CODEX ALIMENTARIUS

THE INTERNATIONAL REFERENCE FOR FOOD SUPPLEMENT LEGISLATION

IADSA

International Alliance of Dietary/
Food Supplement Associations

www.iadsa.org

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INTRODUCTION

IADSA was originally created in 1998 to meet the increasing need for expertise, knowledge and experience on issues relating to supplements and to bring together the sector in Codex discussions. Over the years we have expanded our programmes. Today, our work includes many partnerships in countries and regions where supplement regulation and policy are being developed, modified and/or harmonized. A wide range of tools and publications have also been developed by many global experts to support work on regulation and policy.

This guide has been developed to help build common understanding across the world about the application of Codex measures to food supplements and help in their implementation.

But first it is important to clarify what is a food supplement. Food supplements have been designated with different terms in various parts of the world. For example, they are known as "food supplements" in the European Union and much of Latin America, they are termed "dietary supplements" in the United States and "health supplements" in SE Asia (ASEAN) and India.

Most definitions in use across the world contain elements that cover the following aspects:

- The nature of the product (type and form)
- That it concerns concentrated sources of defined substances
- That they can contain a variety of compounds from food
- That their intake is based on a dose form
- That their intended use is to provide a health or physiological benefit.

Based on the elements above, the essential elements of a food supplement definition are generally:

- foods (referring to the general legal framework applicable) that are concentrated sources of nutrients or other compounds, alone or in combination. These may include nutrients (vitamins/minerals), fish oils (essential fatty acids), botanicals (dried or extracts), microorganisms (probiotics), other substances or bioactives (e.g. polyphenols, glucosamine, CoEnzyme Q10, lutein), for example.
- marketed in dose form (e.g. tablets, capsules, pills, sachets of powder, ampoules of liquids, drop dispensing bottles, etc) and not in conventional food form
- to be taken in unit doses
- intended to supplement the diet for a nutritional or physiological purpose

Understanding what a food supplement is also requires an understanding of what it is not, particularly where other key categories of products are concerned:

- Cosmetics: Cosmetics are not for the purpose of ingestion, whereas food supplements are. Borderline products can still exist in a number of fields, such as tooth paste and chewing gum. In both cases, compounds from the products may be ingested. In such cases the intended use of the product is the determining factor for the product classification.
- Medicinal products: Medicinal products can have the same form as food supplements. Nevertheless, the intended use of the product is different.
- Conventional and dietetic foods: General and dietetic foods can in some cases take the form of a food supplement. This is obviously the case with chewing gum, small sweets/ confectionary, sachets, etc. In a number of cases, dietetic foods can also be genuine food supplements where they are intended for a particular population group. The borderline will therefore depend largely on how dietetic foods are defined and the intended use of the product. In those jurisdictions where no dietetic food category exists, rules will be governed mainly by claims and food supplements for particular groups of the population regulated as food supplements.

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THE CREATION AND IMPORTANCE OF THE GUIDELINES FOR VITAMIN AND MINERAL FOOD SUPPLEMENTS (CAC/GL 55 – 2005)

A BRIEF HISTORY OF THE GUIDELINES

The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was one of the first to be created and its focus is on nutrition and safety linked to nutrition. A key part of its activities focuses on the development of standards in areas of specialised nutrition, such as for infant formula and other areas of dietetic food.

By the late 1980's the CCNFSDU had begun to build up an extensive range of standards for specialised nutrition products. With the growth of the food supplement market globally and the increasing questions by regulators of where to place these products in regulation and how to regulate them, it was proposed in the late 1980s that the Committee should expand its work into this area. Discussion was initiated in 1988 (16th session of the CCNFSDU) and the Codex Alimentarius Commission (CAC) at its 18th session in 1989 agreed to send out a Circular Letter seeking government views on whether work on vitamin and mineral supplements should be undertaken within the Codex system. The CAC approved this as new work in 1991.

At the 17th session of the CCFNSDU (1991) a discussion was held on the approach to take for such work and it was agreed that Guidelines not a Standard for food supplements would be the most appropriate. In 1992 a first draft was proposed by the German Secretariat of the CCNFSDU and circulated for comments.

At an early stage in the discussions, it was noted that there was a wide diversity of approaches taken by countries towards regulating food supplements and in a number there was simply no specific regulation at all.

For a start, there were many different terminologies in use, including 'food supplement', 'dietary supplement', 'health supplement' to name a few. In some countries products were regulated as dietetic foods, in others under pharmaceutical law and in some it was very unclear where the products fitted into the overall regulatory framework.

Between 1992 and 1996 there was substantial discussion on many core issues in the text before, eventually, the 20th Session of the CCNFSDU in 1996 then advanced the proposal to CAC for adoption at Step 5. However, it was quickly clear that the necessary consensus had not been achieved and the text was returned to the Committee in 1997 for redrafting.

Some fresh thinking was now required on moving forward and this took the form of a Discussion Paper drafted by the delegations of Canada, the EU and the USA, with the assistance of the delegations of Brazil and Mexico. This identified the range of issues involved, the diversity of regulation and some of the potential options, with their advantages and disadvantages. This document had the effect of bringing all countries up to speed on what it would take to achieve consensus and had the positive effect of building confidence and trust in a number of the options that were finally agreed.

After a few more years of discussion at the CCNSFDU the Guidelines were moved up the Codex decision making process for adoption by the Codex Alimentarius Commission in 2005 in Rome. Many said that it had taken a long time. However, this statement needs to be looked at in the context of a number of other factors:

- Discussion on the draft text only occurred once a year at a Codex Nutrition Committee meeting and in the 1990's Committee meetings did not happen ever year.
- Discussion in Committee was on occasions limited to only a few hours each meeting due to the volume of other issues that were on the agenda.
- At the time of adoption, there was still significant diversity in the regulation of food supplements worldwide and this was far from an easy sector to reach agreement on at the global level.

It needs to be mentioned that the adoption of the Codex Guidelines was far from the end of the story. Noting that according to the Guidelines, the maximum levels of vitamins and minerals would need to be developed based on scientific risk assessment, the FAO/WHO initiated a process to develop "A model for Establishing Upper Levels of Intake for Nutrients and Related Substances". This took the form of a report from a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment which took place in Geneva in May 2005. The report of this meeting was issued in January 2006[1] and still today provides an essential document for any government wishing to develop science-based maximum levels of vitamins and minerals in food supplements.

To complete the picture, in 2009 CCNFSDU adopted Nutrient Risk Analysis Principles for application by Codex. They specify that the FAO/WHO nutrient risk assessment report is the internationally accepted approach for the safety evaluation of nutrients. These principles are critically important for the setting of maximum levels based on risk assessment. This document is therefore an excellent basis for the potential future application of the risk assessment method by Codex and for the development of an internationally accepted table of maximum levels.

When the two reports and the CCNFSDU principles and guidelines are used in conjunction, the regulator has all the necessary data to make key decisions on maximum levels.

[1] www.who.int/ipcs/highlights/full_report.pdf

THE CONTENT OF THE GUIDELINES: WHY OPTIONS WERE CHOSEN

Scope of the Guidelines

In a global analysis of the definitions of food supplements incorporated in national law carried out by IADSA more than 90% of definitions are sufficiently broad to include a wide diversity of ingredients with a nutritional or physiological effect. The scope of food supplement regulation worldwide is therefore very wide and generally includes in addition to vitamins and minerals ingredient categories ranging from amino acids to botanicals and from fish oils to glucosamine.

While the diversity of ingredients used in supplements was recognised in the CCNFSDU, Member States were well aware that with the diversity of regulation, tradition and experience, it would be a significant challenge just to agree Guidelines on the vitamins and minerals or the vitamin and mineral content of supplements. It was however noted that this may be the first stage of a process, not the end of the process and that other substances could be added later if that was the will of the Committee. In addition, it was accepted that the Guidelines should not be seen as restricting supplements to vitamins and minerals only. In addition, it is important to note that while the scope of the Guidelines is only vitamin and mineral supplements, paragraph 1.2 states clearly that food supplements containing vitamins and/or minerals as well as other substances should also be in conformity with the specific rules on vitamins and minerals laid down in these Guidelines.

