Talking to the Scientific Community

Over the years, considerable time and energy has been spent by many in the sector to educate the regulators who write the legislation on food supplements: definitions, the category, safety, GMP, labelling, claims etc. This investment has clearly been both important and effective in many countries as we see a slowly increasing support for our category, or at least a reduction in negativity.

Investment has also been made in educating the scientific community. However, many factors make this challenging:

- The sheer diversity and numbers of scientists involved.

- The sensitivity of many scientists about talking to industry or allowing them to speak at their meetings.

- Entrenched negative perceptions about supplementation.

- The widely held belief that food can meet the nutrition requirements of individuals and supplementation brings no value.

At the International Congress of Nutrition in Buenos Aires in October, the size of the challenge ahead was clear. This event brings together representatives of the world's nutrition societies for a once-every-four years nutrition week. While so much scientific information was presented that clearly makes supplementation compelling, supplementation was not often presented as a delivery form. It was not identified as the solution, even if it was the only viable way of providing the optimum or effective level of the ingredient(s).

The IADSA-sponsored session was the first supplement-focused event to take place at ICN. The goals were modest: indicating that the supplement sector is structured, regulated and serious and that we may have a role to play in nutrition and health policy.

As could be expected, the debate was mixed, but provided some interesting perspectives on future cooperation with the scientific community.

As a sector, we invest considerably in science around product safety, claims and ingredient/product approval. This is vital to obtain market access and protect that. But in many countries, it is the national, and sometimes regional nutrition societies, that are key to defining policy. Few, if any, governments are prepared to go against the views of their nutrition community.

Over the past decade, the engagement of supplement companies in the work of nutrition societies has increased. While it was only major conventional food companies who were heavily engaged a few years back, supplement companies are now partnering on projects and supporting activities.

However, there is still a long way from the type of engagement that we have today with governments. If we are to shape policy, this will need to change.

The ICN has established itself as a platform as much to drive policy as science from within the nutrition community. It therefore provides a unique role and platform for discussion. The potential of ICN is significant, but only if partnership is also underway at the national and regional level led by associations and companies. The opposition to working with the supplement sector may sometimes be intense, but we have faced such opposition many times before from regulatory bodies, and overcome it.

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

IADSA
International Alliance of Dietary/ Food Supplement Associations

Regulatory news

ASEAN

Finalisation of the agreement delayed to April 2019

The October meeting of the Traditional Medicine Health Supplement Product Working Group of ASEAN made some moves forward on many practical aspects of the implementation of the regulatory framework, particularly related to the range of training programmes now underway.

However a further delay related to the finalisation of the Agreement is foreseen. This relates to a point regarding the Dispute Settlement Mechanism which is under discussion at a high level in the ASEAN Senior Economic Officials Meeting (SEOM) and on which not all Member States are agreed.

Next steps are:
• 15 April 2018: Indonesia to provide their updated position on the dispute mechanism issue, after reviewing progress in the relevant ASEAN meetings.

• May 2018: Legal scrubbing of the Agreement.

• July 2018: Finalisation / Endorsement of the Agreement by the Product Working Group

• Aug 18 - Jan 19: National approval procedures as required.

• February 2019: Endorsement by ACCSQ (group above the PWG in the ASEAN hierarchy)

• March 2019: Endorsement by SEOM (group with broad responsibility for the ASEAN Economic Market)

• April 2019: Signing by ASEAN Economic Ministers

• until May 2024: Member States to deposit instruments of ratification/notification/acceptance to the ASEAN Secretariat.

China

New provisions about excipients for Health Food notification/filling

China FDA announced in September detailed provisions for the use of food flavouring in solid and liquid preparations, the usage of coating premix agents and the usage of excipients in the preparation process of embedded and microencapsulated raw materials.

More information at the following link: http://bjba.zybh.gov.cn/#

Tender Notice on health food raw material /health function directory

So as to carry out the revision plan of health food raw material directory and health function directory, the China FDA have issued a tender notice. Interested parties had until 24 October to participate.

The research aims to evaluate the current methods, revise the evaluation methods and criteria, clarify the functional interpretation, and establish a list of health function information for 10 of the 27 health functions, namely: Antioxidative Alleviating eye fatigue; facilitating faeces excretion; assisting memory improvement; weight control; assisting the protection against chemical injury of liver; improving child growth; eliminating skin chloasma; facilitating digestion; increasing bone density.

