ReC HaN
Resource Centre for Health supplements and Nutraceuticals

Health Supplements and Nutraceuticals

Compliance Guidance

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Confederation of Indian Industry

IADSA
International Alliance of Dietary/ Food Supplement Associations

Contents

Preface

India has implemented its first regulation for Health Supplements and Nutraceuticals, from 1 January 2018. Health supplements and nutraceuticals are food products that differ significantly from food products in appearance and purpose of use. They are also known as dietary supplements or food supplements.

While being controlled by the specific regulation, health supplements are also subject to several complementary regulations such as labelling, claims, GMP, licensing, import etc. that food businesses must consider and comply.

This RecHaN compliance guidance serves as a place for food business operators to find key regulatory requirements, similarities and where indicated differences with global practice. This guidance provides a simplified understanding of the regulation by use of text and graphics to enable understanding at a glance.

It is intended for all food business operators engaged in manufacturing, import, distribution and sale of health supplements and nutraceuticals as well as food safety officers implementing the regulation. This guidance attempts to encourage dialogue and the finding of common ground between all stakeholders based on global practice, including globally accepted interpretations.

The authors recognise that as is the case with many first-time regulations, several interim and temporary measures may be taken by the competent authorities to reduce the burden of compliance during the initial makeover of products in the market. The Food Business Operator is required to be closely engaged with the competent authority and the issuance of amendments.

The authors realise that several more facets of the regulation remain to be tackled, including revisions to this document, and expect to release updated and new additions at the appropriate time.

Section 1

Introduction

The International Alliance of Dietary/Food Supplements Associations (IADSA) and Confederation of Indian Industries (CII) have established a collaborative initiative under the Resource Center on Health Supplements and Nutraceuticals (RecHaN).

IADSA brings together associations from 6 continents in the food supplement sector to coordinate discussions in Codex Alimentarius and support governments and the private sector on appropriate and effective regulation and policy. A leading international expert association, it aims to build science based interactive platforms for policymaking and harmonised approaches to legislation.

CII (Confederation of Indian Industries) a premier business association of industries serves as a reference point for Indian industry and the international business community. CII through the Food and Agriculture Centre of Excellence (CII-FACE) provides an integrated approach of action-oriented programs and capacity building addressing issues from the farm gate to consumers. It works in partnership with government, FSSAI, Industry and other stakeholders.

The Food Safety and Standards (Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purpose, Functional Foods and Novel Food) Regulations, 2016, due for implementation from 1st January 2018, requires businesses to be compliance ready. As with many first-time regulations, stakeholders may, in the initial stages face uncertainty with compliance requirements and require ongoing guidance. It is appropriate RecHaN should as its first initiative help strengthen compliance efforts.

This guidance is prepared based on reading of the Act; FSSA (2006) and regulations; Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Uses, Food for Special Medical Purpose, Functional Foods and Novel Foods) Regulations 2016. In addition, the document provides guidance on international regulation and best practice where this can prove helpful in the process of ensuring compliance in India.

This document reflects the best understanding of the authors at the time of writing and has no legal bearing, nor is it intended to substitute the implementation procedures of the competent authority.

Section 2

Definition and Identity of Health Supplements and Nutraceuticals

1. How are Health Supplements defined?

A reading of section 22 of the Food Safety and Standards Act (FSSA) provides the scope for use of the term Health Supplements, which is harmonised with global definitions.

'Health supplement' is described as a dietary substance(s) for use by human beings to supplement the diet by increasing the total dietary intake, and may contain one or more of any of the following ingredients:

(a) plant or botanicals or their parts in the form of powder, concentrate or extracts in water, ethyl alcohol or hydro-alcoholic extracts, single or in combination;
(b) minerals or vitamins or proteins or metals or their compounds or amino acids, or enzymes, or
(c) substances from animal origin and
(d) whereby such products may be formulated in the form of powders, granules, tablets, capsules, liquids, jelly or other dosage forms;

and which are not represented for use as conventional foods.

2. How are Health Supplements defined in other countries?

The term Health Supplements is also used to refer to the category in ASEAN, but they are referred to as food supplements in the EU and dietary supplements in the US. Whatever the name used, they belong to the food category number 13.6 of the global Food Category System used by Codex Alimentarius and in international trade.

In ASEAN (ASEAN Agreement on Heath Supplements), the following definition has been agreed:

"Health Supplements" mean any product that is used to supplement a diet and to maintain, enhance and improve the healthy function of human body and contains one or more, or a combination of the following:

i. Vitamins, minerals, amino acids, fatty acids, enzymes, probiotics and other bioactive substances.
ii. Substances derived from natural sources, including animal, mineral and botanical materials in the forms of extracts, isolates, concentrates, metabolites.
iii. Synthetic sources of ingredients mentioned in (i) and (ii).

It is presented in dosage forms (to be administered) in small unit doses such as capsules, tablets, powder, liquids and it shall not include any sterile preparations (i.e. injectable, eye drops).

The definition of food supplements in the EU is established in the Food Supplement Directive: 2002/46 EC on the approximation of the laws of the Member States relating to food supplements.

'Food supplements' means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.

In the US Dietary Supplement Health Education Act (1994) the term 'dietary supplement' means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(A) A vitamin;
(B) A mineral;
(C) An herb or other botanical;
(D) An amino acid;
(E) A dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
(F) A concentrate, metabolite, constituent, extract or combination of any ingredient described in clause (A), (B), (C), (D) or (F) and enzymes

Are not represented for use as a conventional food or as sole item of a meal or the diet.

At the global level, a definition is provided by Codex Alimentarius on vitamin and mineral food supplements.

Guidelines for Vitamin and Mineral Food Supplements CAC/GL 55-2005: vitamin and mineral food supplements for the purpose of these guidelines derive their nutritional relevance primarily from the vitamins and/or minerals they contain. Vitamin and mineral food supplements are sources in concentrated forms of those nutrients alone or in combination, 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 vitamin and/or minerals for the normal diet.

