

PRINCIPLES FOR GLOBAL ALIGNMENT ON HEALTH FOOD INGREDIENTS

MICHELLE STOUT, CHAIR



IADSA

Created due to the increasing regulation at global, regional
and national level

&

the need for global expertise and experience on scientific,
technical, regulatory and policy issues.

IADSA is a non-profit organization with more than 20 years
close involvement in Codex Alimentarius.

THE CHALLENGE

More than 70 governments worldwide are developing or significantly amending legislation in the food supplement area.

Food supplements have their own specific requirements.

OUR APPROACH

Partnerships in countries and regions where supplement regulation and policy is being developed, modified or harmonized.

A wide range of publications and tools for all involved in the food supplement sector.



SCIENTIFIC



Concepts of Health Maintenance and Promotion: Integrating Nutritional and Botanical Products



Nutritional risk analysis approaches for establishing maximum levels of vitamins and minerals in food (dietary) supplements



Vitamin and Mineral Safety handbook 3rd Edition



Bioactive Food Components: Changing the Scientific Basis for Intake Recommendations



Ensuring micronutrient adequacy for vulnerable groups around the world: the role of food supplements



Scientific Substantiation of health claims: A global analysis



The Updated Risk Assessment of Vitamin D

TECHNICAL



Tolerances for food supplements: An introductory guide



Certificates of Analysis for Supplement Ingredients: Guidelines on Their Preparation and Use



Shelf-Life Recommendations for Supplements



Global Guide to the Handling of Adverse Event Complaints



Global Guide to Good Manufacturing Practice for Supplements

VALUE



The evolution of the health supplements sector



Realising healthcare cost savings through more widespread use of dietary supplements



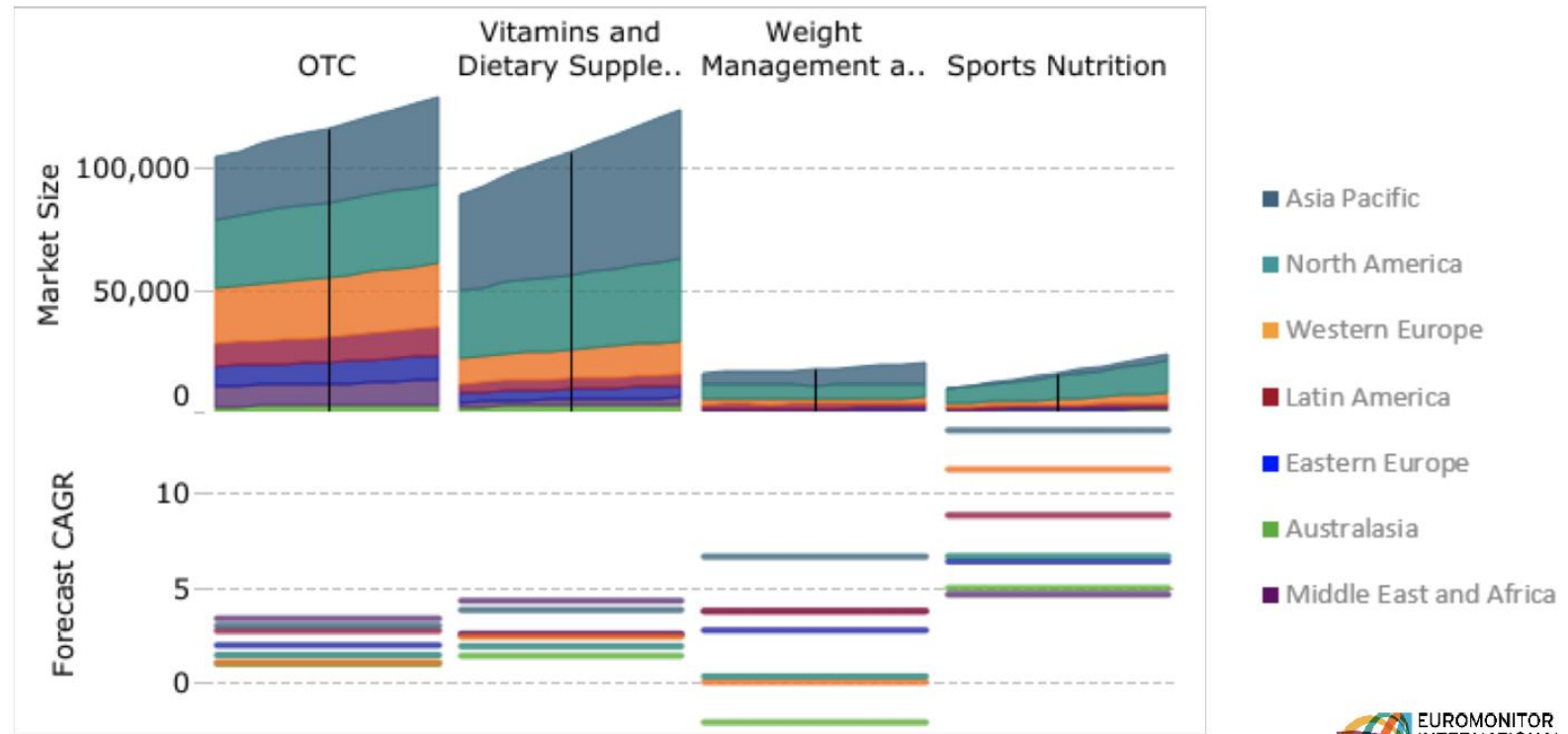
Nutrition, Healthy Ageing and Public Policy

