Suggested Structure of Regulation for Foods for Special Purposes and Nutritional Uses

Food Safety and Standards Authority of India
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Introduction

This document is an attempt towards formulating a structure of the new regulation on special purpose foods targeted at particular needs and sections of population to be introduced in India under Section 22 of the Food Safety and Standards Act. This is based on review of current PFA provisions, discussions with industry experts, and the learnings from international best practices in the field, mainly those of USFDA, EU, CODEX and Australia New Zealand. A section on Food Fortification has also been added, which may not form part of the special foods regulation but could be inserted at an appropriate place in the FSS regulations.

The purpose is to provide a framework for initiating a discussion of the issues involved and options available. All the suggestions, comments and structures laid down here are meant for detailed discussion, scrutiny and fine tuning. On the technical issues and associated claims, existing provisions in other international laws have been provided as Annexures, which needs to be deliberated upon and adapted for Indian conditions. They are indicative only.

The last section (Page 25) lists out the specific areas which need to be deliberated upon by the experts and based on the final recommendations, the regulation will be drafted.

Suggestive structure of the Regulation for Foods for Special purpose and Nutritional Uses

Contents

I. A Background

The Food Safety and Standards Act mandates vide Section 22, that manufacturing, selling, distributing or importing of new type of foods like Novel Foods, Foods from GM articles, irradiated Foods, organic Foods, Foods for special dietary uses, Functional foods, nutraceuticals, health Supplements, proprietary foods shall be guided by specific regulations. For this purpose, the Act has also provided broad definitions of these categories.

This requires drafting of specific regulations for these types of food to govern their manufacture, distribution, sale and import. Based on the Concept Note presented on this subject, a suggestive regulatory structure is being presented here.

The definitions provided in the Act are as follows:

(A) Provision in the Food Safety & Standards Act

"foods for special dietary uses or functional foods or nutraceuticals or health supplements" means:

(a) foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition or specific diseases and disorders and which are presented as such, wherein the composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist, and may contain one or more of the following ingredients, namely:-

(i) plants or botanicals or their parts in the form of powder, concentrate or extract in water, ethyl alcohol or hydro alcoholic extract, single or in combination;
(ii) minerals or vitamins or proteins or metals or their compounds or amino acids (in amounts not exceeding the Recommended Daily Allowance for Indians) or enzymes (within permissible limits);
(iii) substances from animal origin;
(iv) a dietary substance for use by human beings to supplement the diet by increasing the total dietary intake;

(b) (i) a product that is labelled as a "Food for special dietary uses or functional foods or nutraceuticals or health supplements or similar such foods" which is not represented for use as a conventional food and whereby such products may be formulated in the form of powders, granules, tablets, capsules, liquids, jelly and other dosage forms but not parenterals, and are meant for oral administration;

(ii) such product does not include a drug as defined in clause (b) and ayurvedic, sidha and unani drugs as defined in clauses (a) and (h) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and rules made thereunder;

(iii) does not claim to cure or mitigate any specific disease, disorder or condition (except for certain health benefit or such promotion claims) as may be permitted by the regulations made under this Act;

(iv) does not include a narcotic drug or a psychotropic substance as defined in the Schedule of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) and rules made there under and substances listed in Schedules E and EI of the Drugs and Cosmetics Rules, 1945;

B. Provision for foods based on ayurvedic, sidha and unani ingredients or principles

Thus this definition given in the Act, does not include ayurvedic, sidha and unani drugs as defined in clauses (a) and (h) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and rules made there-under;

Section 3 (a) of Drugs and Cosmetics Act
Ayurvedic, Siddha or Unani drug" includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in, the authoritative books of Ayurvedic, Siddha and Unani Tibb systems of medicine, specified in the First Schedule of the said Act;

Section 3 (h) - "patent or proprietary medicine",—
in relation to Ayurvedic, Siddha or Unani Tibb systems of medicine all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda, Siddha or Unani Tibb systems of medicine specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books as specified in clause (a);

And Food is defined under the FSS Act as
"any substance, whether processed, partially processed or unprocessed, which is intended for human consumption and includes primary food to the extent defined in clause (zk), genetically modified or engineered food or food containing such ingredients, infant food, packaged drinking water, alcoholic drink, chewing gum, and any substance, including water used into the food during its manufacture, preparation or treatment but does not include any animal feed, live animals unless they are prepared or processed for placing on the market for human consumption, plants, prior to harvesting, drugs and medicinal products, cosmetics, narcotic or psychotropic substances"

Hence by this definition any substance intended for human consumption but is not a drug will also qualify as food under this Act.