Regarding the heath food raw material directory, 26 raw materials in total are planned to be studied: Hippophae rhamnoides L. (oil), Ginseng Radix ET rhizome (Ginseng Radix ET rhizome rubra), Panacis quinauefolii radix, Gastrodiae rhizoma, Notoginseng radix ET rhizoma, Ganoderma, Ganoderma spore powder, Lycii fructus, Spirulina, Ginkgo folium (extract), Carthami flos, Astragali radix, Dendrobii caulis, Rhodiolae crenulatae radix ET rhizoma, Fish oil, Seal oil, Cod liver oil, Garlic oil, Bovine colostrum, Royal jelly, hytosterols (Phytosterol esters), Lycopene, Coenzyme Q10, Melatonin + Vitamin B6, Squalene, Cistanches herba.

Results of this research are expected in 2019.

Positive changes foreseen in the management of Health Food

CFDA has recently published the draft amendment of Administrative Measures for Registration and Notification of Health Food and justifications. Under the proposed rules the main responsibilities for technical evaluation and approval of health food registration would be changed from the experts designated by the Evaluation Center to the Center directly, the application for extension period of validity (renewal) of registration (certificate) would need to be submitted 6 months before the expiry date according to the current requirements. It would allow an application to be submitted for renewal after 6 months, but it would not allow production of the product before re-obtaining the approval. The Evaluation Center would make its decision directly on the approval for changes or renewal of registration in the name of CFDA.

e-Commerce import: Transition period extended

The transition period for supervision of cross border e-commerce retail import has been prolonged for one more year, from the end of 2017 to the end of 2018. The supervision of cross-border e-commerce retail imports was originally offered a period of transition which was scheduled to end in May 2016. Online shopping bonded goods entering the bonded zones in these eligible cities will be exempted from checks of their Customs Clearance Certificates. Import permits, registration or filing will not be required for first-time imported cosmetics, baby formula, medical equipment and special food products (including health food products and food for special medical purposes).

India

FSSAI Letter on illegal products made from hemp and hemp seeds

The Food Safety and Standards Authority of India (FSSAI) has recently warned in its letter of 17 October companies about selling on the e-platform (eg Amazon) products made from hemp and hemp seeds using their FSSAI License number on their product labels.

FSSAI recalled that no Standards have been prescribed for Hemp and Hemp products under the Food Safety and Standards Act 200, this due to a t lack of data and information on the variety of the plant to be used in the manufacturing process to allow a

detailed risk assessment.

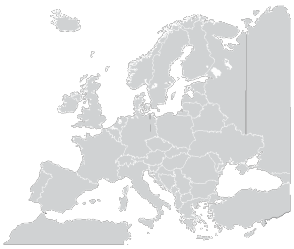
More information
http://fssai.gov.in/dam/jcr:b4d5fb0b-a32a-47cb-aaa9-4866dc04e80b/Letter_Hemp_Seeds_18_10_2017.pdf

Australia

Pilot phase for new health claims to be launched in 2018

Supplement firms wanting to make Australia's new higher-level health claims will be able to register their interest by the end of this year. To qualify to make such claims, products must be supported by rigorous scientific evidence, and tested by the TGA for efficacy. A pilot phase will be launched in 2018 and there will be full implementation in 2019.

General Regulations to the Medicines and Related Substances Act, 101 of 1965 (Regulations, 2017) were published on 25 August 2017



European Union

EU to slash glycidyl esters limits

The European Commission has launched a four-week public consultation on a draft Regulation as regards maximum levels of glycidyl fatty acid esters in vegetable oils and fats. A maximum level of 1000 µg/kg is proposed to any vegetable oil or fat used as an ingredient in foods including food supplements to be placed on the EU market.

The decision followed the recommendations of the European Food Safety Authority whose opinion of May 2016 revealed that the levels of contamination was highest in refined vegetable oils and fats and highlighted the genotoxic and carcinogenic potential of glycidol.

EU to tweak its nanomaterial definition

The European Commission's DG environment published mid-September its roadmap concerning the review of the EU definition of nanomaterials, under the feedback mechanism that allows interested stakeholders to comment on its initiative within 4 weeks.

A definition of nanomaterials is currently provided in the 2011 Recommendation No 2011/696 that foresaw a review of the definition 3 years after its adoption. Currently, the definition provides that a nanomaterial is 'A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm'.