3. Are the definitions of Health Supplements, Food Supplements and Dietary Supplements harmonised globally?

Over many years, the definitions of the category have become aligned. Definitions across the world include the following definitive terms;

- Supplements are designed to 'supplement' the diet;
- They are marketed in pre-dosed forms such as tablets, pills, capsules, powders, liquids;
- They have a nutrition or physiological effect;
- They are taken in small measured quantities;
- They are not to be presented as ordinary or conventional foods;

4. How are Health Supplements distinct from other food products?

In the FSS (HSN) 2016 regulation several other food categories are included namely foods for special dietary uses (FSDU), food for special medical purpose (FSMP).

As stated above, Health Supplements are categorised in sub-category 13.6 of Category 13.0: Foodstuffs intended for particular nutrition, of the Codex Food Category System (GSFA 192: 1995) and FSS (Food Products Standards and Food Additives) Regulation 2011: (7th Amendment, 2016).

Category 13.0 contains several sub-categories:

Food Category System [1, 2]

13.0 Foodstuffs intended for particular nutrition

- 13.1 Infant formulas, follow-on, and formulas for special medical purposes for infants
  - 13.1.1 Infant formulas
  - 13.1.2 Follow-up formulas
  - 13.1.3 Formula for special medical purposes for infants
- 13.2 Complementary foods for infants and young children
- 13.3 Dietetic foods intended for special medical purposes (excluding products of food category 13.1)
- 13.4 Dietetic formulas for slimming purposes and weight reduction
- 13.5 Dietetic foods (e.g. supplementary foods for dietary uses) excluding products in food categories 13.1, 13.4 and 13.6
- 13.6 Food Supplements [3]

1. Food Category System: Codex Stan 192-1995
2. Food Safety and Standards (Food Product Standards & Food Additives) Regulations 2011; (7th Amendment 2016)
3. Products in the category 13.6 are also described as 'Health Supplements', or 'Dietary Supplements'

Health Supplements belong to sub-category 13.6 and are distinct from other food categories in terms of their physical form and purpose of use. These distinguishable factors are extremely important for the purpose of consistency in compliance and enforcement.

It is to be noted that Health Supplements are not similar to foods for special dietary uses or foods for special medical purposes or normal foods as the purpose of use differs.

5. How are Nutraceuticals defined?

FSS (HSN) 2016[7(1)(iii)] highlights that Nutraceuticals may be prepared and sold in the food format of granules, powder, tablet, capsule, liquid, jelly or gel, or semi-solids and other formats and may be packed in sachet, ampoule, bottle, and in any other format as measured unit quantities except those formats that are meant for parental administration.

Food products intended to supplement the diet and be marketed in forms such as capsules, tablets, powders or liquids etc. are described in regulations worldwide with a single terminology. e.g. dietary supplements, food supplements or Health Supplements.

- The descriptions of Nutraceuticals and Health Supplements are similar in terms of their identifying features; these similarities are emphasised in the document.

These similarities between Health Supplements and Nutraceuticals are emphasised in the document.

6. How are Health Supplements distinct from normal foods?

Two criteria distinguish Health Supplements and set them apart from normal (ordinary or conventional foods):

01. Their marketable forms such as capsules, tablets, powders or liquids to be taken in small measured quantities;
02. Their purpose of use as presented (declared as “Health Supplement” on the label);

In some cases challenges may occur with some foods or food ingredients, which being a normal food can be identical in terms of their form to Health Supplements.

For example; psyllium husk a popular food (fiber) marketed for several years as a normal food to be added (1-2 teaspoons) to water, milk, or porridge, according to instructions for use.

The same fiber (psyllium husk) preparation may also be marketed as a Health Supplement, being a concentrated source of fiber, meant to supplement the diet and marketed to be taken in small measured quantities; for example (1-2 capsules a day) or as a powder (1-2 tablespoons). It therefore complies in form. However, its purpose of use is the next criteria to be fulfilled. The intended purpose of use in this case is a Health Supplement and the same is to be declared on the label.

Similarly a Health Supplement may be marketed in the form of pastilles, soft chews, lozenges; but must meet all the labelling declarations provided in the regulation, including packaging that supports the purpose of use such as the advisory “Keep out of reach of children”, as these forms may be indistinguishable from normal foods eaten for enjoyment.

7. How are Health Supplements distinct from fortified food products

Fortified foods in terms of their physical form are more similar to normal foods than to Health Supplements. Fortified foods include, for example, milk (Vitamin A and/or D), edible oil (Vitamin A and/or D), wheat flour (Iron, folic acid, Vitamin B12), malted beverages, juices (vitamin C), etc. The addition of some vitamins and minerals to foods may be mandatory in the context of national nutritional goals.

Fortified foods are also consumed in larger quantities and as part of the conventional diet unlike Health Supplements. They play a significant role in contributing to the total daily energy intake, again unlike Health Supplements. They are marketed as normal or ordinary foods (milk, edible oil etc.), and in conventional food forms (beverages, juices, biscuits etc.).

Health Supplements are consumed in small unit quantities and not designed to provide a significant amount of energy.

8. How are Health Supplements distinct from foods for special dietary uses

Foods for special dietary uses (FSDU) are intended for vulnerable consumer groups and often used to replace all, one or more meals. These foods are specially prepared for those with a specific dietary need due to a physiological condition or disorder and when normal foods are incapable of meeting their needs.

For example, specially prepared meals for those on weight control diets; providing 400kcal or 800-1200kcal. Another example is gluten-free foods for persons with celiac disorder. They are eaten in conventional food forms (biscuits, shakes, soups etc.).

Since these foods are required to provide the daily dietary needs of energy and macronutrients, FSDU's are not produced or marketed in the form of tablets, capsules etc.; foods in these forms are considered health supplements.

9. How are Health Supplements distinct from foods for special medical purpose?

The regulation FSS (HSN) 2016 recognises this special category of foods designed for a medical purpose for a particular target group, who may rely on these products for their sole source of nutrition.