The Definition

The agreement of a clear definition was a central pillar to progress on the Guidelines. While the definition could only relate to vitamins and minerals due to the decision on limiting the scope, it was considered at the time that if the scope was widened at a later stage, the definition could also be widened.

This definition has since been used as a key reference point for the development of legislation across the world and in many cases the wording from it can be found in that national legislation, even if the scope is broader:

Vitamin and mineral food supplements for the purpose of these guidelines derive their nutritional relevance primarily from the minerals and/or vitamins they contain.

Vitamin and mineral food supplements are sources in concentrated forms of those nutrients alone or in combinations, marketed in forms such as capsules, tablets, powders, solutions etc., that are designed to be taken in measured small-unit quantities but are not in a conventional food form and whose purpose is to supplement the intake of vitamins and/or minerals from the normal diet.*

* This refers to the physical forms of the vitamin and mineral food supplements not to the potency of the supplements.

Ingredients

By limiting the Guidelines to vitamin and mineral supplements, which were traded in all countries, CCNFSDU did not have to consider the diverse range of ingredients used in supplements across the world. It thereby limited its work to a manageable focus.

It was debated on a number of occasions whether botanicals and other ingredients should be added and the decision was consistently taken that regional diversity was significant and the committee did not have the resource to resolve such issues.

However, while other ingredients are not specified in the text, it is important to note that ingredients such as amino acids and essential fatty acids and some other food components (e.g., some plant extracts and botanicals) are covered by other Codex Standards (either of a general nature or commodity Standard) and/or by specific national legislations in certain cases. In addition a standard on a very important ingredient category for food supplements – fish oils – is under development in the Codex Committee on Fats and Oils.

Contents of Vitamins and Minerals

There are four key issues which form the basis of most discussion in the development of legislation on vitamins and minerals.

1 The choice of vitamins and minerals

It was accepted over time by the CCNFSDU that the creation of a single list of vitamins and minerals was not necessary for the purposes of the Guidelines. Many such lists existed in Codex texts related to other categories and Member States were free to develop their own list according to these and other considerations.

2 The sources of vitamins and minerals

While it was noted that different chemical forms of the vitamins and minerals were widely sold on the market, it was not a viable task for the CCNFSDU to build up a single list for international trade. First, there was no mandate for this work; second, it would require significant scientific assessment; and third it would need to be kept updated in view of innovation. It was accepted that where countries require such lists, some have already been developed by national and regional bodies which can be referenced.

3 Natural and Synthetic sources

In order to avoid any confusion the terms natural and synthetic were included in the text. This was to ensure that Member States would be clear that both sources of vitamins and minerals were permitted in international trade.

4 Minimum and Maximum levels of vitamins and minerals

Both minimum and maximum levels took many years to resolve. Eventually the 15% minimum level was established to ensure coherence with other Codex texts. On maximum levels, the debate was much longer. For many years two options existed in the draft Guidelines: 100% of the RDI or a maximum level based on scientific risk assessment. The final outcome which was agreement of the CCNFSDU and Codex Alimentarius Commission was that scientific risk assessment was the only route that could be taken in the light of the science-based approach to food regulation required by the international bodies. In addition, it was soon realised that while maximum levels in food supplement legislation had been limited in many countries in the 1970s and 1980s to a multiple of the RDA/RDI huge changes in regulation had happened and this basis for regulation was fast disappearing.

The text itself states that:

The minimum level of each vitamin and/or mineral contained in a vitamin and mineral food supplement per daily portion of consumption as suggested by the manufacturer should be 15% of the recommended daily intake as determined by FAO/WHO [....]

Maximum amounts of vitamins and minerals in vitamin and mineral food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following criteria into account:

(a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups;

(b) the daily intake of vitamins and minerals from other dietary sources.

When the maximum levels are set, due account may be taken of the reference intake values of vitamins and minerals for the population. This provision should not lead to setting of maximum levels that are solely based on recommended nutrient intakes (e. g. Population Reference Intake or Recommended Daily Allowance values).

Labelling requirements

In addition to the relevant Standard for labelling; the Codex Standard for the Labelling of Prepackaged Foods (Codex-Stan 1-1985, Rev. 1-1991) as well as according to the General Guidelines on Claims (CAC/GL 1-1979), the CCNFSDU also agreed to have specific labeling requirements for food supplements[2]:

1 Name of the category

The name of the product shall be "food supplement" with an indication of the category(ies) of nutrients or of the individual vitamin(s) and/or mineral(s) contained in the product as the case may be.

This also recognizes the specific food category of food supplement, which is also cross referenced in the General Standard on Food Additives as category 13.6.

2 Vitamin and minerals amount declaration

The amount of the vitamins and minerals present in the product should be declared in the labelling in numerical form. The units to be used should be units of weight consistent with the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985 Rev.1-1993).

3 Declaration per portion

The amounts of the vitamins and minerals declared should be those per portion of the product as recommended for daily consumption and if different, the amount per unit for single use may also be given.

[2] Part 5 on labeling of the Guidelines for Vitamin and Mineral Food Supplements - CAL/GL 55-2005

4 Amounts expressed as percentage of NRVs

Information on vitamins and minerals should also be expressed as a percentage of the nutrient reference values mentioned, as the case may be, in the Codex Guidelines on Nutrition Labelling

5 Conditions of use

The label should indicate how the product should be used (quantity, frequency, special conditions).

6 Advice on excess

The label shall contain advice to the consumer not to exceed the maximum one-day amount.

7 Meal or varied diet replacement

The label should not state or imply that supplements can be used for the replacement of meals or a varied diet.

8 Children safety

The label must contain a statement that the product should be stored out of reach of young children.

At an early stage there was broad agreement that a statement should be required on products, which makes it clear that vitamin and mineral supplements should not replace conventional nutrition. However, it was challenging for agreement to be reached on the precise wording of this text due to widely varying perceptions about how consumers used or would use products.

This could have potentially been a major block to agreement but government, consumer associations and industry ultimately became aligned on a single message which today has been transferred through various wording into legislation in many countries. Paragraph 5.8 states that 'The label should not state or imply that supplements can be used for the replacement of meals or a varied diet'.

CHRONOLOGY OF KEY DEVELOPMENTS IN CCNFSDU RELATING TO THE VITAMIN AND MINERAL FOOD SUPPLEMENT GUIDELINES

Year	Discussion	Result
1988	Agreement to seek approval of the Codex Alimentarius Commission to undertake work on food supplements.	Committee requested approval to begin work.
1991	Agreement reached for the development of Guidelines on vitamin and mineral supplements as foods.	Committee advised Commission that work would be progressing. Germany agreed to prepare working paper.
1992	First discussion of the drat Guidelines submitted by Germany. Agreed that supplements should be treated as foods in the Codex system. Range of issues raised including maximum levels, lists of nutrients and combinations.	German delegation asked to redraft Guidelines.
1995	Revised version introduced. Concept of a preamble established regarding access to a balanced diet. UK and US delegations expressed concern about development of the Guidelines. Most delegations were however supportive of moving forward. Section on claims deleted since covered by Guidelines on claims.	Revised text circulated to Member States for comments at Step 3.