While there is a general consensus on the main elements of the current definition (notably focussed on particles size), there has been debate as to how the threshold is expressed (number concentration or mass), threshold value (e.g. 50% or less), the use of particle size as the only factor to define the nano- aspect.

The revision of the definition is expected in in Q1 2018.

EFSA to seek confirmation on the use of starch aluminium octenyl succinate (E 1452) in food supplements

EFSA has now published the re-evaluation of oxidised starch (E 1404), monostarch phosphate (E 1410), distarch phosphate (E 1412), phosphated distarch phosphate (E 1413), acetylated distarch phosphate (E 1414), acetylated starch (E 1420), acetylated distarch adipate (E 1422), hydroxypropyl starch (E 1440), hydroxypropyl distarch phosphate (E 1442), starch sodium octenyl succinate (E 1450), acetylated oxidised starch (E 1451) and starch aluminium octenyl succinate (E 1452) as food additives.

While the European Food Safety Authority concluded that there was no safety concern for the use of modified starches as food additives for the reported uses and use levels and that there is no need for a numerical ADI, the Authority provided specific recommendations for specific population groups and specific issues including the need to seek confirmation on the actual use of E1452 in food supplements (only vitamin preparations for encapsulation purposes).

The EFSA opinion is available at:
http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4911/epdf

EFSA green light for Ecklonia cava phlorotannins used a novel supplement ingredients

The European Food Safety Authority advised that use of up to 265 mg a day in adults of Ecklonia cava would not cause safety concerns. Ecklonia cava is an edible marine brown alga species with a long tradition of food use in a number of Asian countries. The Novel Food is an alcohol extract rich in phlorotannins (90.5%). Phlorotannins are polyphenolic compounds found as secondary metabolites in certain brown algae species.

The request was originally submitted to the Irish authorities in 2015. On 4 April 2016, the Irish authorities concluded that an additional assessment was required and their initial report was forwarded to the Commission.

The EFSA opinion is available at:
http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.5003/epdf

EFSA clears Hoodia parviflora as novel supplement but at a much lower level

Following a request from the European Commission, the European Food Safety Authority (EFSA) was asked to deliver a scientific opinion on dried aerial parts of Hoodia parviflora as a novel food (NF).

Hoodia parviflora has successfully received the green light of EFSA but at a much lower level: 9.4 mg in adults instead of the 40 mg/day requested by the applicant. EFSA also flagged up the safety of Hoodia parviflora as a food ingredient highlighting that the intake of 15 mg/serving sought by the applicant would exceed intake levels considered safe in humans.

More information
http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.5002/epdf

Member States back up the use of N-acetyl-D-neuraminic acid (NANA) in supplements

Member States have given backing to a draft implementing decision to authorise the used N-acetyl-d-

neuraminic acid (NANA) as a novel food (NF) for a wide range of foodstuffs. For food supplements a maximum daily use level of 300 mg for individuals above 10 years.

NANA is naturally present in human milk, in a bound and free form. The EFSA opinion available at: http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4918/epdf

EFSA positive opinion on use of 1-MNA (methylnicotinamide chloride) as novel food in FS

EFSA has agreed the use in food supplements of novel Food 1-MNA (methylnicotinamide chloride) at a level up to 58 mg/day as requested by the applicant.

The opinion can be found at the following location: http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.5001/full

Adoption of the safety of hydroxyanthracene derivatives and green tea catechins postponed

EFSA has announced at its meeting in September that more time would be needed to finalise the assessment of the two opinions. A request for an extension of the deadline will be sent to the European Commission for green tea while a possible adoption of the opinions on the safety of hydroxyanthracene derivatives could possibly be adopted during the next meeting on 22-23 November in Parma.

EFSA seek data on monacolin K

The European Food Safety Authority has launched a public call for data in order to acquire documented information on monacolins in red yeast rice, with a specific focus on monacolin K.

In March, EFSA was mandated to review the safety of the ingredient in the context of the so-called Article 8 of Regulation 1925/2011 which allows the European Commission to either prohibit ingredients, permit them under of use or put under scrutiny ingredients that represent a potential risk to consumers.

Concerns on the use of monacolin K in supplements have been raised by several Member States over the last years including Belgium, France, Germany the Netherlands.

High values of perchlorate reported for food supplements

EFSA has published a scientific report relating to dietary exposure assessment to perchlorate in the European population. Perchlorate is known to be an environmental food contaminant particularly in fruits and vegetables.

Although a few results with relatively high values were reported for food supplements, these are not considered important contributors to exposure.