The regulation sets the minimum and maximum requirements for vitamins and minerals for FSMP (Schedule III) of the FSS (HSN) 2016 which is suitable for use as the sole source of nutrition and ensures their nutrition needs are met. Foods marketed as “Foods for Special Medical Purpose” have restricted access as they are labelled “RECOMMENDED TO BE USED UNDER MEDICAL ADVICE ONLY” and those who use them need medical supervision.

10. How are Health Supplements distinct from medicinal products?

Health Supplements are not intended to diagnose, treat, mitigate or prevent, any disease or disorder in human beings and are not to be marketed or presented or claimed as having such properties.

Even though Health Supplements share some of the marketable forms of drugs, such as capsules, pills, tablets etc. they are closely regulated in terms of the nutritional and health claims they may include disease risk reduction claims. Foods products are prohibited from making claims that suggest or imply that they can diagnose, treat, mitigate or prevent a disease or disorder.

Additionally every package of Health Supplements must be labelled “HEALTH SUPPLEMENT” and “NOT FOR MEDICINAL USE”

Section 3

Information on Labels

Labelling requirements

Applicable to	
Health Supplements	Nutraceuticals
✓	✓

Labelling of "Health Supplements" and "Nutraceuticals" is subject to compliance with the following regulations:

(a) Compliance with the specific requirements under the Food Safety and Standards (Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purpose, Functional Foods, Novel Foods) Regulation 2016.

(b) Compliance with the general labelling regulation requirements for pre-packaged foods; Food Safety and Standards (Packaging and Labelling) Regulation 2011.[1] Under 2.2.1.1: General Requirements "every pre-packaged food shall carry a label containing information as required hereunder unless otherwise provided";

(c) The FBO is advised to also follow the requirements, as applicable, under the Legal Metrology (Packaged Commodity) Rules 2011 and amendments thereto.

Additionally, the FBO is responsible for providing sufficient information on the nature and purpose of the product along with detailed instructions and precautions for its use, the target consumer group it addresses and recommended duration of use.

1. The general regulation on labelling is under review and Food Business Operators should refer to the regulation in force at the time of marketing the product

A. Specific labelling requirements – FSS (HSN) 2016

According to the FSS (HSN) 2016: ((6(3)(iii) and 7(4)(iii)) the labelling of Health Supplements and Nutraceuticals should provide the following information.

1. Name of the category

Applicable to	
Health Supplements	Nutraceuticals
✓	✓

The category name under which the product is sold shall be “HEALTH SUPPLEMENT” or “NUTRACEUTICAL” as applicable.

Global Practice

National terminology

India	Canada	China	Korea	USA	Russia
Health Supplement + Nutraceutical	Natural Health Product (NHP)	Health Food	Health Functional Food (HFF)	Dietary Supplement	Biologically Active Supplement (BAS)

National terminology

ASEAN	European Union	Pacific Alliance
Health Supplement	Food Supplement	Food Supplement

2. The common name

01. The common name of the Health Supplement or Nutraceuticals should be a description sufficient to indicate the true nature of the product, including the common names of the categories of nutrients or substances that characterise the product. It is important to note that the overriding principle is that the name or description of the product should be sufficient for the consumer to make an informed choice.

02. Examples of categories of nutrients or substances that characterise the product:
e.g. amino acids and botanicals.

03. Several categories could be used to characterise the product:
e.g. Health Supplements with vitamins, minerals and amino acids.

3. Nutrition labelling

Applicable to	
Health Supplements	Nutraceuticals
✓	✓

The amount of nutrients or substances with a nutritional or physiological effect present in the product shall be declared as provided under FSS (HSN) 2016 [6(3)(iii)(c) and [7(4)(iii)(c)].

01. Though not specifically stated this information constitutes the Nutrition Information required to be provided to consumers in the same way that regulation [FSS (PL) 2011 (2.2.2.3)] requires it for general foods.

02. Information may be provided in a Nutrition Information panel.

03. The information should be consistent with the category definition of providing concentrated sources of substances to be taken in small measured quantities and in forms such as capsules, tablets, powders or liquids.

04. The nutrition information should therefore be on a per serving basis [and **not** per 100g or 100ml as these products are consumed on a serving or dose basis.

    If the recommended amount to be taken per day - more than 1 unit (e.g. 1 tablet, capsules etc) – it is good practice that the declaration of the serving size should reflect the maximum amount to be taken per day (e.g. the number of tablets or capsules) as recommended on the label.

    e.g. If the recommended serving (dosage) on the label is 1-3 tablets per day, the serving size in the nutrition panel will be 3 tablets.

Global Practice

Dietary Supplements / Health Supplements are generally exempted from the nutrition declaration per 100g or 100ml (e.g. ASEAN, USA, European Union)

05. The manner of such a declaration, (i.e. per serving) - according to FSS (PL) 2011 [2.2.2.3(v)] which states that "where the nutrition declaration is made per serving, the amount in (g) or (ml) should be included for reference beside the serving measure", – e.g. given below;

    i. 1 capsule (200mg)
    ii. 1 scoop (28g)
    iii. 1 teaspoon (5ml)
    iv. The recommended daily consumption of the product (dose) recommended by the Food Business Operator should be clear and consistent to the consumer.

06. Quantity of nutrients [FSS (HSN) 2016 [6(3)(iii)(e) and [7(4)(iii)(d)] [1]

Applicable to	
Health Supplements	Nutraceuticals
✓	✓

Where applicable the amount of nutrients must be expressed as a percentage of the relevant recommended daily allowances (RDA) as specified by the Indian Council of Medical Research (ICMR) and where these are not specified by ICMR, the NRV provided by Codex Alimentarius apply.

This requirement is typically to be provided in the Nutrition Information panel which is a specific requirement for Health Supplements and Nutraceuticals; FSS (HSN) 2016 [6(3)(iii)(e)] and [7(4)(iii)(d)].

Global Practice

Under Global Practice this requirement of declaration of percentage of RDA for the nutrient is supported by the definition of 'nutrients':

- Codex Guidelines on nutrition labelling: CAC/GL/2-1985:
  - Nutrient means any substance normally consumed as a constituent of food:
    - (a) which provides energy; or
    - (b) which is needed for growth, development and maintenance of life; or
    - (c) a deficit of which will cause characteristic bio-chemical or physiological changes to occur.