Consequently, products marketed as food supplements with natural or Ayurvedic ingredients with definite claims on addressing certain physiological or physical condition or such products labelled as "not a drug" will qualify under the above mentioned broad category of "foods for special dietary uses or functional foods or nutraceuticals or health supplements' provided in the FSS Act and will have to be regulated under this regulation.

Requirement of enlisting Ayurvedic /unani/sidhai ingredients/nutrients

List of nutrients like vitamins, minerals etc and their safe composition and related claims are well established internationally (under WHO and FAO) and as in other countries FSSAI will also need to follow a similar list for the purposes of this regulation. However, such list does not exist in the current regulations in India or internationally for foods using Ayurvedic or unani nutrients and ingredients.

FSSAI may deliberate and prepare such list of nutrients or ingredients of natural and ayurvedic origin, excepients and the claims associated with their use and quantity.

C. Proprietary food and Novel foods

These two have been defined together in the Act since both have no specified standard. However they will have to be defined separately in the Regulations with separate regulatory mechanism for each due to their complex and completely different nature. Proprietary Food is an existing category in the current law (for which there is no prescribed standard but it can use additives allowed under PFA), but Novel food is a complete new category being introduced.

The common factor in each of the special purpose food categories

These are special foods by virtue of enrichment of common foods or making new foods with addition of various nutrients in the food for special nutritional or other purposes. The manufacturer producing such food will need to convey to the consumer the special characteristics and enrichment through claims and declarations made on the label.

Hence the regulation for these foods shall focus only on two main aspects i.e.

1. The type, quality and quantity of the nutrients. The quantity should not be too high or too low based on the requirement of the target population and the quality or purity of the nutrient added and their intended effect should be ensured.

2. The claims made on the label of the food in order to convince consumers. The claims should not be misleading or false.

World over there is general consensus over types of nutrients and their daily consumption limit which can be added for enriching , supplementing, fortifying or for preparing foods having specific dietetic purpose or to address specific dietary condition including weight management, performance enhancement etc. on the basis of FAO / WHO data. New nutrients can be added to the existing list of nutrients, provided they pass the safety assessment criteria.

II. The broad categories identified for the suggested structure

As mentioned above, the Act basically provides the overall general categorisation of any type of special foods whether named “foods for special dietary uses” or “functional foods” or “nutraceuticals or health supplements”..

However, each one of these is substantially different in the purposes for which they are intended and the manner in which each of them is generally regulated.

For example Nutraeuticals generally mean “food or parts of food that provide isolated or concentrated form of nutrients which when added can provide medical or health benefits including prevention & treatment of diseases”, and Functional foods are generally defined as “foods which are intended to be consumed as part of the normal diet and that contain biologically active components which offer the potential of enhanced health or reduced risk of disease”. A broad difference between the two is that functional food is essentially a food, but nutraceuticals could be in an isolated form or concentrated form. But either of them can be marketed for a special section of population with definite physiological or physical needs or for the general population to address some common health needs.

Similarly Foods for Special Dietary purpose is also a broad definition and may include certain types of functional foods,neutraceuticals,foods for special medical purpose, foods for weight Management and reduction, Infant foods, sports foods etc. and many of these may again qualify as nutraceuticals. But each of these subcategories, meant for different sections of population , will need to comply with specific requirements for that particular target group or condition and hence will require separate set of specifications and controls.

Different countries have looked at these foods in different manner. Japan has a broad category of Functional foods bringing under its definition all types of special foods which offer the potential of enhanced health or reduced risk of disease. In EU and Codex, this general category has been divided into four or five different subcategories based on their final use with specific quality and safety requirements and this pattern has been followed in the following section. This will enable regulation to be adjusted for specific categories keeping in view the country's requirements.