Nevertheless, relatively high occurrence values were found in dried products, such as tea and herbs for infusion (324 ug/kg) and herbs, spices and condiments (63 ug/kg), along with some fresh vegetables, like radishes (117 ug/kg), rocket (75 ug/kg) and spinach (fresh) (132 ug/kg). In general, vegetable and vegetable products, milk and dairy products and fruit and fruit products were found to be important contributors to exposure across all population groups and teas and herbal infusion (beverage) in adults.

In 2014, EFSA established a TDI for perchlorate at 0.3 µg/kg body weight per day. The current exposure assessment seems to confirm that intake in the general population is below that TDI, although P95 intakes are higher and also intake in certain infant, toddlers and young children may be above this TDI. It is not foreseen that EFSA will update this 2014 scientific opinion.

In 2015 the Commission adopted guidance levels for enforcement (including for dried tea and herbal and fruit infusions). On the basis of this exposure assessment the Commission may now move to put these levels in legislation.

Belgium

Belgium revises its levels of vitamin and minerals as EU harmonisation still pending

The Belgium Royal Decree on Food Supplement amending the 1992 Decree notably regarding maximum levels for Vitamins and Minerals has now been published.

These new levels are based on the opinion of the Superior Health Council of September 2016.

Denmark

Denmark to give more responsibility to food supplement companies

The Danish Food Safety Authority is intending to amend its current food supplement legislation, in particular the approach on maximum levels for vitamins and minerals to take account of current scientific knowledge.

The authority is proposing to: 1) delete from the legislation itself the current maximum levels for vitamins and minerals in food supplements (adults and children from 11 years of age) and provide in a separate document updated guidance values. This means that it will be the producers' responsibility to ensure that the food supplements on the market are safe. 2) delete the minimum levels of vitamins and minerals in food supplements (adults and children from 11 years of age). 3) set up a simplified notification for food supplements.

The updated legislation would apply from 1 January 2018 but a transition period is foreseen so that food supplements can be produced and labelled according to the current legislation until 1 January 2020 and sold until stock is exhausted.

Italy

Labelling of production facilities become mandatory

Italy has recently adopted its contested law requiring companies to indicate on the label the name and address of the production facility. The new requirements will, according to the Italian Authorities, help provide complete and accurate information to consumers, ensure better and immediate traceability of foods by the supervisory authorities and therefore better health protection.

The law applies from April 2018 and stocks already produced can continue to be sold. The law also specifies the fines for not complying with the law (2,000-15,000 Euro).

http://www.gazzettaufficiale.it/eli/gu/2017/10/07/235/sg/pdf

Norway

Mattilsynet to assess the safety of liquorice

The Norwegian Food Safety Authority (Mattilsynet) has requested the Scientific Committee for Food Safety

(VKM) to evaluate the safety of glycyrrhizin from the liquorice root plant in response to several Finnish studies which show long-term adverse effects on the child as a result of high consumption of liquorice during pregnancy.

In order to describe the dietary recommendation further and to have a scientific basis for assessing if other measures are necessary, Mattilsynet has requested VKM to identify and characterize potential adverse effects to the foetus and long-term effects to the child that can result from maternal consumption of glycyrrhizin from licorice.

In the meantime, the Norwegian Food Safety Authority is advisong pregnant women against eating large amounts of liquorice.

The Finnish authorities already recommend that pregnant women should avoid large consumption of liquorice confectionery. Likewise, the Norwegian Food Safety Authority advises pregnant women against eating large amounts of liquorice.

The opinion of VKM is envisaged to be published in May 2018.

The official request of Mattilsynet to VKM is available at: https://www.vkm.no/download/18.53b03efd15ecf6f80a3d301d/1507709598005/Bestilling%20inntak%20av%20glycyrrhizinzyre%20i%20lakris.pdf

Norway finalises the safety assessment of so-called 44 other substances

The Norwegian Scientific Committee for Food Safety (VKM) has now finalised the assessment of the health risk of 44 substances in food supplements and energy drinks.

This work is aimed to be used to regulate the addition of “other substances” to food supplements and other foods at a national level.

The latest opinions released include Beta-alanine, Lecitine and L-alanine.

Sweden

Sweden challenges the use of botanical on-hold claims

The Swedish consumer agency has initiated a case against a company over the use of a health claim on a supplement product containing botanicals currently on the ‘on-hold'-list. The agency claims that the company has failed to show scientific evidence to support the claims being made.