Where no RDA is set by ICMR, the percentage of the nutrient declared should be based on the NRV provided by Codex.

Vitamins	ICMR (RDA)	Codex (NRV)	Minerals	ICMR (RDA)	Codex (NRV)
Vitamin A (retinol)	600 µg				
Vitamin A (β – carotene)	4800 µg		Calcium	600 mg	
Vitamin B1	1.2 mg		Chloride		
Vitamin B2	1.4 mg		Chromium	33 µg	
Vitamin B6 (pyridoxine)	2 mg		Copper	1.35 mg	
Vitamin B12	1 µg		Iodine	150 µg	
Vitamin C	40 mg		Iron	17 mg	
Vitamin D	10 µg		Magnesium	340 mg	
Vitamin E	7.5 – 10 mg		Manganese	2 - 5 mg	
Vitamin K	55 µg		Molybdenum		
Vitamin K2 (MK-7)			Phosphorus	600 mg	
Vitamin K3 (MK-4)			Potassium	3750 mg	
Biotin		30 µg	Selenium	40 ug	
Folate dietary	120 µg		Sodium	2092 mg	
Niacin equivalent	16 mg		Zinc	12 mg	
Pantothenic acid		5 mg	Boron		

Reference to clause 6.2 (iii)

- RDA set by ICMR for man of sedentary work: Nutrient requirements and recommended dietary allowances for Indians (Final Draft) 2009.
- NRV provided by Codex: Guidelines on nutrition labelling (CAC/GL 2-1985)

Advisories

07. An advisory warning 'NOT FOR MEDICINAL USE' prominently written FSS (HSN) 2016 [6(3)(iii)(d)] and [7(4)(iii)(f)]

Applicable to	
Health Supplements	Nutraceuticals
✓	✓

08. A statement that the product should not be used as a substitute for a varied diet FSS (HSN) 2016 6(3)(iii)(f)

Applicable to	
Health Supplements	Nutraceuticals
✓	✗

09. A warning or any other precautions to be taken while consuming, known side effects, if any FSS (HSN) 2016 [6(3)(iii)(g)] and [7(4)(iii)(h)]

Applicable to	
Health Supplements	Nutraceuticals
✓	✓

e.g. Do not use if pregnant and nursing

10. A statement that the product is required to be stored out of reach of children FSS (HSN) 2016 [6(3)(iii)(h)] and [7(4)(iii)(i)]

Applicable to	
Health Supplements	Nutraceuticals
✓	✓

11. Products should bear the warning 'not to exceed the stated recommended daily usage'.FSS (HSN) 2016 [6(3)(iii)(e)] and [7(4)(iii)(d)]

Applicable to	
Health Supplements	Nutraceuticals
✓	✓

12. In the case of vitamins and minerals, the activity of the compounds must also be taken into account and indicated for the characteristic substances as the proportion with physiological activity

Applicable to	
Health Supplements	Nutraceuticals
✓	✓

e.g. thiamine hydrochloride must be indicated as free-form thiamine).

B. General labelling requirements for pre-packaged foods FSS (PL) 2011[2]

1. List of Ingredients: FSS 2011 (2.2.2.2. (c))

Applicable to	
Health Supplements	Nutraceuticals
✓	✓

01. The list of ingredients should be declared under an appropriate title e.g. “Ingredients”.

02. All ingredients must be listed by weight in descending order in accordance with the formula, except for e.g. water and other volatile substances, which are listed in order of their weight in the finished product.

03. It is also recommended that vitamins and minerals be indicated in the labelling using the names listed in Schedule I FSS (HSN) 2016 e.g. vitamin C. The name of the nutrient can also be supplemented with the name of the nutrient compound, e.g. vitamin C (ascorbic acid).

04. Regarding the use of the names of botanicals in the list of ingredients, the common name as specified in Schedule IV of FSS (HSN) 2016 should be used. It is also advisable to use the full scientific name of the botanical (botanical family + species, e.g. *Acacia arabica*).

05. Food additives should be declared with their functional class and specific name or INS number.

2. The general regulation on labelling is under review and Food Business Operators should refer to the regulation in force at the time of marketing the product.

06. The indication of ingredients causing allergies or intolerances, while not specifically provided in the regulation should always be declared as a concern for the risk they may provide to certain individuals. They may be emphasised in the list of ingredients by using a different font size or style or a background colour for example.

    e.g. whey protein, casein, lecithin, fish oil

    Ingredients causing allergies or intolerances

    (i) Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridised strains and products of these
    (ii) Crustacean and their products
    (iii) Milk and Milk products
    (iv) Eggs and egg products
    (v) Fish and fish products
    (vi) Peanuts, tree nuts and their products
    (vii) Soybeans and their products
    (viii) Sulphite in concentration of maximum 10mg/kg

07. Where the ingredient or category of ingredients is emphasised on the labelling in words, pictures or graphics, the percentage of the ingredient/category of ingredients should also be declared next to the ingredients in the list of ingredients. FSS (PL) 2011 (2.2.2.(f)). The amount is declared as a percentage.

08. Generally a specific name should be used for ingredients; however a category or class title may be permitted FSS (PL) 2011 (2.2.2.2 (c)) e.g.
    - All vitamins as “Vitamins” (class title)
    - All minerals and trace elements as “Minerals” (class title)

09. While not specified in the regulation – it is good practice – when a category of ingredients is declared it is followed by, (in brackets) the individual ingredients in the category declared in descending order. For example
    - Vitamins (Vitamin C, Vitamin A, Vitamin E)
    - Minerals’ (Calcium, Iron, Zinc)

2. Nutritional information

01. Nutrition information is to be given for nutrients or substances present in the product, which provide a nutritional or physiological effect.

02. Unless proteins, fats or carbohydrates are added to Health Supplements or nurtraceuticals on a voluntary basis for nutritional /physiological purposes, good practice would be to exempt the labelling of these macronutrients and energy intake from the nutritional information provided they do not contribute significantly to the daily food intake.