Year	Discussion	Result
1996	Exchange of view on proceeding with the Guidelines. Japan, UK and US opposed due to incompatibility of their own regulations with the Guidelines as proposed. Canada and Netherlands emphasised importance of applying risk assessment methodology if maximum levels were to be set. The Committee agreed to focus on safety considerations based on scientific evidence. Committee addressed potential confusion between dietary supplements and food supplements. The Committee agreed that supplements could also be used for specific dietary purposes in addition to general use. The Committee could not agree on a minimum level of vitamins and minerals of 15% of RDI. Opposition expressed to maximum level of 100% of RDI for vitamin and minerals. Committee agreed to include an alternative proposal to establish a safe level based on risk assessment.	Committee agreed to forward the proposed draft Guidelines to the Codex Commission at Step 5, despite recommendation from Australia, Canada, Japan, Netherlands, New Zealand, United States and United Kingdom to keep at Step 3 for further discussion.

Year	Discussion	Result
1998	Guidelines returned to Step 3 by the Codex Commission requesting the Committee to hold a fundamental discussion on the need for the Guidelines. In particularly, extensive debate was held on the basis for establishing maximum levels for vitamins and minerals. European Union delegation proposed the elaboration of an impartial discussion paper to help find common ground.	Canada, EU, USA with support from Brazil and Mexico to develop Discussion Paper.
2000	Discussion paper submitted prior to the meeting was presented and discussed. This addressed many issues including positive and negative lists, GMPs, packaging, marketing, labelling and maximum levels. After discussion on the need for the Guidelines, Committee concludes that necessary to proceed. Progress is made on the wording of many aspects of the Guidelines.	Committee agrees to return the draft Guidelines to Step 3 for discussion at the next session for the Committee.

Year	Discussion	Result
2001	Revised text discussed. Proposal to expand the Guidelines to cover herbs traditionally used in supplements was rejected, based on previous agreement. Both options for establishing maximum levels maintained.	Committee agrees to return the draft Guidelines to Step 3 for discussion at the next session of the Committee.
2002	Revised text discussed. Final name 'vitamin and mineral food supplements' agreed. Proposal to expand to other ingredients once again rejected. It was noted that when the Guidelines were completed the extension to other substances could be considered. No consensus reached on establishing maximum levels and both options maintained.	Committee agreed to return the draft Guidelines to Step 3 for discussion at the next session for the Committee.

Year	Discussion	Result
2003	Revised text discussed. The Committee clarified in the text that products containing vitamins, minerals and other ingredients were also covered by the Guidelines in respect of their vitamin and mineral content. Significant discussion on whether to establish a minimum level of 33% of the RDI for vitamins and minerals or to retain the 15% level. It was agreed to retain 15% since it corresponded to the value for "source" in the Guidelines for Use of Nutrition Claims. Detailed discussion on the establishment of maximum levels for vitamins and minerals: Committee agreed to delete the option to establish maximum levels based on a maximum of the RDI/RDA. Establishment of maximum levels based on scientific risk assessment retained and committee discussed the need to take into account the reference intake for the population during this risk assessment process. Deletion by the Committee of the sentence requiring that products should be taken on the advice of a nutritionist, dietetician or medical doctor. Requirement for child-resistant packaging deleted and alternative wording related to keeping the product out of reach of children agreed.	Based on considerable progress made, Committee forwarded the draft Guidelines to the Codex Alimentarius Commission for adoption at Step 5. Adoption at the CAC was achieved.

Year	Discussion	Result
2004	Revised text as adopted at Step 5 discussed, focussing solely on the areas where consensus still not achieved. Amendment to the section on the selection of vitamins and minerals, clarifying that sources may be natural or synthetic but also that selection should be based on considerations of safety and bioavailability. Clarity provided in the text that the establishment of maximum levels should not be solely based on recommended nutrient intakes.	Recommendation of the text to the Codex Alimentarius Commission for Adoption of the Guidelines.
2005	Codex Alimentarius Commission adopts the Codex vitamin and mineral food supplement Guidelines at their 28th Session.	

CODEX GUIDELINES FOR NUTRITION AND HEALTH CLAIMS

BACKGROUND

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.

PROVISION IN CODEX GUIDELINES FOR CLAIMS

The current version of the *Codex General Guidelines on Claims (CAC/GL 1-1979)* consists of 5 sections on provisions of the Scope and General Principles, Definition, Prohibited Claims, Potentially Misleading Claims, and Conditional Claims.

The *Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)* set out 9 sections of provisions including the Scope, Definitions, Nutrition Labelling, Nutrition Claims, Nutrient Content Claims, Comparative Claims, Non-addition Claims, Health Claims, and Claims related to Dietary Guidelines or Healthy Diets, as well as a Table of Conditions for Nutrient Content Claims and an Annex on Recommendations on the Scientific Substantiation of Health Claims. These guidelines relate to the use of nutrition and health claims and are intended to supplement the *Codex General Guidelines* on Claims but do not replace any prohibitions contained therein.

1 Prohibited Claims

The *Codex General Guidelines on Claims* prohibit the following claims:

- Claims stating that any given food will provide an adequate source of all essential nutrients, except for products for which a Codex standard regulates such claims as admissible or where accepted by appropriate authorities.
- Claims implying that a balanced diet or ordinary foods cannot supply adequate amounts of all nutrients.
- Claims which cannot be substantiated.
- Claims for use in the prevention, alleviation, treatment or cure of a disease, disorder, or particular physiological condition, unless they are included in CCNFSDU Guidelines or Standards or permitted by national legislation.
- Claims which could give rise to doubt about the safety of similar food or which could arouse fear in the consumer.

The *Codex Guidelines for Use of Nutrition and Health Claims* also emphasize that nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation.

2 Types of Claims, Definitions and Provisions

The *Codex Guidelines for Use of Nutrition and Health Claims* have categorized two general types of claims, Nutrition Claims and Health Claims.

Nutrition Claims

Nutrition Claim means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals.

The only nutrition claims permitted shall be those relating to energy, protein, carbohydrate, and fat and components thereof, fibre, sodium and vitamins and minerals for which Nutrient Reference Values (NRVs) have been laid down in the *Codex Guidelines for Nutrition Labelling*.

Health Claims

Health Claim means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health.

The Guidelines also suggest that health claims should:

- be based on current relevant scientific substantiation;
- arise from the consumption of a reasonable quantity of the food or food constituent in the context of a healthy diet; and
- have a clear regulatory framework for qualifying and/or disqualifying conditions for eligibility to use the specific claim.

The Codex Guidelines further allocate the above two types of claims into a number of sub-categories, which are presented in the table below:

Types of Claims	Sub-Categories	Definition	Example
Nutrition Claims	Nutrient Content Claims*	A nutrition claim that describes the level of a nutrient contained in a food.	"source of calcium"; "high in fibre and low in fat"
	Nutrition Comparative Claims	A claim that compares the nutrient levels and/or energy value of two or more foods.	"reduced"; "less than"; "fewer"; "increased"; "more than"
	Non-addition Claims	Any claim that an ingredient has not been added to a food, either directly or indirectly. The ingredient is one whose presence or addition is permitted in the food and which consumers would normally expect to find in the food.	

Types of Claims	Sub-Categories	Definition	Example
Health Claims	Nutrient Function Claims	A nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body.	"Nutrient A (naming a physiological role of nutrient A in the body in the maintenance of health and promotion of normal growth and development). Food X is a source of/ high in nutrient A."
	Other Function Claims	These claims relate to specific beneficial effects of the consumption of foods or their constituents in the context of the total diet on normal functions or biological activities of the body. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health.	"Substance A (naming the effect of substance A on improving or modifying a physiological function or biological activity associated with health). Food Y contains x grams of substance A."

Types of Claims	Sub-Categories	Definition	Example
Health Claims cont.	Reduction of Disease Risk Claims	Claims relating to the consumption of a food or food constituent in the context of the total diet, to the reduced risk of developing a disease or health-related condition. Risk reduction means significantly altering a major risk factor(s) for a disease or health-related condition. Diseases have multiple risk factors and altering one of these risk factors may or may not have a beneficial effect. The presentation of risk reduction claims must ensure, for example, by use of appropriate language and reference to other risk factors, that consumers do not interpret them as prevention claims.	"A healthful diet low in nutrient or substance A may reduce the risk of disease D. Food X is low in nutrient or substance A."