The Swedish consumer agency has asked the Swedish court to refer the case to European Court of Justice for a preliminary ruling on the interpretation of article 28.5 of the Health Claims Regulation (Regulation 1924/2006) regarding claims made on botanicals. Article 28.5 currently provides for a transition period for the use of article 13.1 claims (generic claims) under the responsibility of the manufacturer (and in compliance with the general provisions of the claims Regulation and national provisions that may exist), until an EU list is adopted.

United Kingdom

UK consults on an application for a new galacto-oligosaccharides product

The UK Advisory Committee on Novel Foods and Processes (ACNFP) has launched a consultation on a novel food application for a new galacto-oligosaccharides-product (Vivinal® GOS PT) produced by FrieslandCampina Domo, derived from lactose and applying a ß-galactosidase enzyme isolated from Papiliotrema terrestris.

The non-confidential version of the submission to the UK Food Standards Agency requesting consideration of Substantial Equivalence is available here: https://acnfp.food.gov.uk/sites/default/files/gos.pdf

The intended uses for Vivinal® GOS PT as proposed by the applicant are very diverse and include use in food supplements.

Argentina

Online import procedures in place

From 6 November, all applications have to be made only through the TAD Platform (Trámites a Distancia), an online procedure for the registration of imported food products, including food supplements. The online procedure, applies to both domestic and import companies.

Argentina approves Regulation for allergens labelling

Argentina has issued a regulation for the mandatory declaration of allergens on the label of food products, including food supplements. The declaration must be done with the following expressions:
“CONTAINS…” or “CONTAINS DERIVATIVES OF…” or “CONTAINS… AND DERIVATIVES OF…”
-In case of cross-contamination: “CAN CONTAIN…” or “CAN CONTAIN DERIVATIVES OF…” or “CAN CONTAIN… AND DERIVATIVES OF…”.
The following substances shall be declared: Wheat, rye, barley, oats and its derivatives; Crustacean and its derivatives, Egg and its products, Fish and its derivatives, Peanut and its derivatives, Soybean and its derivatives, Milk and its derivatives, Treenuts and its derivatives (almonds, hazelnuts, chestnuts, cashew nuts, Brazil nuts, nuts, walnut pecan and pistachios), Sulfur dioxide and sulphite in concentration equal or higher than 10ppm.

The Resolution will come into force in 12 months, meaning that by 9 October 2018 all the labels must be in compliance with the regulation.

Dominican Republic

Draft regulation for food

Dominican Republic has proposed a new draft for a Sanitary Regulation of Foods, which seeks to unify sanitary requirements under one single regulation. The proposal defines food supplements as “products incorporated to the diet with the intention of maintaining or improving health, or preserving it, through all the physiological stages” that can contain nutrients, mix of nutrients or other components naturally present in foods, such as vitamins, minerals, amino acids, fats, carbohydrates, proteins, and dietary fibre. It can be presented in different forms: powder, liquid, granulated, pills, capsules, tablets and other medicinal forms. It foresees also the use of health and nutrition claims, along with other labelling requirements. Maximum levels for vitamins and minerals will be established by the Ministry of Health as a next step. Comments will be received by the Ministry until 1 December 2017.

United Sates

Dietary Supplement Usage Increases

The latest results from an annual survey on dietary supplements reveals an all-time high for supplement usage among US adults, with 76 percent reporting they consume dietary supplements, up five percentage points from last year's results. The new survey, 2017 CRN Consumer Survey on Dietary Supplements, was commissioned by the Council for Responsible Nutrition (CRN) and conducted by Ipsos Public Affairs. The survey also found that nearly nine in ten (87 percent) U.S. adults have confidence in the safety, quality and effectiveness of dietary supplements overall. Additionally, 76 percent of US adults perceive the dietary supplement industry as trustworthy, up three percentage points from last year.

New Bill to make supplements leigible under SNAP benefits

Four members of Congress have recently introduced a bill to make multivitamins eligible for purchase using benefits appropriated by the Supplemental Nutrition Assistance Program (SNAP). The SNAP Vitamin and Mineral Improvement Act of 2017 (H.R. 3841) defines a multivitamin-mineral dietary supplement as "a substance that provides at least half of the vitamins and minerals for which the National Academy of Medicine establishes dietary reference intakes, at 50% or more of the daily value … as determined by the Food and Drug Administration; and does not exceed the tolerable upper intake levels for those nutrients for which an established tolerable upper intake level is determined by the National Academy of Medicine."