III. Categorisation of Different type of special purpose Foods

The Special foods for the purpose of the proposed regulation are broadly categorized under the following five categories and subcategories:

A. Health/ food Supplements ~~(will also cover functional foods as well as nutraceuticals)~~

B. Food for Special Dietary Uses or FSDUs which comprise of the following sub categories: (basically nutraceuticals)

i. **Dietary Foods for specific nutritional** purposes like types of food to address some specific nutritional requirement but can be taken without medical advice

ii. **Dietary foods intended for special medical purposes, to be used under medical advice**

iii. **Dietary Foods For use in Weight Management**

iv. **Performance Foods & beverages**

C. Proprietary Foods – not to be part of this regulation but will have to be inserted at appropriate place in the regulation

D. Novel Foods

IV. *Suggested structure for the Regulation of Supplements, FSDUs and others along with set of requirements and restrictions:*

If Pro-biotic or Pre-biotic cultures are used in the preparation of foods falling under these categories, then the said food will also have to adhere to the general requirements to be laid down in the Pre & Pro-biotic regulation being developed by FSSAI.

A. Health/ food Supplement ~~(may include some forms of functional foods and nutraceuticals)~~

1. Definition

"Health/ food supplement" is a food product including those of natural or ayurvedic origin (but not a drug as defined under the Drugs and Cosmetics Act), which have been specifically processed or formulated to supplement the normal diet. The dietary ingredients in these products may include vitamins, minerals, herbs or other botanicals and amino acids or their extracts or concentrates ***and any other nutrients, ingredients and food additives suitable to the product***. The purpose of such foods is to supplement the normal diet and are concentrated sources of nutrients or other substances alone or in combination, marketed in ~~single use~~ **packaging like cans, bottles** or 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 with a nutritional or physiological effect.

2. General Regulation for Health/ Food Supplements

Here a definite list of approved vitamins, minerals and other nutrients along with their forms and approved quantities of usage need to be listed. ***The approved list of EU is given here in Annex I & II, which may serve as the basis. (In the list of minerals Ferrous Ammonium Phosphate should be added)***

The purity criteria for substances approved have to be set and for those substances for which purity criteria are not specified in India and until such specifications are adopted, generally acceptable purity criteria recommended by international bodies can be made applicable.

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

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

(b) Intake of vitamins and minerals from other dietary sources

(c) To ensure that significant amounts of vitamins and minerals are present in food supplements, minimum amounts as per daily portion of consumption as recommended by the authority shall be set, as appropriate.

(e) Additives allowed to be used in these products also need to be specified. The codex list of approved additives are given in Annexure 8. Codex also allows all Table 3 Additives to be used in these products.

3. Approval

Once the list of approved nutrients and their quantities are specified, no approval, permission or notification from concerned authority should be required for Health Supplements provided the product complies with the requirements laid down and specific labelling requirements for nutritional and health claim. A document on labelling and claims is being developed by FSSA. A suggestive compilation of claims is given in **Annexure 6 (**based on Codex, EU, ANZ and USFDA).

EU, USFDA actually specifies the exact quantity of nutrient to be present or added or reduced as the case may be and the exact wordings for the claim (for example: nutritional claims like "high fibre", "calcium rich" etc. is allowed to be used only if the product meets the given nutritional

profile.) Health claims which are approved and fall in the 'positive list' like 'calcium is good for your bones' can be used as long as they are proven to be in the product.

Provided a manufacturer or distributer shall have to notify the authority if it intends to market a food supplement containing a 'new ingredient or nutrient' which is not in the approved list but has been proven to be safe and allowed in other countries or under FAO/WHO. The product can be marketed only after approval and the nutrient shall then be listed in the permitted list of nutrients.

Any new nutrient which has no previous history of general or mass use shall follow the approval procedure laid down for novel foods.

4. Labelling & Claims

Labelling of Food Supplements shall follow the requirements laid down under general labelling including nutritional and claims regulation (being developed by FSSA). In addition the following requirements also should be made:

(a) the names of the categories of nutrients or substances that characterise the product (b) The amount of the nutrients or substances with a nutritional or physiological effect present in the product . The units to be used for vitamins and minerals shall be those specified in Annex I.

(c) Information on vitamins and minerals can also be expressed as a percentage of the reference values mentioned, as given in Annex 3, as applicable and available.