* Nutrient Content Claims

The conditions for Nutrient Content Claims are further illustrated by the Guidelines in a Table, which sets out numerical values or percentages for specific nutrient contents in the food in order for the food to be eligible for making such claims. The values set in the Table were developed by the CCNFSDU.

For example, the conditions for making nutrient content claims for vitamins and minerals are specified in the table as below:

Component	Claim	Conditions (not less than)
Vitamins and Minerals	Source	15% of NRV per 100g (solids) 7.5% of NRV per 100ml (liquids) or 5% of NRV per 100 kcal (12% of NRV per 1MJ) or 15% of NRV per serving
	High	2 times the value for "source"

CODEX RECOMMENDATIONS: SCIENTIFIC SUBSTANTIATION OF HEALTH CLAIMS

As stated in the Preamble of the Codex Guidelines for Use of Nutrition and Health Claims, "health claims should be supported by a sound and sufficient body of scientific evidence to substantiate the claim". The Recommendations are intended to assist national authorities in their evaluation of health claims in order to determine their acceptability for use by the industry.

The Recommendations have focused on processes and criteria for the substantiation of health claims, and the general principles for the systematic review of the scientific evidence. These shall apply to all types of health claims as introduced before. It is also suggested by the Recommendations that health claims should be re-evaluated by competent national authorities either periodically or following the emergence of significant new evidence which could alter previous conclusions about the health claim.

1 Process for the substantiation of heath claims

The Recommendations suggest that the process for the substantiation of health claims by national authorities typically includes the following steps:

- 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; and
- 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.

2 Criteria for the substantiation of heath claims

The 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 date should be identified and reviewed.
- Evidence based on human studies should demonstrate a consistent association between the food and the health effect.

It was also recommended that 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.

3 Consideration of evidence

The Recommendations state that scientific studies considered relevant for the substantiation of health claims are those addressing the relationship between the food and the health effect. It is also suggested that where a claimed health effect cannot be measured directly, relevant validated biomarkers may be used.

The scientific data should provide adequate characterization of the food, which includes a summary of the studies undertaken on production conditions, batch-to-batch variability, analytical procedures, results and conclusions of the stability studies, and the conclusions with respect to storage conditions and shelf life.

The Recommendations have also addressed the importance of the consistency and quality of scientific data.

CHRONOLOGY OF KEY DEVELOPMENTS RELATING TO CODEX GENERAL GUIDELINES ON CLAIMS (CAC/GL 1-1979)

Year	Discussion	Result
Late 60s early 70s	In depth discussions about the use of claims while developing the General Standard for the Labelling of Pre-packaged Foods.	
1972	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.	CCFL requested to comment on the wording for the definition of 'claim' and possible categories of claims and the possibility of developing criteria for the justification of claims.
1974	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.	Decision to develop general guidelines on Claims. Canadian Secretariat tasked to prepare these Guidelines for comment and discussion at the next full meeting of the CCFL.
1978	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.	Draft Guidelines proposed to the Commission for adoption as a final text.
1979	Codex Alimentarius Commission adopts the Codex General Guidelines on Claims. Guidelines subsequently revised in 1991 and then only amended again in 2009.	

CHRONOLOGY OF KEY DEVELOPMENTS RELATING TO CODEX GUIDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS (CAC/GL 23-1997)

Year	Discussion	Result
1989	Concerns raised that divergence of national regulations on nutrition claims might present a potential barrier to trade.	CCFL agrees that Canada should prepare an inventory of national requirements with regards nutrition claims.
1990	The Codex Coordinating Committee for North America and the South West Pacific (CCNASWP) proposes the need to develop a uniform policy concerning the use of nutrition and health claims on labels and recommends to the Executive Committee the elaboration of the subject Guidelines by the CCFL.	The Executive Committee agrees with the CCNASWP proposal for CCFL to develop Guidelines for nutrition and health claims.
1995	Discussion on issues including provisions for nutrient function claims and health claims and the criteria for comparative claims. Extensive exchange of views on the need to retain the reference to "disease" in the definition of health claims. General consensus on the prohibition of medicinal claims, relating to the cure, treatment or prevention of illness.	CCFL agrees to advance to Step 5 the Proposed Draft Guidelines for Use of Health and Nutrition Claims after in depth discussion at the two last sessions. Draft Guidelines adopted by Commission at Step 5 including the Table of Conditions for Claims for Nutrient Contents.

Year	Discussion	Result
1996	Agreement to include a Preamble indicating that health and nutrition claims should be consistent with national nutrition policy. Extensive discussion on the extent to which health-related claims should be permitted and included in the Guidelines. Consensus to exclude claims relating to the prevention, cure and treatment of disease and adverse health-related condition. No agreement on other health claims. Health claims should be removed from the Guidelines at this stage.	Deletion of all references to health claims throughout the text including the definitions. CCFL agrees to forward the Draft Guidelines for Use of Nutrition Claims to the Commission for adoption at Step 8.
1997	Codex Alimentarius Commission adopts the Guidelines for Use of Nutrition Claims (including Part A of the Table) at Step 8.	CCFL agrees to circulate the sections on Health Claims as previously contained in the Draft Guidelines for Use of Health and Nutrition Claim with a view to developing a draft amendment to the Guidelines for Use of Nutrition Claims.

Year	Discussion	Result
1999	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. Some delegations propose that development of guidelines concerning health claims should be left to the national authorities in view of their specific public health concerns.	CCFL agrees to return to Step 3 the Proposed Draft Recommendations for the Use of Health Claims.
2001	A redrafted document is presented. The 'Proposed Draft recommendations for the use of health claims' is incorporated into the 'Guidelines for Use of Nutrition Claims' and name changed to 'Proposed Draft Guidelines for the Use of Nutrition and Health Claims'. Agreement of the CCNFSDU on the possibility and opportunity of developing criteria on the scientific basis of health claims and that the Committee is prepared to proceed with this work when the definition of health claims has been further developed.	CCFL agrees to return to Step 3.
2003	CCFL considers the draft section by section and makes amendments throughout the text.	CCFL agrees to advance the Draft Guidelines, as amended at the current session, to Step 8 for adoption by the 26th Session of the Codex Alimentarius Commission.

Year	Discussion	Result
2004	The Commission returns the Draft Guidelines to Step 6 since there was no consensus especially, as to the inclusion of "advertising" in paragraph 1.1. ' These guidelines relate to the use of nutrition and health claims in food labelling and, where required by the authorities having jurisdiction, in advertising'.	CCFL agrees to advance to Step 8 the Draft Guidelines for Use of Nutrition and Health Claims.
2006	Codex Alimentarius Commission adopts the inclusion of the definition to the Guidelines for Use of Nutrition and Health Claims.	
2009	Codex Alimentarius Commission adopts the recommendations on the Scientific Basis of Health Claims – Annex to the Guidelines for Use of Nutrition and Health Claims.	

CODEX COMMITTEE ON FOOD ADDITIVES

BACKGROUND

The Codex Committee on Food Additives (CCFA) has been working since 1968, initially as a joint committee covering both food additives and contaminants with the title of 'The Codex Committee on Food Additives and Contaminants' (CCFAC). The host country was the Netherlands.

In the early 2000s it was found that the essential items on the agenda were exceeding the time available at the annual Plenary Session of the Committee and a one-day Physical Working Group meeting was introduced on the Saturday preceding the Plenary.

In 2005/6 it was decided to separate the CCFAC into two committees, the Codex Committee on Food Additives (CCFA) and the Codex Committee on Contaminants in Foods (CCCF). The CCFA was to be hosted by China whilst the CCCF remained in the Netherlands.

The first meetings of the separate committees took place in 2007. Since then the Physical Working Group meeting has increased to two days.