IADSA

International Alliance of Dietary/ Food Supplement Associations

South Africa

Regulations published

The long-awaited General Regulations for Medicines and Related Substances Act, 101 of 1965 (Regulations, 2017) were published in August 2017. The cost of compliance is foreseen to be onerous, particularly with regard to licensing and responsible pharmacist requirements.

Saoudi Arabia

Saoudi Arabia consults on Technical Regulation for Food Supplements

Saudi Arabia has notified a draft Technical Regulation entitled Food Supplements on the behalf of the Cooperation Council for the Arab States of the Gulf.

This draft regulation applies to food supplements marketed as food products and presented as such which marketed to the final consumer. But the regulation does not apply to any medical products.

The Regulation is based on:
Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements.
Codex standard CAC/GL 55-2005 Guidelines for Vitamin and Mineral Food Supplements

Russia

Inspection control of registered food supplements in Russia

The Eurasian Economic Commission's (EEC) Consultative Committee has made a decision at its session to slightly amend the draft standard compliance assessment models. The latest version of the document contains revised conformity assessment types: certification, declaration and registration. In particular, a new third procedure was introduced for the registration of food, including food supplements, information about which has already been entered into the uniform register of state registrations and which requires no laboratory tests. An important element of the compliance assessment procedure will come in the form of inspections of registered food, including supplements. For registered supplements, the authorised agency will be conducting inspections with the prior agreement of the applicant at least once every two years. Samples will be taken from the warehouse of the manufacturer or importer. Registration certificates will now be valid for the entire period during which a product continues to be manufactured or imported into the EAEU, depending on the best-before date established by the manufacturer. However, the draft document calls for a restriction to one year of the validity of the product test protocol issued as part of the state registration procedure.

Ukraine

Harmonisation of health claims legislation with EU

The Ukrainian Health Ministry has published on its website two documents for discussion:

- Draft decree on the list of health claims permitted for use on food labels and in advertisements for foods, with the exception of those relating to reduced risk of disease and to children's development and health.

- Draft decree on requirements for nutrient content claims, complete with a list of nutrient content claims and their terms of use. On adopting hygienic requirements for dietary supplements (2013) and the decree on adopting hygienic requirements for baby foods, safety requirements and selected parameters of their quality (2013).The documents come as a logical step on the way to harmonising Ukrainian laws with EU legislation on food safety. For now the draft decrees however omit health claims related to reduced risk of disease and children's development and health (embraced in the EU legislation).

FOCUS ON CODEX GUIDELINES FOR NUTRITION AND HEALTH CLAIMS

There are two Codex Guidelines providing general guidance for the use of claims in food products. These are the General Guidelines on Claims (CAC/GL 1-1979) and the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997). Both of these Guidelines were drafted by the Codex Committee on Food Labelling (CCFL), with the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) being asked to establish conditions for the use of claims.

PROCESS FOR THE SUBSTANTIATION OF HEALTH CLAIMS

CODEX RECOMMENDATIONS

Identify the proposed relationship between the food and the health effect

⇩

Identify appropriate measurements for the food and for the health effect

⇩

Identify and categorize all relevant scientific data

⇩

Assess the quality of and interpret each relevant scientific study;

⇩

Evaluate the totality of the available relevant scientific data, weigh the evidence across studies and determine, if and under what circumstances, a claimed relationship is substantiated.

CRITERIA FOR THE SUBSTANTIATION OF HEALTH CLAIMS

The Codex recommendations suggest the following criteria that are applicable to all types of health claims:

Health claims should be primarily based upon well-designed human intervention studies. Human observational studies may contribute to the totality of evidence. Animal studies, ex vivo or in vitro data may provide supporting knowledge.

The totality of the evidence, including both published and unpublished data should be identified and reviewed.

Evidence based on human studies should demonstrate a consistent association between the food and the health effect.