(d) The amounts of the nutrients or other substances declared shall ideally be those per portion of the product as recommended for daily consumption

(e) Additionally, food supplements are required to be labelled clearly as "Food Supplement" & Nutritional information to be given in a separate 'Supplement Panel"

(f) Any claim to prevent, cure or treat a specific disease or sign on label of food supplement shall be strictly prohibited (unless otherwise approved by the authority). ~~Manufacturers can however make statements about nutrient deficiency diseases as long as these statements disclose the prevalence of such diseases in India. Statements related to structure / function or general well being of the body is allowed as long as those are truthful and also bear a statement *"This product is not intended to diagnose, treat, cure or prevent any disease."*~~

B. Foods for Special Dietary Uses

This is a broad category defined as those foods which are not conventional foods and are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such and might require medical supervision or advice. The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist.
Following are the sub categories under this broad category:

a. **Dietary Foods for specific nutritional purposes**

b. **Dietary foods for special medical purposes**

c. **Dietary Foods For use in Weight Management**

d. **Performance Foods including beverages**

a) Dietary Foods for specific nutritional purposes

1. Definition

The foods under this category are defined as those foods which are specially processed or formulated to satisfy particular dietary or nutritional requirements which exist because of a particular physical or physiological condition having required nutritional content to cater to specific conditions and can be taken without medical advice, in liquid or solid form, but not intended for weight management purposes or as performance foods. This category includes foods particularly intended for convalescents, aged, pregnant mothers ~~or for specific diseased conditions like diabetes, high blood pressure~~ etc.

Special purpose foods for infants are generally categorized under this broad category, however, in India, though such special food category did not exist under PFA, all types of Infant foods because of their extra sensitive nature have been well regulated both in respect of the ingredients and nutrients that can be used and the claims and declarations that can be made on the label. Currently these foods are subcategorized under the general Standards for the Category of Milk & Milk products in Appendix B of PFA. Moreover, it is also regulated by another specific law enacted to regulate marketing and labelling of such foods namely "Infant milk substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992. Under the aegis of both these laws, the standards, the nutrient lists and claims have come up for discussion and debate quite often and have been amended also in a dynamic manner in recent past.

Hence no changes have been suggested in this document on these standards or their categorization. If required, those standards in their current or modified form can be shifted from Appendix B to this section.

2. General Regulation for Dietary Foods for Specific Nutritional uses

Foods for specific nutritional uses are intended for various physical or physiological conditions and can use food additives allowed for other special types of foods. The codex list of additives are attached here as reference in annexure 8.

This category shall follow all the General conditions for food, labelling, Nutritional information and claim requirements as applicable, which is being developed simultaneously by FSSA

However, for use of any new ingredient or additives in such foods shall follow the regulatory requirements laid down for novel foods.

Additives allowed to be used in these products also need to be specified. The codex list of approved additives is given in Annexure 8. Codex also allows all Table 3 Additives to be used in these products.

b) Dietary foods intended for special medical purposes

1. Definition

Dietary foods intended for special medical purposes means a type of food which are specially processed or formulated and presented for the dietary management of patients and may be used only under medical ~~supervision~~advice. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary foodstuffs or certain nutrients contained therein, or who have other special medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet or supplements or by a combination of the two.

2. General Regulation for Foods for special medical purpose

Dietary foods for special medical purposes are foods which are intended to meet the particular nutritional requirements of persons affected by or malnourished because of a specific disease, disorder or medical condition; The composition of these foods may differ substantially depending on the specific disease, disorder or medical condition or age of the patients for whom they are intended, but the requirements laid down for their safe use needs to address the issues arising out of the nature of the product i.e. whether the foods are intended to be used as the sole source of nourishment or not.

However, 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.

Hence Dietary foods for special medical purposes are classified in two broad subcategories

~~i.~~A. Dietary foods for special medical purposes other than those intended for infants

~~j.~~B. Dietary foods for special medical purposes intended for infants

Part A: General Conditions for Dietary foods for special medical purposes other than those intended for infants

Part A is further divided into following two Sub categories (because the specifications on quantity and nutrients will vary substantially)

~~1~~a. Nutritionally complete foods with a standard nutrient formulation or nutrient-adapted formulation specific for a disease, disorder or medical condition which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended;

~~2~~b. Nutritionally incomplete foods with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which are not suitable to be used as the sole source of nourishment.

The foods referred in a. above may also be used as a partial replacement or as a supplement to the patient's diet.

1. Generally there will be no prior requirement of notification, permission or approval from the authority. A manufacturer / distributor of such products shall however, intimate the authority about marketing such products by **sending an application along with sample label of the product** for information before placing the product in the market. For existing products which will fall under this category (since there is no such category under current law) – the manufacturers may be required to submit label samples of all their products within six months of this regulation coming into force.

