

# FSDU & FSMP

March 23, 2017

# Food Category System

Indian Food Code	Codex Alimentarius
13. Foodstuffs intended for particular nutritional uses	13. Foodstuffs intended for particular nutritional uses
13.1 Infant formula, Follow-up formula, Formulae for special medical purposes for infants	13.1 Infant formulae, follow-on formulae, and formulae for special medical purposes for infants
13.2 Complementary foods for infants	13.2 Complementary foods for infants and young children
13.3 Foods intended for special medical purposes (excluding products of food category 13.1)	13.3 Dietetic foods intended for special medical purposes (excluding products of food category 13.1)
13.4 Formulae for slimming purposes and weight management	13.4 Dietetic formulae for slimming purposes and weight reduction
13.5 Dietetic Foods excluding products of food categories 13.1, 13.4 and 13.6	13.5 Dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1- 13.4 and 13.6
13.6 Health supplements	13.6 Food supplements

# GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES

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CODEX STAN 146-1985

## 1. SCOPE

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This standard applies to the labelling of all prepackaged foods for special dietary uses as defined in Section 2.1 to be offered as such to the consumer or for catering purposes and to certain aspects relating to the presentation thereof; and to claims made for such foods.

# CODEX STANDARD FOR THE LABELLING OF AND CLAIMS FOR FOODS FOR SPECIAL MEDICAL PURPOSES CODEX STAN 180-1991

## 1. SCOPE

This standard applies to the labelling of and claims for foods for special medical purposes as defined in Section 2 below, and presented as such.

# Structure

- Definition
- Scope
- Composition
- Labelling
- Identity standards

# FSDU- Definition

- Foods for Special Dietary Use, other than infants, and those products intended to be taken under medical advice
  - Meaning assigned to in section 22 of the Act
- Formats
  - Oral feeding, not for parenteral use
  - granules, capsules, tablets, pills, jelly, semi-solid, sachets of powder, or any other similar forms of liquids and powders designed to be taken in measured unit quantities with a nutritional or physiological effect

# FSDU-Scope

- Includes-
  - (a) Low weight, obesity, diabetes, high blood pressure;
  - (b) Pregnant and lactating women; and
  - (c) Geriatric population and celiac disease and other health conditions.
- Excludes-
  1. Enriched or modified for mass consumption
  2. Not intended for managing any disease conditions
  3. Nutritionally complete as in FSMP

# FSDU- Composition

- Ingredients- Schedules I, II, III, IV, VI, VII, VIII
- Food additives- Schedule VB, VE, VF
- Nutrients
  - Can be higher than RDA, but not exceeding the limits of vitamins & minerals levels in Schedule III
  - Need prior approval for new nutrient which has no history of safe use in India

# FSDU- Labelling

- NOT FOR MEDICAL USE
- FOOD FOR SPECIAL DIETARY USE
- Food for.....(Physiological or health condition)
- For weight control and management
- Target consumer group, rationale for use of the product
- Not to be used by pregnant, nursing and lactating women or by infants, children, adolescents and elderly, except when medically advised
- Warnings- not for parenteral use, dangers of excess consumption, known side effects, contraindications,
- Osmolality/osmolarity/acid-base balance
- Precautions while consuming & storage (out of reach of children)
- Permits claim relating to structure or function or general well-being of the body
- Needs prior approval of Food Authority for claims implying prevention, cure or treatment of disease or its diagnosis..



# Standards

(2)(v) Food for **slimming, weight management and weight control** purposes : -

## **CODEX STANDARD FOR FORMULA FOODS FOR USE IN WEIGHT CONTROL DIETS CODEX STAN 181-1991**

### **1. SCOPE**

This standard applies to formula foods for use in weight control diets, as defined in Section 2.

It does not apply to prepackaged meals controlled in energy and presented in the form of conventional foods.

### **2. DESCRIPTION**

Formula foods for use in weight control diets are foods which, when presented as "ready-to-serve" or when prepared in conformity with the directions for use, are presented as a replacement for all or part of the total daily diet.

# FSMP- Definition

- Foods for Special Medical Purpose, (*other than those intended for infants*)
  - Aligned with the definition in Codex & Indian Food Code for Category 13.3
- Formats- Oral feeding, not for parenteral use.