Although a high quality of scientific evidence should always be maintained, substantiation might also take into account specific situations such as:

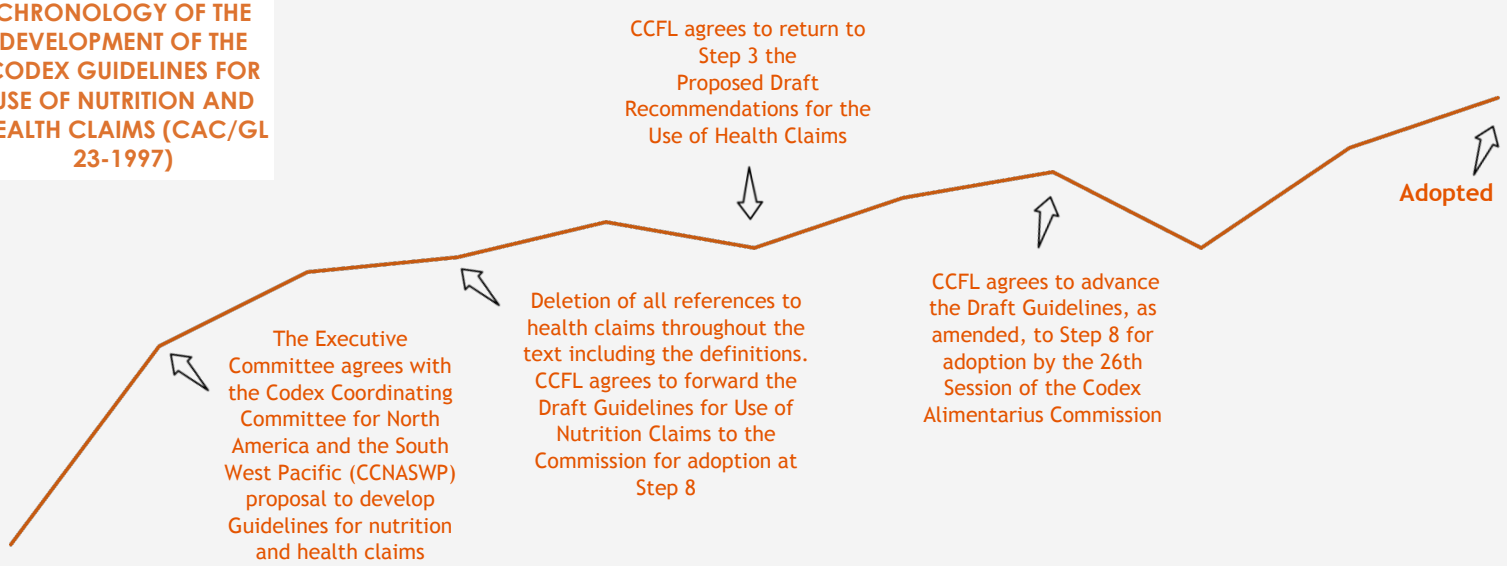
'Nutrient function' claims may be substantiated based on generally accepted authoritative statements by recognized expert scientific bodies that have been verified and validated over time.

Some health claims may be substantiated based on observational evidence such as epidemiological studies.

Evidence-based dietary guidelines and authoritative statements meeting the same scientific standards may also be used.

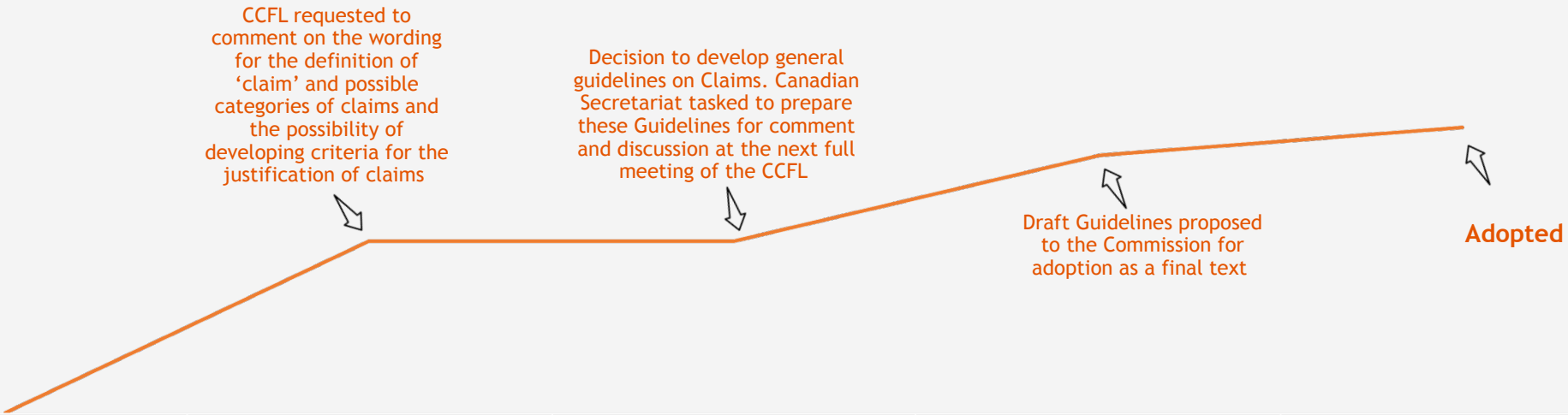
CODEX GUIDELINES FOR NUTRITION AND HEALTH CLAIMS