Global Practice

In the USA, dietary ingredients that contribute amounts in excess of the listed amounts (based on one serving, as indicated in the table below) must be declared on the product label. If the protein content is composed only of individual amino acids, these must be listed separately and not as protein.

*DV= Daily Value

Category	Amount
Total calories	5 kcal
Calories from fat	5 kcal
Total fat	0.5g
Saturated fat	0.5g
Cholesterol	2mg
Sodium	5mg
Total carbohydrate	0.5g
Dietary fiber	0.5g
Sugars	0.5g
Protein	0.5g
Vitamin A	2% DV
Vitamin C	2% 0V
Calcium	2% DV
Iron	2% 0V

03. Nutritional Information or nutritional facts per 100 g or 100ml is not applicable.

04. The amount of any other nutrient for which a nutrition or health claim is made:
    - When a health claim is made the amount of the nutrient for which the claim is made is required to be listed. When the claim relates to the type of fatty acid, the amount of saturated fatty acid, monounsaturated fatty acid and polyunsaturated fatty acid, trans fats in (g) and cholesterol in (mg) are to be declared.

05. For vitamins and minerals the amount shall be declared in metric units (gram or milligram or microgram). This is provided in the Table on RDA above.

3. Name and complete address

01. The name and complete address of the manufacturer; and where the manufacturer is not the packer or bottler the name and complete address of the brand owner along with the licence number of the packing or bottling unit.

02. The address shall be preceded by the words “Manufactured by” or “Mfg. by” or “Mfd. by” or Pkd. by” or “Marketed by” or “Mkt by” or “Imported by”.

03. Where the food is imported into India, the package shall also carry the name and complete address of the importer in India. If the food is manufactured outside India and thereafter packed and bottled in India, the package shall also bear the name of the country of origin and the name and complete address of the importer and the premises of packing or bottling in India.

04. The FSSAI logo and licence number shall be displayed against a contrasting background on the label of the food package as below (refer to Order dated 10th February 2017 for details).

4. Net Quantity

Net quantity by weight or volume or number, as the case may be, shall be declared.

01. Under the Legal Metrology Act every unit of weight or measure shall be in accordance with the Metric System on the International System of Units. Every numeration shall be made in accordance with the decimal system.

02. For food products sold by number, the number declared should be followed by the symbol N or U:
    - e.g. 100 capsules may declared as: Net Quantity: 100N or 100U[3]

03. The height of the numeral and letter when the net quantity is in weight, volume or number declared on the principal display panel (PDP) of the package according to recent amendment under LM (PCR) 2017 [7(2)][3] is given below:

Table I: Minimum height of numeral

Sl. No.	Area of PDP in square centimeters (A)	Minimum height of numerals and letters in millimeters	
		Normal	When blown, formed, moulded on surface of container.
	(1)	(2)	(3)
1	A ≤ 50	1.0	1.5
2	50 < A ≤ 100	1.5	3.0
3	100 < A ≤ 500	2.5	4.0
4	500 < A ≤ 2500	4.0	6.0
5	2500 > A	6.0	6.0

3. Legal Metrology (PCR) 2011 and amendments LM (PCR) 2017

Global Practice

USA: The net quantity of contents statement must be expressed either in weight or measure, numerical count, or a combination thereof (e.g. “60 capsules” or “90 soft gels – 1,000 mg”). If the quantity is provided in weight or measure, it must be expressed using both metric units and the U.S. customary system (e.g. “net wt. 18 oz. (510 g)”).

EU: In most EU Member States, the net quantity must be expressed in numerical count, (e.g. “60 capsules”) in combination with the weight or measure expressed using metric units.

ASEAN: The net contents shall be declared in the metric system. The net contents shall be declared in the following manner: - For liquid form, by volume; - For solid form such as tablet, soft capsule, hard capsule, powder, etc. by weight or amount; - For semi-solid or viscous form, either by weight or volume.

5. Lot/Code/Batch Identification

The batch/code or lot number is a mark of identification by which the food can be traced in manufacture and identified in distribution of the product should be given on the label.

6. Instruction for use

Instructions for use, including reconstitution where applicable, shall be included on the label if necessary to ensure correct utilization of the food, or other directions for purpose of quality and safety of the food (e.g. “refrigerate after opening”, one effervescent tablet a day to be dissolved in a glass of water).

7. Date of Manufacture or Packing

01. The date, month and year in which the food is manufactured, packed or pre-packed, shall be given on the label in accordance with the applicable best before date (BBD); as below:

02. When the BBD of the food is more than 3 months, only the month and year of manufacture, or packing should be declared.

03. When the BBD of the food is less than 3 months the day, the date, month and year in which the product is manufactured, prepared or pre-packed should be given.

8. Size of Letter/Numerals

01. The height of letters shall not be less than 1mm and when blown, formed, moulded, embossed or perforated, it shall not be less than 2mm;

02. The width of the letter or numeral shall not be less than one-third of its height but this provision shall not apply in case of the numeral "1" and letters "i" "I" and "l"

03. In case of declaration of net quantity (weight, volume or number), the height of numerals is given above under net quantity (see table).

9. Best Before Date (BBD)

01. General labelling regulations regarding the time indication under specified storage conditions is to be given so that measured values of nutrients and substances should be within the tolerances around the declared value during the entire shelf life.

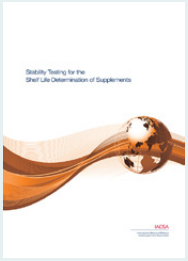
02. The time indication may be provided either as the Best Before Date (BBD) or the Expiry/ Last consumption/Use by date, as applicable. The BBD is to be provided as given in the regulation;

    The month and year shall be declared in capital letters;

BEST BEFORE	declare	**MONTH AND YEAR**	e.g. **JUN 2018**
OR			
BEST BEFORE	declare	**MONTHS FROM PACKAGING OR MANUFACTURING**	e.g. **BEST BEFORE 10 MONTHS FROM MANUFACTURE OR PACKING** (as applicable)
OR			
BEST BEFORE	declare	**DAYS FROM MANUFACTURE**	e.g. **14 DAYS FROM MFD**

    Month and year may be given in numerals; and year may be given in two digits.