**FOOD SUPPLEMENT MARKET TO
OVERTAKE OTC DRUG MARKET BY 2023**



GLOBAL

Consumer Health: Region Size and Growth by Category 2013-2023
Retail Value RSP USD Million

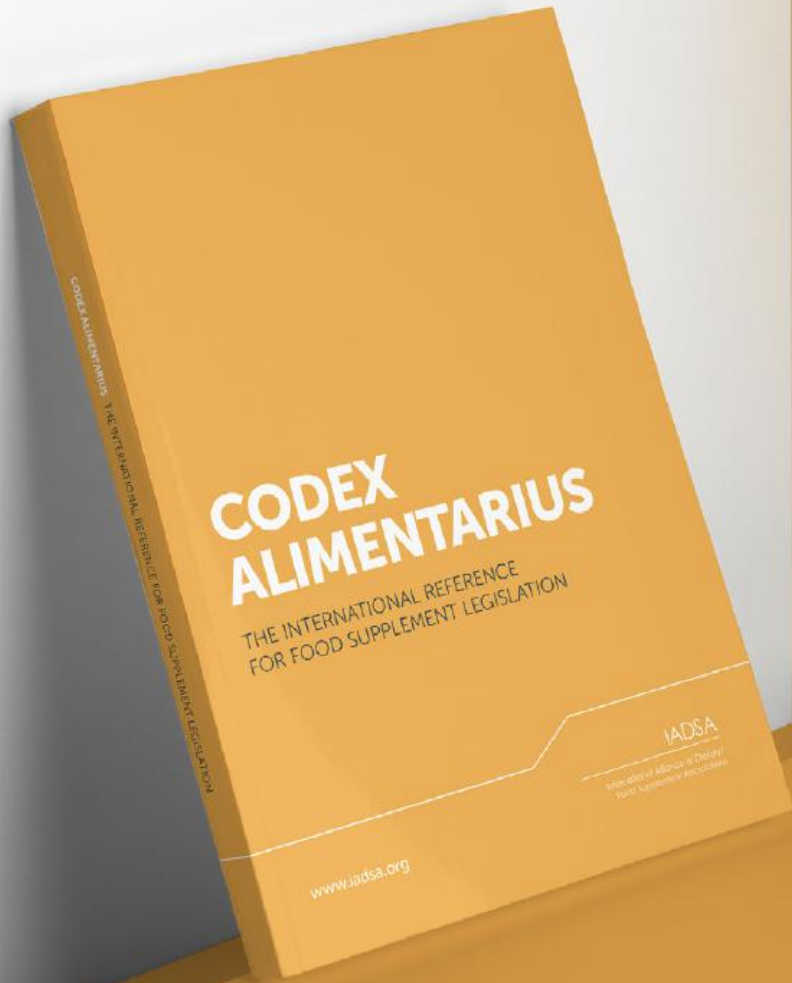


ALIGNMENT ON REGULATORY FRAMEWORK FOR FOOD SUPPLEMENTS



Codex alimentarius

Codex alimentarius: The international reference for food supplements



English version



French version



Spanish version



ALIGNMENT ON ADDITIVES

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CODEX COMMITTEE ON FOOD ADDITIVES (CCFA)

FOOD SUPPLEMENTS Category 13.6



GSFA Online

Updated up to the 42nd Session of the Codex Alimentarius Commission (2019)

FOOD CATEGORY DETAILS

Food supplements (13.6)

Description:

Includes vitamin and mineral supplements in unit dose forms such as capsules, tablets, powders, solutions etc., where national jurisdictions regulate these products as food.¹

This page provides information on the food additive provisions that are acceptable for use in foods conforming to the food category.

