µg) 200 [1993]
- Vitamin B12 (µg) 1 [1993] to 2.4 [2013]
- Pantothenate (mg) 5 [2013]
- Biotin (µg) 30 [2013]
- Vitamin E (mg) 9 [2016/2017]

\* up to 15 minimal sunlight exposure