Global Practice



'Stability Testing for Shelf Life Determination of Supplements' is part of a series of Technical Guidance for the supplement industry, which have been produced by the IADSA Technical Group over the past few years. 'Stability Testing for Shelf Life Determination of Supplements' outlines the principles for setting up scientifically based stability studies, which are specifically designed to assess the stability and potential shelf life of supplements. It discusses the various important aspects that need to be taken into consideration when designing a stability study.

10. Declaration of Vegetarian / Non-vegetarian Logo:

01. Under regulation 2.2.2.4 of FSS (PL) 2011 every package of food shall bear a declaration on the label by symbol and colour to indicate whether the food is Vegetarian or Non-vegetarian.

02. The size of the logo is determined on the size of the principal display panel of the product and details provided in the regulation.

03. The symbol (logo) shall be placed on the principal display panel of the package, in close proximity to the name or brand name of the product.

04. It shall also appear in pamphlets, leaflets and advertisements in any media used in relation to the product.

11. Principal Display Panel (PDP)

Under the general labelling regulation FSS (PL) 2011 the following mandatory declarations should be given on the PDP.

01. Definition: “Principal Display Panel” means that part of the container/package, which is intended or likely to be displayed or presented or shown or examined by the customer under normal and customary conditions of display, sale or purchase of the commodity contained therein.

02. The following declarations are to be made on the PDP;
    - Name of Food Product
    - Net Quantity: weight, volume or number as applicable
    - Veg/Non Veg Logo

12. Country of Origin for Imported Foods

01. The country of origin of the food shall be declared on the label of food imported into India.

02. When the food undergoes processing in a second country, which changes its nature, the country in which the processing is performed shall be considered to be the country of origin for the purpose of labelling.

13. Advisories and Warnings

01. The FBO is advised to refer to the general labelling regulations FSS (PL) 2011 and the specific labelling required for Health Supplements and Nutraceuticals FSS (HSN) 2016, for special declarations regarding advisories or warnings or non-recommendations;

02. Under general labelling regulations the following warnings are required, when such ingredients or substances are present in the food:

- When a food package contains polyols; declaration surrounded by and enclosing line (boxed)

  POLYOLS MAY HAVE LAXATIVE EFFECT

- When a food package contains polydextrose; declaration surrounded by an enclosing line (boxed)

  POLYDEXTROSE MAY HAVE LAXATIVE EFFECT

- When a food package contains added caffeine; declaration surrounded by an enclosing line (boxed); provided also that the quantity of caffeine is declared in the list of ingredients

  CONTAINS ADDED CAFFEINE

C. Tolerances and Overages

Applicable to	
Health Supplements	Nutraceuticals
✓	✓

01. The regulation FSS (HSN) 2016 provides a general tolerance level of all articles of food covered in the regulation pertaining to analytical variations of finished products. The minimum tolerance for the amount of nutrients or substances declared should not be less than 90% of the declared label value.

02. Overages for vitamins and minerals: Schedule I Table C provides the amounts of overages for a list of vitamins and in case these are not provided, overages used should be based on a proper scientific assessment of the amount that may be required.

03. Overages are a provision made for the addition of an excess amount of nutrients added above the label declaration during manufacture to maintain the claimed amount for the stated shelf life of the product to compensate for the expected manufacturing / storage loss and to allow for variation in assays. Where overages are more than those listed, proper justification should be provided.

Table C: Permissible overages*

S. No.	Micronutrient	Overages (percent)
1	Vitamin A	30
2	Vitamin C	20
3	Vitamin D	30
4	Vitamin E	10
5	Thiamine (Vitamin B1)	25
6	Riboflavin (Vitamin B2)	25
7	Niacin (Vitamin B3)	10
8	Vitamin B6	25
9	Vitamin B12	25
10	Folic acid	25
11	Pantothenic acid	10
12	Vitamin K1	30
13	Minerals	10
14	Iodine	20

* Overage means the amount of excess nutrients added above label claim during manufacture as a means of maintaining at least the claimed amount of the ingredient(s) for the normal shelf life of the product to compensate for the expected manufacturing/storage loss and to allow for variation in assay performance. Where overages are more than those listed in Schedule I Table C, the same shall be scientifically substantiated.

D. Rounding of numerals

While not specified in FSS (HSN) 2016, it is good practice to provide relevant and accurate information to consumers. Rounding means making a number simpler but keeping its value close to what it was.

For the purpose of the amounts of nutrients declared in the nutrition information table, the rounding may be provided in accordance to the Indian Standard: Rules for rounding off numerical values: IS:2-1960 (Reaffirmed 2000) Edition 2.3(2000-08) of the Bureau of Indian Standards.

Rule I — When the figure next beyond the last figure or place to be retained is less than 5, the figure in the last place retained shall be left unchanged.

Rule II — When the figure next beyond the last figure or place to be retained is more than 5 or is 5 followed by any figures other than zeros, the figure in the last place retained shall be increased by 1.

Rule III — When the figure next beyond the last figure or place to be retained is 5 alone or 5 followed by zeros only, the figure in the last place retained shall be (a) increased by 1 if it is odd and (b) left unchanged if even (zero would be regarded as an even number for this purpose).

Examples of rounding off values to unit fineness

Value	Fineness of rounding							
	1		0.1		0.01		0.001	
	Rounded value	Rule	Rounded value	Rule	Rounded value	Rule	Rounded value	Rule
7.2604	7	I	7.3	II	7.26	I	7.260	I
14.725	15	II	14.7	I	14.72	III	14.725	–
3.455	3	I	3.5	II	3.46	III	3.455	–
13.545001	14	II	13.5	I	13.55	II	13.545	I
8.725	9	II	8.7	I	8.72	III	8.725	–
19.205	19	I	19.2	I	19.20	III	19.205	–
0.5499	1	II	0.5	I	0.55	II	0.550	II
0.6501	1	II	0.7	II	0.65	I	0.650	I
0.04950	0	I	0.0	I	0.05	II	0.050	III

Section 4

Composition of Health Supplements and Nutraceuticals

Health Supplements or Nutraceuticals comprise ingredients (including vitamins and minerals) that provide nutritional and physiological effect, and other substances, such as additives, required in preparation of the products.