GSFA Provisions for Food Category 13.6

INS No.	Food Additive or Group	Max Level	Notes	Defined In
	ASCORBYL ESTERS			13.6
950	Acesulfame potassium	2,000 mg/kg	Note 10 Note 188 Note 144	13.6
129	Allura red AC	300 mg/kg		13.6
951	Aspartame	5,500 mg/kg	Note 191	13.6
962	Aspartame-acesulfame salt	2,000 mg/kg	Note 113	13.6
	BENZOATES			13.6
901	Beeswax	GMP	Note 3	13.6
133	Brilliant blue FCF	300 mg/kg		13.6
320	Butylated hydroxyanisole (BHA)	400 mg/kg	Note 196 Note 15	13.6
321	Butylated hydroxytoluene (BHT)	400 mg/kg	Note 196 Note 15	13.6
	CAROTENOIDS			13.6
	CHLOROPHYLLS AND CHLOROPHYLLINS, COPPER COMPLEXES		Note 3	13.6
	CYCLAMATES			13.6
902	Candelilla wax	GMP	Note 3	13.6
150c	Caramel III - ammonia caramel	20,000 mg/kg		13.6
150d	Caramel IV - sulfite ammonia caramel	20,000 mg/kg		13.6
120	Carmines	300 mg/kg	Note 178	13.6
903	Carnauba wax	5,000 mg/kg	Note 3	13.6
160a(ii)	beta-Carotenes, vegetable	600 mg/kg		13.6
1503	Castor oil	1,000 mg/kg		13.6

ALIGNMENT ON APPROACH ON MAXIMUM LEVELS FOR VITAMINS & MINERALS



GUIDELINES FOR VITAMIN AND MINERAL FOOD SUPPLEMENTS

CAC/GL 55 - 2005

3.2 Contents of vitamins and minerals

3.2.1 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.

3.2.2 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).

GUIDELINES FOR VITAMIN AND MINERAL FOOD SUPPLEMENTS CAC/GL 55 - 2005

PREAMBLE

Most people who have access to a balanced diet can usually obtain all the nutrients they require from their normal diet. Because foods contain many substances that promote health, people should therefore be encouraged to select a balanced diet from food before considering any vitamin and mineral supplement. In cases where the intake from the diet is insufficient or where consumers consider their diet requires supplementation, vitamin and mineral food supplements serve to supplement the daily diet.

1. SCOPE

1.1 These guidelines apply to vitamin and mineral food supplements intended for use in supplementing the daily diet with vitamins and/or minerals.

1.2 Food supplements containing vitamins and/or minerals as well as other ingredients should also be in conformity with the specific rules on vitamins and minerals laid down in these Guidelines.

1.3 These Guidelines apply only in those jurisdictions where products defined in 2.1 are regulated as foods.

1.4 Foods for special dietary uses as defined in the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985) are not covered by these Guidelines.

2. DEFINITIONS

2.1 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 quantities¹ 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.

3. COMPOSITION

3.1 SELECTION OF VITAMINS AND MINERALS

3.1.1 Vitamin and mineral food supplements should contain vitamins/provitamins and minerals whose nutritional value for human beings has been proven by scientific data and whose status as vitamins and minerals is recognised by FAO and WHO.

3.1.2 The sources of vitamins and minerals may be either natural or synthetic and their selection should be based on considerations such as safety and bioavailability. In addition, purity criteria should take into account FAO/WHO standards, or if FAO/WHO standards are not available, international Pharmacopoeias or recognized international standards. In the absence of criteria from these sources, national legislation may be used.

¹ This refers to the physical forms of the vitamin and mineral food supplements not to the potency of the supplements.

ALIGNMENT ON TRADITION OF USE FOR BOTANICAL INGREDIENTS



Traditional Use of Botanicals and Botanical Preparations

An International Perspective

Robert Anton, Basil Mathioudakis, Suwijiyu Pramono, Ekrem Sezik and Surinder Sharma*

Botanicals are used worldwide in food and supplements for their nutritional and physiological effects and have become part of the local and regional cultural heritage. The use of botanicals has evolved from experience over a long period of time, often over centuries. Folk knowledge of this use has been passed on from generation to generation and later been systematically recorded. This information is collectively called 'traditional use' and is the largest body of observational evidence in humans available. It is recognised as a valid body of knowledge to support the safe use of botanicals and document their health benefits. This paper describes the experience on how traditional use is accepted as a basis for support of the safety and benefits for health of botanical preparations used in food supplements. It proposes a common basis for the mutual acceptance of the evidence as assessed by expert judgement that may lead to recognition of the safety and benefits of botanicals in different parts of the world.

Keywords: Traditional use; botanicals; folk use; systematic use; conditions of use; physiological benefits; safety; food law; supplements.

I. Introduction

The use of botanicals and botanical preparations (hereafter referred to as botanicals) is as deeply rooted in local and regional culture as are traditional dishes and dietary habits. It is part of the heritage of knowledge that has accumulated over time and is transferred from generation to generation.