# FSMP-Scope

- Includes-
  - (1) Weight reduction.
- Categories-
  - (a) 'nutritionally complete food with a standard nutrient formulation'
  - (b) 'nutritionally complete food with a nutrient-adopted formulation specific for a disease, disorder or medical condition'
  - (c) 'nutritionally incomplete food with a standard formulation or a nutrient-adopted formulation specific for a disease, disorder or medical condition'

# FSMP- Composition

- Ingredients- Schedules I, II, III, IV, VII, VIII & Enzymes from VI
- Food additives- Schedule VC, VD, VE, VF
- Nutrients
  - Can be higher than RDA, but not exceeding the limits of vitamins & minerals levels in Schedule III
  - Need prior approval for new nutrient which has no history of safe use in India

# FSMP- Labelling

- RECOMMENDED TO BE USED UNDER MEDICAL ADVICE ONLY
- FOOD FOR SPECIAL MEDICAL PURPOSE
- For the dietary management of.....(disease/disorder/medical condition)-  
Needs prior approval of Food Authority
- NUTRITIONALLY COMPLETE, if it constitutes as sole source of nourishment
- Target consumer group, rationale for use of the product
- Nutrient which has been reduced, deleted, increased or modified
- Warnings- not for parenteral use
- Osmolality/osmolarity/acid-base balance, RSL, PRSL
- Instructions for preparation & storage (out of reach of children)
- No advertisement suggesting its use by general public...

# Standards

(2) (iv) Food for **weight reduction & for total replacement of diet** : -

**CODEX STANDARD FOR FORMULA FOODS  
FOR USE IN VERY LOW ENERGY DIETS  
FOR WEIGHT REDUCTION**

*CODEX STAN 203-1995*

**1. SCOPE**

This standard applies to formula foods for use in very low energy diets for weight reduction as defined in Section 2. These foods are defined as foods for special medical purposes and must be used under medical supervision by individuals with moderate or severe obesity. The matter of sale on prescription should be a decision made at national level.

It does not apply to prepackaged meals presented in the form of conventional foods.

# Opinion of Scientific Experts on FSMP

- Because of the wide diversity of such foods and the rapidly evolving scientific knowledge on which they are based, it is not appropriate to lay down detailed compositional rules;
- Some basic rules concerning vitamin and mineral substances content can be laid down for these products.

# Vitamin & Mineral Limits

## Schedule III vs RDA

Nutrient	Unit	Per 100 kcal as specified in Schedule III		Estimated Per Day Intake 2320 kcal (for a man with Sedentary Lifestyle )		RDA
		Min.	Max.	Min.	Max.	Per day
Vitamin A	mcg RE	35	180	700	3600	600
Vitamin D	mcg	0.5	2.5	10	50	
Vitamin E	mg	0.1	3	2	60	
Vitamin K	mcg	3.5	20	70	400	
Vitamin B1	mg	0.06	0.5	1.2	10	1.2
Vitamin B2	mg	0.08	0.5	1.6	10	1.4
Niacin	mg NE	0.9	3	18	60	16
Vitamin B6	mg	0.08	0.5	1.6	10	2
Vitamin B12	mcg	0.07	0.7	1.4	14	1
Pantothenic acid	mg	0.15	1.5	3	30	
Folic Acid	mcg	10	50	200	1000	100
Vitamin C	mg	2.25	22	45	440	40
Biotin	mcg	0.75	7.5	15	150	
Iron	mg	0.5	2	10	40	17
Calcium	mg	50	250	1000	5000	600
Phosphorus	mg	30	80	600	1600	
Magnesium	mg	7.5	25	150	500	340
Sodium	mg	30	175	600	3500	
Chloride	mg	30	175	600	3500	
Potassium	mg	80	295	1600	5900	
Manganese	mg	0.05	0.5	1	10	
Iodine	mcg	6.5	35	130	700	
Selenium	mcg	2.5	10	50	200	
Copper	mcg	60	500	1200	10000	
Zinc	mg	0.5	1.5	10	30	12
Chromium	mcg	1.25	15	25	300	
Molybdenum	mcg/ d	3.5	18	70	360	



# Summary of Schedules

Schedule	GR	HS	Nutra	FSDU	FSMP	Probiotic	Prebiotic	Specialty
I Sources of Vitamins & Minerals	✓	✓	✓	✓	✓			
II Amino Acids	✓	✓	✓	✓	✓			
III Limits of vitamins, Minerals & Trace elements	✓			✓	✓			
IV Plants & botanical ingredients	✓	✓	✓	✓	✓			✓
V A Food Additives	✓	✓	✓			✓	✓	
V B Food Additives for FSDU	✓			✓		✓	✓	
V C Food Additives for FSMP	✓				✓	✓	✓	
V D Food Additives for FSMP; Formula for Slimming Purposes, Weight Reduction, Foods with Prebiotics, Probiotics	✓				✓	✓	✓	
V E Food Additives to be used at GMP Levels	✓	✓	✓	✓	✓	✓	✓	✓
V F Food Additives to be used in tablets, capsules and syrups	✓	✓	✓	✓	✓	✓	✓	✓
VI Nutraceuticals (E=Enzymes)	✓	(E)	✓	(E)	✓			
VII Probiotic Strains	✓	✓	✓	✓	✓	✓		
VIII Prebiotic Compounds	✓	✓	✓	✓	✓		✓	

Thank you