The ingredients include vitamins and minerals, plant and botanicals, herbs, other substances from plant and animal sources, amino acids, proteins, dietary fats, fatty acids, carbohydrates, probiotics enzyme etc.

Note: As per FSS (HSN) 2016 [General Requirements 3(21)] products consisting of vitamins and/or minerals only should not be marketed as Health Supplements or Nutraceuticals. This sub-regulation is under notice for suggestions, views and comments.[1]

This provision conflicts with Codex Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55 – 2005) and provisions in countries/regions having regulation in place for food supplements, dietary supplements or Health Supplements. It is likely to create barriers to trade.

1. Notice for suggestions, views, comments on draft FSS (HSN) Amendment 2018 dated 09.01.2018.

A. Vitamins and minerals

1. Forms and sources

Applicable to	
Health Supplements	Nutraceuticals
✓	✓

Vitamins and minerals listed in Schedule I (Tables A, B) of FSS (HSN) 2016 may be added to Health Supplements or Nutraceuticals and in the forms listed therein. The Regulation is amended from time to time as needed.

It should be noted that "Heme Iron" shall not be used as a source of Iron (Fe) in any form in any article of food – as per direction of the FSSAI dated 31 March 2017.

Global Practice

The list of vitamins and minerals given in Schedule I Table A and B are similar to those provided in the EU Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements.

2. Maximum limits for addition of vitamins and minerals

Applicable to	
Health Supplements	Nutraceuticals
✓	✓

01. In accordance with FSS (HSN) 2016 [General Requirements 3(4)], the quantity of nutrients added to health supplements or nutraceuticals should not exceed the recommended daily allowance (RDA) specified by the Indian Council of Medical Research (ICMR), and where these are not laid down, the NRV provided by Codex Alimentarius Commission should be used (refer to Table in Section 2).

02. The maximum amounts of vitamins and minerals in health supplements need to be set taking into account the upper safe levels established by the ICMR using a risk management based approach in accordance with global practice.

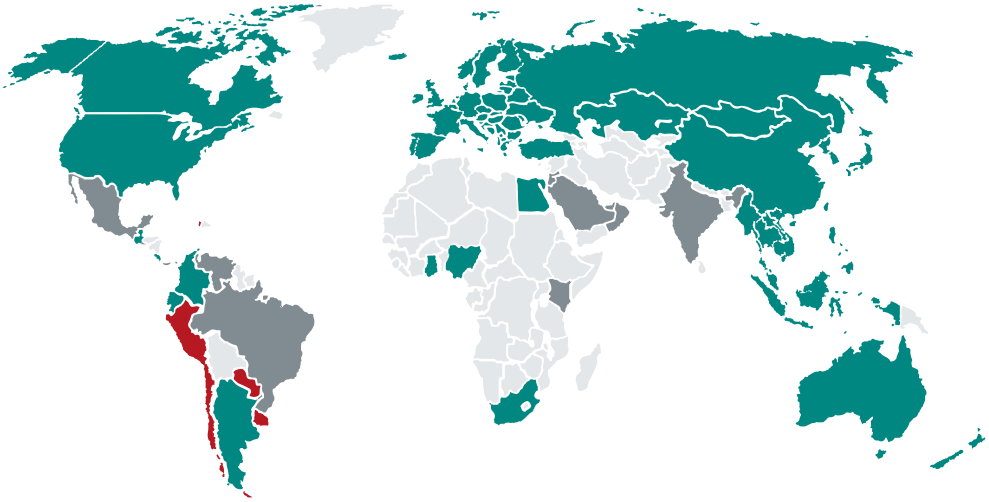
Global Practice

Codex Guidelines for Vitamin and minerals food supplements (CAC/GL 55-2005 Section 3.2) provides guideline that "the 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."

Status of vitamins and mineral maximum levels (2017)



- RDA based levels
- Countries moving to safety based levels
- Safety based levels

B. Ingredients other than vitamins and minerals

01. FSS (HSN) [6(1)(i-iii) and [7(1)(i-iii): These regulatory clauses give the requirements regarding the composition and form for Health Supplements and Nutraceuticals respectively. Health Supplements or Nutraceuticals shall contain ingredients specified in the table.

Ingredients	Schedule No	Health Supplements	Nutraceuticals
Vitamins and Minerals and their forms	I	✓	✓
Amino acids	II	✓	✓
Plant or botanical ingredients	IV	✓	✓
Nutraceuticals as ingredients	VI	✗ ONLY ENZYMES	✓
Probiotic	VII	✓	✓
Prebiotics	VIII	✓	✓

02. Schedule IV FSS (HSN) 2016 lists plants and botanicals, which may be used.

03. They may be used to supplement the normal diet of a person above 5 years of age [6(1)(i)]. However for use by children below the age of 5, the product shall be given only under medical advice by physician/certified dietitican/nutritionist.[4]

04. Plants and botanicals, and their parts that may be used in Health Supplements and Nutraceuticals are provided in the Schedule, with certain clarifications under the Notes.

4. Notice for suggestions, views, comments on draft FSS (HSN) Amendment 2018 dated 09.01.2018

05. A permitted range is indicated for each entry in the Schedule, with recommendations in certain cases e.g.

Name (Latin)	Part	Common or vernacular name	Permitted range: adult/day as raw herb
Abelmoschus esculentus (L.) Moench	Fruit/root	Bhindi	5-10g (as powder)
Camellia sinensis	Tea leaf extract	Chaya	1-2g Not recommended for children below 5y
	Tea catechins	Green tea	0.5-1.0g
Crocus sativus L	Style and stigma	kumkum (Kesar)	25-50 g Not recommended for children below 16y
Daucus carota L.	Seed	Gajar	1-2g (as powder) Not recommended during pregnancy

Note 1: The ingredients listed in the Schedule should be used after due processing or in their extract forms subject to being used within the permissible range indicated in the last column of the Table of Schedule IV.