The terms of reference of the CCFA are:

a) to establish or endorse permitted maximum levels for individual food additives;

b) to prepare lists of food additives for risk assessment by the Joint FAO/WHO Expert Committee on Food Additives (JECFA);

c) to assign functional classes to individual food additives;

d) to recommend specifications of identity and purity for food additives for adoption by the Codex Alimentarius Commission;

e) to consider methods of analysis for the determination of additives in food;

f) to consider and elaborate standards or codes for related subjects such as the labelling of food additives when sold as such.

As all Codex work has to have a sound scientific basis, the CCFA is required to base any risk analysis, and the development of standards and codes, on the advice received from JECFA. The JECFA is an independent expert scientific committee jointly administered by the Food and Agricultural Organisation (FAO) and the World Health Organisation (WHO).

A major task undertaken by the CCFA is the development of the General Standard for Food Additives (GSFA). The GSFA is a compendium containing a list of all approved food additives, the food categories in which they can be used and the maximum level of use for each category.

GENERAL STANDARD FOR FOOD ADDITIVES

The General Standard for Food Additives (GSFA) is a compilation of all food additives which have been adopted by the Codex Alimentarius process, together with a list of the foods in which the additives are used and a maximum level of use for each food.

Specifically the GSFA gives:

- a list of the accepted additives together with their International Numbering System (INS) numbers;
- foods in which the additives may be used. Currently, 16 food categories have been identified and, in most cases, these are divided into sub-categories;
- foods in which additives may not be used, or may be restricted;
- the maximum levels of use in a particular food category or sub-category.

The GSFA is intended to be the single authoritative reference point for food additives worldwide. It is easily accessed on the internet, the recent versions are interactive and searches can be made from different starting points. For example, it can be searched on the basis of the additives and will give all the food categories in which the additive is permitted, or it can be searched on the basis of the food category (in the case of food supplements, category 13.6) and will list all the additives permitted in that category.

The GSFA is regularly updated, normally after the adoption of the CCFA recommendations at the Codex Alimentarius Commission's annual meeting.

The compilation of the GSFA has been a major exercise requiring a very considerable resource and international co-operation, with many countries participating in both electronic and physical working groups. The current programme envisages that it will probably be into the 2020s before all the additive provisions have been reviewed and adopted.

The GSFA is a valuable document that already covers thousands of food additive provisions and all the main technological additives used in each of the food categories. However, the lack of reference to a particular additive or to a particular use of an additive in a food category / sub-category in the GSFA, as currently drafted, does not automatically imply that the additive is unsafe or unsuitable. It may be that the particular provision is still 'work in progress', and has not as yet been formally adopted by the CCFA and the Codex Commission.

THE EVALUATION OF A FOOD ADDITIVE

There are a number of steps involved before a new food additive is adopted and added to the GSFA.

The essential principles associated with the acceptance of a food additive have to be considered for all new additives. These are:

1 Safety

Only those food additives can be endorsed that, so far as can be judged and based on the evidence available from JECFA, present no appreciable health risk to consumers at the usage levels proposed.

Any food additive accepted for inclusion in the GSFA must have had any Acceptable Daily Intake (ADI) levels, or an equivalent safety assessment by JECFA, taken into account, including its probable daily intake from all food sources in which it is used.

Where an additive is to be eaten by special groups of consumers, for example, in dietetic foods and foods supporting sick individuals, account must be taken of the probable daily intake by those individuals.

The quantity of an additive added to a food should be the lowest level necessary to achieve the intended technological effect. The highest level should not exceed the maximum level assigned to that food.

2 Justification of Use

The use of a food additive is only justified when such a use has a clear technological advantage and does not present a health risk to the consumer or mislead the consumer.

The additive also has to serve one or more technological functions as defined by Codex (for example, preservative, thickener, antioxidant etc.). The technological function should not be able to be achieved by other means that are technologically and economically practicable.

The technological justification should be based on one or more of the following:

- to preserve the nutritional quality of the food;
- to enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that it does not change the nature, substance or quality of the food so as to deceive the consumer;
- to provide aids in the manufacture, processing, preparation, treatment, packing, transport or storage of a food. However, the additives must not be used to disguise the effects of the use of faulty raw materials or of undesirable (for example, unhygienic) practices or techniques.

3 Good Manufacturing Practice (GMP)

All food additives accepted for inclusion in the GSFA must be manufactured and used under conditions of good manufacturing practice.

This includes the requirements that:

- the quantity of the additive used in the food must be limited to the lowest possible level required to accomplish the desired effect;
- the quantity of the additive that becomes a component of a food as a result of its use in the manufacturing, processing or packaging of a food, and which is not intended to accomplish any physical or other technological effect in the food, is reduced to the lowest possible extent;
- the additive is of an appropriate food grade quality and is subjected to the same level and controls of good manufacturing practice as a food ingredient.

4 Specifications, Identity and Purity

All food additives added to the GSFA must be used in accordance and conform to an applicable specification covering identity and purity recommended by Codex. In the absence of a Codex specification it must comply with an appropriate specification developed by a responsible national or international body.

Food grade quality of an additive can only be achieved by conformance to the specification and compliance with good manufacturing practice at all stages of manufacture, packaging and distribution of the additive.

INTERNATIONAL NUMBERING SYSTEM (INS)

The International Numbering System (INS) for food additives is intended to be a harmonised naming system for the additive. The intention is also to avoid the use of lengthy specific names and synonyms. The INS does not include flavourings, chewing gum bases and dietetic and nutritive additives. However, enzymes which function as food additives are included.

Under Codex procedures, all accepted additives must have an INS number and new additives should be assigned a number before being submitted for a JECFA evaluation.

Inclusion in the INS list does not automatically imply approval by Codex for use as an additive, as the list may include additives that have not yet been evaluated by JECFA.

The INS list is presented in numerical order and is set out in three columns giving the identification number, the name of the additive and its technological purpose.

The identification number usually consists of three or four digits (for example; 100 for curcumins and 1001 for choline salts and esters). In some cases the number may be followed by an alphabetical suffix. For example; 150a relates to caramel 1 (plain caramel) whilst 150b identifies caramel II or sulphite caramel.

The name of the additive may sometimes be followed by an additional name in parenthesis which can help to further specify the additive.

The third column gives the various technological purposes of the additive. It should be noted that this list should be considered indicative rather than exhaustive. The technological purposes are grouped under functional classes.

When the INS list was originally compiled an effort was made to group the food additives with similar purposes together. Thus colouring agents were assigned numbers from 100 to 199, preservatives 200 to 299 etc. However, over the years extensions to the list have meant that most of the three digit numbers have been allocated and four digit numbers have had to be assigned.

As the primary purpose of the list is the accurate international identification of the additive, it is an open list and additions and deletions to the list take place on an ongoing basis.

Normally, an INS identification of an additive is required before the additive can be put forward for evaluation by JECFA. As part of its evaluation, JECFA will also agree a specification.

JECFA EVALUATION

Acceptable Daily Intake

A JECFA evaluation and safety assessment of a new food additive is required to establish an Acceptable Daily Intake (ADI) for the additive.

An ADI is defined as 'an estimate of the amount of a food additive, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk'.

In some cases, the ADI may be ascribed the category of 'Not Specified' (ADI-NS). This can be used for an additive of very low toxicity which does not, in the opinion of JECFA, represent a hazard to health. If, in the opinion of JECFA an additive falls into the NS category it must be used within the bounds of Good Manufacturing Practice (GMP). This means that the quantity of the additive that is added to a food must be limited to the lowest possible level necessary to achieve the desired technological effect. The GMP level will differ for each application of the additive as it relates to the technological effect on a particular food / food category.

A further aspect is the 'Maximum Use Level' which is the highest concentration of the additive determined to be functionally effective in a food, or food category, and agreed to be safe by the Codex Alimentarius Commission. The maximum use level, is generally expressed as mg additive / kg food.