CHRONOLOGY OF THE DEVELOPMENT OF THE CODEX GUIDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS (CAC/GL 23-1997)



1989	1990	1995	1996	1997	1999	2001	2003	2004	2006	2009
Concerns raised on divergence of national regulations	CCNASWP proposes to develop a uniform policy concerning the use of nutrition and health claims / Request to elaborate Guidelines	Discussion on issues including provisions for nutrient function claims and health claims and the criteria for comparative claims. General consensus on the prohibition of medicinal claims, relating to the cure, treatment or prevention of illness.	Consensus to exclude claims relating to the prevention, cure and treatment of disease and adverse health-related condition. No agreement on other health claims - should be removed from the Guidelines at this stage.	Codex Alimentarius Commission adopts the Guidelines for Use of Nutrition Claims (including Part A of the Table) at Step 8.	Norway reiterates their position that health claims should not be permitted, as they are misleading for consumers, and that only a balanced diet would provide health benefits.	The 'Proposed Draft recommendations for the use of health claims' is incorporated into the 'Guidelines for Use of Nutrition Claims'. Agreement on the possibility of developing criteria on the scientific basis of health claims.	CCFL considers the draft section by section and makes amendments throughout the text.	The Commission returns the Draft Guidelines to Step 6 - no consensus especially, as to the inclusion of "advertising" in paragraph 1.1.	Codex Alimentarius Commission adopts the inclusion of the definition to the Guidelines for Use of Nutrition and Health Claims.	Codex Alimentarius Commission adopts the recommendations on the Scientific Basis of Health Claims - Annex to the Guidelines for Use of Nutrition and Health Claims.

CHRONOLOGY OF KEY DEVELOPMENTS RELATING TO CODEX GENERAL GUIDELINES ON CLAIMS



Late 60s early 70s	1972	1974	1978	1979
In depth discussions about the use of claims while developing the General Standard for the Labelling of Pre-packaged Foods.	Agreement on the need to "define what was meant by a claim" and also to "define certain specific categories" such as dietetic and therapeutic claims.	No agreement reached as to whether it would be possible to revise the corresponding section of the General Standard for the Labelling of Pre-packaged Foods in order to include the questions of claims.	Discussion on the draft General Guidelines on Claims. Agreement to include provisions on the general definition, restrictions on claims, prohibited claims, and restricted general claims.	Codex Alimentarius Commission adopts the Codex General Guidelines on Claims. Guidelines subsequently revised in 1991 and then only amended again in 2009

CODEX GENERAL GUIDELINES ON CLAIMS (CAC/GL 1-1979)

The current version consists of 5 sections on the Scope and General Principles, Definition, Prohibited Claims, Potentially Misleading Claims, and Conditional Claims.

GENERAL PRINCIPLES

No food should be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.

The person marketing the food should be able to justify the claims made.

PROHIBITED CLAIMS

Claims stating that any given food will provide an adequate source of all essential nutrients

Claims implying that a balanced diet or ordinary foods cannot supply adequate amounts of all nutrients.

Claims which cannot be substantiated.

Claims as to the suitability of a food for use in the prevention, alleviation, treatment or cure of a disease, disorder, or particular physiological condition unless they are: In accordance with the provisions of Codex standards or guidelines for foods as developed by the Committee on Nutrition and Foods for Special Dietary Uses and follow the principles set forth in these guidelines or, in the absence of an applicable Codex standard or guideline, permitted under the laws of the country in which the food is distributed.

Claims which could give rise to doubt about the safety of similar food or which could arouse or exploit fear in the consumer.

POTENTIAL MISLEADING CLAIMS

Meaningless claims including incomplete comparatives and superlatives.

Claims such as "wholesome", "healthful", "sound".

CONDITONAL CLAIMS

Claims allowed under particular conditions e.g. natural", "pure", "fresh", "home made", "organically grown" and "biologically grown, religious or ritual preparation, claims which highlight the absence or non-addition of particular substances...