Note 2: The ingredients shall comply with FSS (Contaminants, Toxins and Residues) Regulation 2011, and their products shall comply with the limits provided for "foods not specified".

It is also clarified that if the ingredient used in the product is an extract, its quantity should be the equivalent of extractives obtained from using the raw plant or botanical in the ranges provided in the last column of the Table of Schedule IV.

C. Nutraceutical as ingredients

Schedule VI provides a list of Nutraceuticals as ingredients, including enzymes.
It consists of two parts;

- Part, A which lists, recommended usage (minimum and maximum) per day;
- In Part B of the Schedule, the usage levels have not been provided and these should be based on relevant scientific data on safety and efficacious use, which should be provided to the Authority or during licensing when required;
- For a product to be labelled Nutraceuticals, it must contain one or more ingredients from Schedule VI (Nutraceuticals as ingredients) and may contain permitted ingredients from other Schedules.

D. Specifications, Quality, Purity

The regulation does not provide specification relating to purity for ingredients or their source listed in Schedule II, IV, VI (enzymes only), VII (probiotics and VIII (prebiotics).

- However, ingredients or substances (e.g. food additives) used in Health Supplements, should primarily comply with specifications and standards provided in the applicable FSS regulations; namely
    - FSS (Food Product Standards and Food Additives) Regulation 2011;
    - FSS (Food Product Standards and Food Additives) Regulation 2011: (7th Amendment 2016);
    - FSS (Health Supplements, Nutraceuticals . . ..) Regulation 2016 - [FSS (HSN) 2016].

The regulation FSS (FPS/FA) 2011, contains specifications relating to certain foods and food additives, and these should be complied with if such substances are used;

- Where specifications for ingredients, vitamins, minerals, food additives or other substances used are not provided in FSS regulations, the FBO may rely upon authoritative and internationally recognised texts such as Indian Pharmacopoeia (IP), Ayurveda Pharmacopoeia of India (API), Bureau of Indian Standards (BIS), Quality Standards of Indian Medicinal Plants, British Pharmacopoeia (BP), US Pharmacopoeia (USP), Food Chemical Codex, JECFA as appropriate to the ingredient or substance being used.

The specifications adopted by the FBO for the ingredients or substances used in the manufacture or sale of products should be included in appropriate documentation including their analytical methodology and conformance reports and made available at the time of inspection or when required submitted to the Food Authority.

The FBO is required to comply with the specifications quality and purity of the ingredients being used and the applicable sampling and test methods used to characterise or identify the ingredients. These may be required at the time of licensing or whenever required by the Food Authority.

E. Food Additives

Food additives specified for Health Supplements and Nutraceuticals may be used, provided below.

Food Additives	Health Supplements	Nutraceuticals
Schedule VA	✓	✓
Schedule VE	✓	✓
Schedule VF*	✓	✓
* Food additives to be used in formats such as tablets, capsules and syrups		

F. Ingredients not included in the Schedules

The FSS (HSN) 2016 has entered into force on 1st January 2018, after providing a year for compliance. Products in the market are now required to be fully compliant with the regulation.

The Authority has granted extension up to six months for products to comply if they meet certain conditions. FBO's are further advised to consult the Authority with regard amendments that may follow.

G. Non-specified foods

The FSS (Approval for Non Specified food and food Ingredients) Regulation 2017 has been notified. The regulation will replace the erstwhile product approval procedure that was in place until August 19, 2015.

The regulation relates to the procedure to be followed by FBO's seeking to obtain approval for a novel food or ingredient, product from novel technology, new food additive, processing aids including enzymes, articles of food consisting or isolated from microorganisms, bacteria, yeast, fungi or algae or any other non-specified food.

The regulation applies to all ingredients and substances as stated above including those to be used in food supplements and Nutraceuticals.

Section 5

Licensing and Import

Applicable to	
Health Supplements	Nutraceuticals
✓	✓

1. Licensing: Every Food Business Operator in the supply chain is required to possess a licence, e.g. manufacturing, import, storage, distribution, sale, marketing or transport, on commencement of business.

2. Import of foods, including Health Supplements and Nutraceuticals are subject to the FSS (Import) Regulations 2017. No person shall import any article of food without an import licence from the Central Licensing Authority in accordance with the provisions of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations 2011.

3. The FBO is advised to refer to the regulations and amendments thereof in force namely:
   - FSS (Licensing and Registration of Food Businesses) Regulations 2011
   - FSS (Import) Regulations 2017

Section 6

Glossary and Abbreviations

ASEAN	Association of Southeast Asian Nations
FSSA	Food Safety and Standards Act, 2006
FSS	Food Safety and Standards
FSS (HSN) 2016	Food Safety and Standards (Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purposes, Functional Foods, Novel Foods) Regulation 2016
FSS (PL) 2011	Food Safety and Standards (Packaging and Labelling) Regulations 2011
FSS (FPSFA) 2011	Food Safety and Standards (Food Product Standards and Food Additives) Regulations 2011
FSS (FPSFA) 2011-7A	Food Safety and Standards (Food Product Standards and Food Additives) Regulations 2011: 7th Amendment 2016
FSSAI	Food Safety and Standards Authority of India
FSDU	Foods for special dietary uses
FSMP	Foods for special medical purpose
FBO	Food Business Operator
Food Authority	Food Safety and Standards Authority of India
ICMR	Indian Council of Medical Research
LM (PCR) 2011	Legal Metrology (Packaged Commodity) Rules 2011 and amendments thereto.
NRV	Nutrient reference value
PDP	Principal Display Panel
RDA	Recommended dietary allowance or recommended daily allowance

ReCHaN

Resource Centre for Health supplements and Nutraceuticals

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