Data Requirements

In order to be able to undertake an evaluation of an additive JECFA requires a considerable amount of data.

This data has to include a full characterisation of the additive, detailed specifications, and details of the manufacturing process and controls. The technological aspects of the requirement must be sufficient for JECFA to determine the identity and purity criteria for the ditive.

As the main focus of the evaluation is a safety assessment, there are requirements for a significant amount of toxicological data. These can be grouped into the following categories:

- Metabolic and pharmacokinetic studies.
- Short-term toxicity, long-term toxicity / carcinogenicity, reproductive toxicity and developmental toxicity studies in animals. Genotoxicity studies.
- Epidemiological and / or clinical studies and special considerations.
- Other data (for example: allegenicity).

The toxicological data is essential for the assessment of the safety of the substance. However, this has to be supported by a potential intake assessment. This requires information on the levels of the additive used, or expected to be used in food, based on its technological function, its expected usage levels and the range of foods in which it is likely to be used. Also required is an estimation of the dietary intakes based on food consumption data for foods in which the substance may be used. This latter requirement is often difficult to achieve with any accuracy due to the lack of appropriate food consumption data in some countries and significant variations in diets between populations. The JECFA evaluations have to be based on world-wide consumption and not confined to particular regions.

JECFA can only evaluate an additive from the data submitted and the evaluation and ADI is related to the specific substance for which the application was made. There can be cases where an additive can be manufactured by different methods and have different specifications relating to the manufacturing method or raw material source. In theory, only the substance evaluated should be the recognised form.

Once JECFA have determined the ADI, which is reported as mg additive / kg body weight per day, the experts in the CCFA working groups are required to determine the maximum levels of use for each food category or sub-category. To accomplish this, the working groups require a technological justification of the need for the additive in a particular food and the maximum level of use needed to achieve the technological function in the food. Data on consumption patterns also have to be taken into consideration when determining the potential exposure of the population to the additive.

EFFECTIVE USE OF THE GSFA

The GSFA is an important international resource as it provides Regulators across the world with the same impartial expert advice from international experts in their field.

The data contained in the GSFA allows Regulators to develop or revise their national legislation on food additive usage with the confidence that it is backed by international consensus.

The long-term objective is that the detail of the GSFA will eventually become part of the food legislation of most, if not all, of the member countries of Codex Alimentarius, and thus significantly reduce or eliminate barriers to trade in foods and food products.

The main part of the GSFA is laid out in three tables (Codex General Standard for Food additives, CODEX STAN 192-1995 – page 61-28[3])

Table 1 Additives (in alphabetical order) permitted for use under specified conditions in certain food categories or individual food items.

Table 2 The same additives as in Table 1, but in the order of the food categories or individual food items in which these additives are permitted.

Table 3 Additives permitted for use in food in general, unless otherwise specified, in accordance with GMP.

[3] www.fao.org/gsfaonline/docs/CXS_192e.pdf

Table 3 lists all those additives permitted for use in food in general, unless otherwise specified. The additives in this list have all been evaluated to have a level of safety that does not need it to be limited in its use, to specified categories or low levels of use. Additives listed in Table 3 can be used in the foods at levels that are in accordance with Good Manufacturing Practice (GMP). As outlined above (Section on GMP) this means that the quantity of the additive used in the food must be limited to the lowest possible level needed to accomplish the desired technological effect.

The list in Table 3 should form the basis of any proposed legislation on food additives, as it contains additives that are essential to the manufacture, safety and quality of a wide range of foods.

In addition to Table 3, the food additives from Tables 1 / 2 should also be included in any proposed legislation. Table 1 lists, in alphabetical order, the additives that have a designated maximum level of use, and then states the food categories or individual food items in which these additives are permitted, together with the specified conditions of use. Table 2 contains the same additives as Table 1, but lists them in the order of the food categories or individual food items in which these additives are permitted, together with the maximum permitted levels given as mg/kg food.

Whilst Table 3 is a simple yet essential list, as it applies to all foods where additives are not prohibited or specifically controlled, a legislator effectively has the option of regulating by food category, in the Table 2 format (as in European Union Legislation), or of listing each additive against its permissibility and any specified conditions in each food category, as in the Table 1 format.

FOOD ADDITIVES IN FOOD SUPPLEMENTS

As food supplements are defined as products supplying nutrients and other substances in unit dose form, the technology required to achieve such products is, in some cases, more specialised than for many food products. A considerable proportion of supplements on the market are presented in the form of tablets or hard and soft gel capsules. A smaller proportion are in the form of powders or liquids.

Each method of delivery has its own specific requirement for technological additives, and all these additives have to be permitted in legislation at levels consistent with their technological function in the product.

Since the end of the 1990s, the International Alliance of Dietary / Food Supplement Associations (IADSA), as an accredited Non-Governmental Organisation (NGO) within Codex Alimentarius, has been involved in all the relevant working group and Plenary discussions at CCFA concerning additives for use in food supplements. As required by the CCFA, all additives have to have a justification of their technological need in a product category, together with details of the level of use.

As a consequence of these continuing discussions, the food Category 13.6 (food supplements) is permitted to use the additives listed in Table 3 of the GSFA and also those specifically listed for use in Category 13.6 in Table 2. The additives listed in Table 2 are governed by the maximum level of use (in mg/kg product) and any notes accompanying the provision.

The notes can indicate either restrictions on use or give the method of calculation of the usage levels.

For example, the antioxidant Butylated Hydroxyanisole (BHA) is permitted for use in food supplements 13.6 at a maximum level of 400mg/kg but this is subject to the conditions in notes 15 and 196.

Note 15 states 'on a fat or oil basis' whilst Note 196 applies to specific controls in relation to the use of BHA in combination with other antioxidants as it states, 'singly or in combination;

BHA (INS 320), BHT (INS 321) and Propyl Gallate (INS 310)'. Thus, any combination of the three antioxidants is controlled by a maximum level of 400mg/kg in the product.

Whilst the GSFA is at a very advanced state, it is still 'work in progress' as the CCFA have a number of provisions still to be considered and adopted. In addition, as new food additives are proposed for evaluation by JECFA, the CCFA will be required to discuss and assign maximum levels of the additive in those food categories in which it is justified.

As a consequence, those countries which have already adopted the GSFA as part of their food additive legislation have to make provision in their law for periodic updates.

In the context of food supplements there are a small number of provisions still awaiting adoption by the CCFA and the Codex Commission and this should be borne in mind when developing legislation.

THE EXAMPLE OF MAGNESIUM STEARATE

- Magnesium stearate has been an essential technological additive for food supplement tablets for over 80 years.
- Up until 2009, it was in the GSFA under INS 470 salts of myristic, palmitic and stearic acids.
- At the 42nd Codex Committee on Food Additives (CCFA) in 2010, the electronic working group (eWG) of the International Numbering System (INS) put forward a recommendation that magnesium salts of certain fatty acids be permanently deleted from the INS.

When this was raised in the plenary there was an intervention by IADSA, verbally explaining the importance of magnesium stearate to the food supplements industry. The decision was therefore postponed to the 43rd meeting in 2011.

- During 2010, IADSA submitted to the eWG a full technological justification for the retention of magnesium stearate in the INS.
- This was discussed and agreed by the INS eWG and the proposal was endorsed and adopted at the 43rd CCFA in 2011.
- Under the Codex procedure, as reference to it had been removed from the INS, magnesium stearate had to be assigned a new INS number, INS 470(iii).
- Now the additive has to undergo a safety assessment by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) before inclusion back into the General Standard for Food Additives (GSFA).
- Discussions were held with JECFA at the 44th CCFA in 2012, in order to clarify the data requirements for the safety assessment. JECFA confirmed that a full dossier containing all available toxicological data would be required.