Representing four regions of the world, each with a distinct and extensive history and clear recognition of history of use of botanicals, this paper reflects the collective views of leading experts in the field on what information constitutes traditional use, exploring and describing how such traditional knowledge has accumulated and is used. This paper focuses exclusively on the tradition of use of botanicals used for nutritional or physiological benefits in supplements. In this paper, the term 'supplements' is used to designate a category of products in various jurisdictions referred to as 'food supplements', 'dietary supplements' or 'health supplements'. It covers concentrated forms of botanicals and other food com-

pounds, in small unit dose form, intended to supplement the diet.

The aim of this paper is to:

- Provide an authoritative account of traditional uses of botanicals, principally in foods and supplements, based on knowledge, practice and experience from different parts of the world.
- Identify the key parameters characterising traditional use.

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TRADITIONAL USE OF BOTANICALS AND BOTANICAL PREPARATIONS

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THE AIM OF THE PAPER (1)

Provide an authoritative account of traditional uses of botanicals, principally in supplements, based on knowledge, practice and experience from different parts of the world.

Identify the key parameters characterising traditional use.

THE AIM OF THE PAPER (2)

Describe how the traditional evidence regarding the safe and beneficial use of botanicals is generated, compiled, documented, transmitted and accepted.

Contribute to the reflection of regulatory authorities on the potential use and application of tradition of use in regulation.

ALIGNMENT ON CLAIMS SUBTANTIATION



GUIDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS - CAC/GL 23-1997

GUIDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS

CAC/GL 23-1997

Nutrition claims should be consistent with national nutrition policy and support that policy. Only nutrition claims that support national nutrition policy should be allowed.

Health claims should be consistent with national health policy, including nutrition policy, and support such policies where applicable. Health claims should be supported by a sound and sufficient body of scientific evidence to substantiate the claim, provide truthful and non-misleading information to aid consumers in choosing healthful diets and be supported by specific consumer education. The impact of health claims on consumers' eating behaviours and dietary patterns should be monitored, in general, by competent authorities. Claims of the type described in section 3.4 of the Codex *General Guidelines on Claims* are prohibited.

1. SCOPE

- 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 advertising¹.
- 1.2 These guidelines apply to all foods for which nutrition and health claims are made without prejudice to specific provisions under Codex standards or Guidelines relating to Foods for Special Dietary Uses and Foods for Special Medical Purposes.
- 1.3 These guidelines are intended to supplement the Codex *General Guidelines on Claims* and do not supersede any prohibitions contained therein.
- 1.4 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. DEFINITIONS

- 2.1 **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 following do not constitute nutrition claims:
 - (a) the mention of substances in the list of ingredients;
 - (b) the mention of nutrients as a mandatory part of nutrition labelling;
 - (c) quantitative or qualitative declaration of certain nutrients or ingredients on the label if required by national legislation.
- 2.1.1 **Nutrient content claim** is a nutrition claim that describes the level of a nutrient contained in a food. (Examples: "source of calcium"; "high in fibre and low in fat".)
- 2.1.2 **Nutrient comparative claim** is a claim that compares the nutrient levels and/or energy value of two or more foods. (Examples: "reduced"; "less than"; "fewer"; "increased"; "more than".)
- 2.1.3 **Non-addition claim** means 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.
- 2.2 **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. Health claims include the following:

¹ Advertising means any commercial communication to the public, by any means other than labelling, in order to promote directly or indirectly, the sale or intake of a food through the use of nutrition and health claims in relation to the food and its ingredients.

**ALIGNMENT ON POSITIVE ECONOMIC
IMPACT: HEALTH CARE COST SAVINGS**



WHAT DOES THIS MEAN?

**Regular use of targeted supplementation
by at risk populations could result in significant
cost savings for healthcare systems and providers**

AND

improve the level of individual wellbeing.



ALIGNMENT ON VALUE

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**MIND
THE
GAP**

MIND THE GAP ALREADY

4 STORIES AND MORE TO COME!



BRIDGING THE VITAMIN D GAP

Vitamin D facts, the
good news bad news,
Hip Hip Houray !



FINLAND: THE VITAMIN D PIONEER

How Finland has developed
and implemented policy
around vitamin D



OMEGA 3: THE MAKING OF YOU

The making of you
Omega 3 and the first
1,000 days of life



FOLIC ACID: THE BEST OF BOTH WORLDS

Combining folic acid
fortification and
supplementation for
healthier babies

THE GLOBAL ALLIANCE OF THE FOOD SUPPLEMENT SECTOR

[Explore our resources](#)

[Mind the Gap](#)



Vitamin D is classed as a Nutrient of Public Health Concern.*

That means experts think we're not getting enough of it. Are you?

#iadsamindthegap

* <https://health.gov/dietaryguidelines/2015/guidelines/chapter-2/a-closer-look-at-current-intakes-and-recommended-shifts/#underconsumed-nutrients>

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Thank you

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