- Following prior discussions between IADSA and the European Chemical Industry Council (CEFIC), a proposal was put forward by CEFIC at the 45th CCFA in 2013 for inclusion of magnesium stearate on the priority list for JECFA assessment.
- This proposal was supported in the meeting by IADSA, endorsed by the European Union delegation and agreed by the CCFA.
- During the first part of 2013, IADSA coordinated the data collection from other industries for CEFIC, who are responsible for compilation and submission of the dossier on magnesium stearate. The industries who would potentially be affected by the loss of magnesium stearate include:
  - Food supplements industry
  - Confectionery industry
  - Chewing gum industry
  - Yeast / bakery industry
- Submission of the completed dossier on magnesium stearate is required by November 2013.

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

BACKGROUND

The Codex Committee on Contaminants in Foods (CCCF) was for many years combined with the Codex Committee on Food Additives to form the Codex Committee on Food Additives and Contaminants (CCFAC), which was hosted by the Netherlands.

In the early 2000s it was found that, due to the increasing number of issues relating to both food additives and contaminants, the time available for discussion at the annual Plenary Session of the CCFAC was being exceeded.

In 2005/6 it was decided that the CCFAC should be separated into two specialist committees, the Codex Committee on Contaminants in Foods (CCCF) and the Codex Committee on Food Additives (CCFA). The Netherlands continued with the hosting of the CCCF whilst the CCFA was hosted by China. The first meeting of the CCCF took place in 2007.

The terms of reference for the new committee were to:

a) Establish or endorse permitted maximum levels or guideline levels for contaminants and naturally occurring toxicants in food and animal feed;

b) Prepare priority lists of contaminants and naturally occurring toxicants for risk assessment by the Joint FAO/WHO Expert Committee on Food Additives (JECFA);

c) Consider methods of analysis and sampling of contaminants and naturally occurring toxicants in food and animal feed;

d) Consider and elaborate standards or codes of practice for related subjects;

e) Consider other matters assigned to the CCCF by the Codex Alimentarius Commission in relation to contaminants and naturally occurring toxicants in food and animal feed;

The Codex definition of a contaminant is:

"Any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter".

The remit of the CCCF applies to any substance that meets the terms of the Codex definition for a contaminant, including contaminants in feed for food-producing animals, except:

a) Contaminants having only food and feed quality significance (e.g. copper), but no public health significance, in the food(s) given that the standards elaborated within the Codex Committee on Contaminants in Foods (CCCF) has the objective to protect public health.

b) Pesticide residues, as defined by the Codex definition, that are within the terms of reference of the Codex Committee on Pesticide Residues (CCPR).

c) Residues of veterinary drugs, as defined by the Codex definition, that are within the terms of reference of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF).

d) Microbial toxins, such as botulinum toxin and Staphylococcus enterotoxin, and microorganisms that are within the terms of reference of the Codex Committee on Food Hygiene (CCFH).

e) Residues of processing aids that are within the terms of reference of the Codex Committee on Food Additives (CCFA).

The Codex definition of a contaminant also implicitly includes naturally occurring toxicants, including toxic metabolites of certain microfungi that are not intentionally added to food and feed (mycotoxins).

Toxins that are produced by algae (phycotoxins) and that may be accumulated in edible aquatic organisms such as shellfish are also covered by the CCCF. Mycotoxins and phycotoxins are both subclasses of contaminants.

Endogenous natural toxicants, such as solanine in potatoes, that are implicit constituents of food and feed resulting from a genus, species or strain ordinarily producing hazardous levels of a toxic metabolite(s) (phytotoxins) are also within the terms of reference of the CCCF and have to be dealt with on a case by case basis.

As can be seen from the above definitions the CCCF has a very wide remit covering a highly diverse range of contaminants in foods. Subjects considered by the Committee include:

- heavy metals (e.g. lead, cadmium, mercury etc.)
- mycotoxins (e.g.aflatoxins)
- chloropropanols (e.g. 3-MCPD)
- acrylonitrile
- melamine
- polycylic aromatic hydrocarbons
- vinylchloride
- cyanogenic glycosides
- radionuclides

The above list, which is by no way exhaustive, covers contamination from external sources such as heavy metals, melamine and radionuclides and also chemical substances that can be formed during the processing of foods, such as chloropropanols and acrylamide.

A major task also undertaken by the CCCF is the development and maintenance of the Codex General Standard for Contaminants and Toxins in Food and Feed (GSCTFF).

GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED (CODEX STANDARD 193 – 1995 AS AMENDED)[4]

This Codex Standard has been developed to contain the main principles which are recommended by the Codex Alimentarius to deal with contaminants and toxins in food and animal feed.

It lists the maximum levels and associated sampling plans for contaminants and natural toxins in food and feed which have been recommended by the CCCF and adopted by the Codex Alimentarius Commission. These levels should be applied to food commodities moving in international trade.

The standard includes only the maximum levels of contaminants and toxicants in animal feed where the contaminant of the feed can be transferred to human food of animal origin and where this can be relevant for public health.

The GSCTFF is intended to eventually become the authoritative reference for contaminants and toxins in food on a worldwide basis. This has become increasingly important due to the greater reliance on international trade in food commodities.

The format of the GSCTFF is that there is an explanatory section giving the background and definitions. This is followed by a listing of each of the contaminants which have been considered by the Committee and for which an evaluation has been undertaken by the joint Expert Committee on Food Additives (JECFA) and maximum levels agreed.

More specifically, the tables are laid out giving the details of the JECFA evaluation at the top of the first page for each specific contaminant, together with the toxicological guidance for the substance and other details.

Maximum levels for the contaminant are then listed for each of the commodities in which they can be found, together with any relevant notes.

The sampling plans and sampling preparation procedures are specified for the analysis of the contaminant in the commodity.

[4] www.fao.org/input/download/standards/17/CXS_193e_2015.pdf

For example, in the reference to Total Aflatoxins there are background details to the relevance of aflatoxins and their hazard in food. Maximum levels are then listed for the relevant commodities, such as a maximum level of 15µg/kg for peanuts and a note stating that this applies to peanuts intended for further processing. In addition there are detailed sampling plans for the examination of aflatoxins in shelled and un-shelled peanuts intended for further processing, together with details of sample preparation and analytical methods.

MAXIMUM LEVEL OF CONTAMINANTS

In Codex terms the maximum level (ML) for a contaminant or toxin in a food commodity is defined as 'the maximum concentration of that substance recommended by the Codex Alimentarius Commission (CAC) to be legally permitted in that commodity'.

The Codex principles for establishing maximum levels (MLs) of contaminants in food and feed state that they should only be set for food in which the contaminant may be found in amounts that are significant for the total exposure of the consumer, taking into consideration the policy of the CCCF for the Exposure Assessment of contaminants and toxins in foods or groups of foods.

The maximum levels have to be set in such a way that the consumer is adequately protected, but at the same time other legitimate factors need to be considered. Consideration of other factors should be carried out in accordance with the Codex 'Working Principles for Risk Analysis for Food Safety for Application by Governments'. The principles of Good Manufacturing Practice and Good Agricultural Practice as defined and outlined by Codex must apply.

The maximum levels must be based on sound scientific principles which lead to levels that are acceptable worldwide, so that no unjustified barrier to international trade can be incurred.

There is also the requirement that the maximum levels should be clearly defined with respect to their status and intended use.

THE ESTABLISHMENT OF MAXIMUM LEVELS

The starting point for setting maximum levels of a contaminant is integrated expert toxicological advice regarding a safe / tolerable intake level of the substance. The main basis for decisions by the CCCF is a full evaluation of an adequate toxicological database on the contaminant from which JECFA are able to make a recommendation on the maximum allowable or tolerable intake.

In urgent cases it may be possible to rely on less developed evaluations from JECFA, or on expert toxicological advice from other international or national bodies.

The toxicological data that should be available for an evaluation for maximum levels of the contaminant in a food should include the following:

- identification of the toxic substance(s);
- metabolism in humans and animals, as appropriate;
- toxicokinetics and toxicodynamics, including information on possible carry-over of the contaminant from feed to edible animal tissue/products;
- information about acute and long term toxicity in animals and humans, including epidemiological data on humans and other relevant toxicity data;
- conclusions and advice of toxicological expert(s) (groups), with references, including information on specially vulnerable population groups or animals.

Where data relies on analyses, validated qualitative and quantitative analytical data on representative samples should be supplied. Information on the analytical and sampling methods used and on the validation of the results should also be given. A statement on how representative the samples are for the contamination of the product in general (e.g. on a national basis) should be added. The portion of the commodity that was analysed and to which the contaminant content is related should be clearly stated and preferably should be equivalent to the definition of the commodity for this purpose or to existing related contaminant regulation.

Information on appropriate sampling procedures should also be supplied. Special attention to this aspect is necessary in the case of contaminants that may not be homogeneously distributed in the product (e.g. mycotoxins in some commodities).

INTAKE DATA

In order for a risk assessment of the public health impact of a contaminant or toxin to be carried out, it is important to have information on the contaminant concentration in those foods or food groups that cumulatively are responsible for at least half, and preferably 80% or more, of the total dietary intake of the contaminant. This should be assessed both for consumers with average and for those with high consumption patterns.

Where a contaminant is present in a food which is widely consumed (a staple food), it is desirable to have as much information as possible of the contaminant intake by the population so that a realistic risk assessment can be carried out.

Aspects to be considered when collecting intake data are:

- presence in food of dietary significance for the contaminant;
- presence in foods that are widely consumed;
- presence in animal feed and feed components;
- food intake data for average and most exposed/high consumer groups;
- results from total diet studies;
- calculated contaminant intake data from food consumption models;
- data on intake by susceptible groups; and
- data on intake by food producing animals.

For those contaminants which can be present in food of animal origin as a consequence of the carry-over from animal feed, information about the presence of the contaminant in the feed and feed components is also necessary. In addition, the intake of contaminants by the different food producing animals, and the resulting levels of the contaminant in the food of animal origin should also be estimated.

Food consumption data for the average consumer, the high (most exposed) consumer and for susceptible consumer groups are also important.

SETTING OF MAXIMUM LEVELS

Maximum levels for food should only be set where the presence of the contaminant can pose a significant risk to public health, and should only be set for food that is significant for the total exposure of the consumer to the contaminant.

It is a Codex principle that the MLs should be set at levels as low as reasonably achievable and which are necessary to protect the consumer.

MLs should be based on data from various countries and sources encompassing the main production and processes for the food.

It is also important that MLs are set at a level which is (slightly) higher than the normal range of variations of levels in food and feed that are produced with adequate technological methods based on Good Manufacturing Practice and / or Good Agricultural Practice. The MLs should not be set lower than a level which can be analysed using methods of analysis that can be readily set up and applied in laboratories in the different countries. The only exception would be if the potential public health risks are such that more elaborate methods of analysis with lower detection limits are justified by the potential risk to public health.

RISK ASSESSMENT

Chemical contaminants and toxins in foods come in a wide variety of chemical forms and there are also a number of ways in which foods can become contaminated. It is therefore much more difficult to control contamination in food and animal feed than it is to control, for example, food additives. In addition, the maximum levels of contaminants vary greatly, with some requiring control at milligram (1 thousandth of a gram) levels, whilst others can be as low as picograms (1 trillionth of a gram).

It is very important that assessments on the impact of proposed maximum levels are carried out in a consistent and realistic way.

The CCCF has to base the risk assessment on the toxicological evaluation of the contaminant carried out by JECFA together with the best estimate of dietary intake across the world, particularly where the food can form part of a national staple diet.

In support of the risk assessments the Codex Alimentarius Commission has adopted 'The Policy of the Codex Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods and Food Groups' (Section iii of the CAC Procedural Manual). This policy document gives the methodology for assessing the intake contributions needed for a risk assessment.

Under proposed Risk Analysis Principles developed by the CCCF:

- CCCF is primarily responsible for recommending risk management proposals for adoption by the CAC.
- JECFA is primarily responsible for performing the risk assessment upon which the CCCF and ultimately the CAC base their risk management recommendations.
- CCCF and JECFA must recognise that interaction between risk assessors and risk managers is critical to the success of risk analysis.
- CCCF and JECFA should ensure that their respective contributions to the risk analysis process, involve all interested parties, are fully transparent and thoroughly documented.
- JECFA, in consultation with CCCF, should continue to explore developing minimum quality criteria for data requirements necessary for JECFA to perform its risk assessments.

CODEX COMMITTEE ON CONTAMINANTS AND FOOD SUPPLEMENTS

IADSA has been involved with contaminants at Codex since 2002 when it was within the remit of the CCFAC. IADSA has represented the global supplement industry in CCCF working parties and meetings.

As all foods and ingredients which originate from natural sources are susceptible to contaminants and naturally occurring toxicants, food supplements are potentially as vulnerable as all other foods.

Over the years IADSA has been involved in CCCF working groups and discussions on a number of potential contaminants relevant to supplement ingredients including:

- dioxins and PCBs in fats and oils;
- heavy metals in ingredients of natural origin;
- the control of polycyclic aromatic hydrocarbons (PAHs) in foods;
- the presence of mycotoxins in botanical materials;
- the control of melamine in foods.

IADSA has long recognised that, due to the global nature of the ingredient supply chain, international dialogue on contaminants in foods is essential to ensure the responsible and safe production of food supplements.

CODEX COVERING FOOD SUPPLEMENTS

Disclaimer: This list is indicative only and non-exhaustive

INFORMATION TO CONSUMER	
Labelling	**Claims**
General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985)	General Guidelines on Claims (CAC/GL 1-1979)
Guidelines on Nutrition Labelling (CAC/GL 2-1985)	Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)
General Guidelines for Use of the Term Halal (CAC/GL 24-1997)	
Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CAC/GL 32-1999)	

COMPOSITION					
General Principles	**Vitamins and Minerals**	**Probiotics**	**Additives**	**Processing Aids**	**Flavourings**
General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9-1987) A model for Establishing Upper Levels of Intake for Nutrients and Related Substances – Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment WHO Headquarters, Geneva, Switzerland 2-6 May 2005	Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55-2005)	Guidelines for the Evaluation of Probiotics in Food: Joint FAO/WHO Working Group meeting, London Ontario, Canada, 30 April-1 May 2002	General Standard for Food Additives (CODEX STAN 192-1995) Class Names and the International Numbering System for Food Additives (CAC/GL 36-1989) List of Codex Specifications for Food Additives (CAC/MISC 6-2012) Guidelines for Simple Evaluation of Food Additive Intake (CAC/GL 3-1989)	Guidelines on Substances used as Processing Aids (CAC/GL 75-2010)	Guidelines for the Use of Flavourings (CAC/GL 66-2008)

QUALITY & SAFETY
General Principles
General guidelines on sampling (CAC/GL 50-2004)
Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999)
Guideline for the Validation of Food Safety Control Measure (CAC/GL 69-2008)
General Principles of Food Hygiene (CAC/RCP 1-1969)

CHEMICAL SAFETY	
Contaminants	**Pesticides**
General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995)	Guidelines on Good Laboratory Practice in Pesticide Residue Analysis (CAC/GL 40-1993)
Recommended Methods of Sampling for Pesticide Residues for the Determination of Compliance with MRLs (CAC/GL 33-1999)	Maximum Residue Limits (MRLs) for Pesticides (CAC/MRL 1)
Maximum Residue Limits for Veterinary Drugs in Food (CAC/MRL 2)	

BIOLOGICAL SAFETY	
Irradiation	**Microbiology**
Code of Practice for Radiation Processing of Food (CAC/RCP 19-1979) General Codex Methods for the Detection of Irradiated Foods (CODEX STAN 231-2001)	Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997) Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007)

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