2. For Dietary Foods for Special Medical Purposes defined under (a) FSSA will have to specify a list of vitamins, minerals and other nutrients. (The list as specified by ~~Codex~~ European Commission is given in Annexure 4). ~~Codex~~ European Commission allows modifications of one or more of these nutrients if necessary for the intended use of the product.

3. Maximum levels of vitamins and mineral substances present in Dietary Foods for Special Medical Purposes defined under (b), shall not exceed those specified in the list mentioned against Point 2 above. (Annexure 4 as suggested, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product).

4. The codex list of approved additives is given in Annexure 8..

5. Provided a manufacturer or distributor shall have to notify the authority if it intends to market a food for specific nutritional uses containing a 'new ingredient' which is not listed in the permitted list of ingredients in India but has a history of general safe use in other countries and have been allowed by FAO/WHO..

6. Any new nutrient which has no previous history of safe use shall follow the approval procedure laid down for novel foods.

Part B: General Conditions for Dietary Foods for Special Medical Purposes Intended for Infants

These can be in liquid or powdered form intended for use, where necessary, as a substitute for human milk or infant formula in meeting the special nutritional requirements arising from the disorder, disease or medical condition for whose dietary management the product has been formulated.

Only products that comply with the criteria laid down in the provisions of this part of this standard would be accepted for marketing as Dietary Foods for special medical purposes intended for infants.

Product definition: ~~Dietary~~ Formula for Special Medical Purposes Intended for Infants means a substitute for human milk or infant formula and is specially manufactured to satisfy, by itself, the special nutritional requirements of infants with specific disorders, diseases or medical conditions during the first months of life up to the introduction of appropriate complementary feeding.

Essential Composition And Quality Factors:

- **FSSA will have to specify a list of the vitamins, mineral and other nutrients and their Maximum levels of usage in these foods intended specifically for infants. The list as specified by ~~Codex~~ European Commission is given in Annexure 5. Codex also allows modifications of one or more of these nutrients if necessary for the intended use of the product.**

- The composition of Formula for Special Medical Purposes Intended for Infants shall be based on sound medical and nutritional principles. The nutritional safety and adequacy of the formula shall be scientifically demonstrated to support growth and development in the infants for whom it is intended, as appropriate for the specific products and indications. Their use shall be demonstrated by scientific evidence to be beneficial in the dietary management of the infants for whom it is intended.
- The energy content and nutrient composition of Formula for Special Medical Purposes intended for infants shall be based on the requirements for infant formula, except for the compositional and nutrient provisions which must be modified to meet the special nutritional requirements arising from the disease(s), disorder(s) or medical condition(s) for whose dietary management the product is specifically formulated, labelled and presented.
- In addition to the requirements in the point above the following requirements shall also be taken into account, where appropriate:

Chromium			
Unit	**Minimum**	**Maximum**	**GUL**
µg/100 kcal	1.5		10
µg/100 kJ	0.4		2.4
Molybdenum			
Unit	**Minimum**	**Maximum**	**GUL**
µg/100 kcal	1.5		10
µg/100 kJ	0.4		2.4

- In addition to the compositional requirements when listed, other ingredients may be added in order to provide nutrients ordinarily found in human milk or required to ensure that the formulation is suitable as the sole source of nutrition for the infant and for the dietary management of his/her disease, disorder or medical condition.
- ~~The suitability for the particular nutritional use of infants and the safety of these nutrients shall be scientifically demonstrated. The formula shall contain sufficient amounts of these substances to achieve the intended effect.~~
  - Only L(+)lactic acid producing cultures may be used in Formulas for Special Medical Purposes for infants
  - ~~i.~~ For Lactose Free - ~~with~~ the maximum limit of Lactose fixed is at 0.05mg / 100g (which is already cleared by CCFS) ~~and shall be given on the label~~.

3. Labelling & Claims for Foods for special medical purpose

Foods from the above category shall follow the requirements as laid down in General Labelling, nutritional & claim regulation (to be drafted)

This type of food shall specifically be labelled giving the name of its sub category.

Specific claims made on such foods for prevention, alleviation, treatment or cure of a disease, disorder or a particular physiological condition shall be prohibited unless they are in accordance with the provisions of the regulation for food for specific nutritional uses and follow the principles set forth for those.

Over and above the general labeling requirements for food, Dietary foods for specific Medical purposes shall also bear on label the following:

- The average quantity of each nutrient and /or their components if any, added and as mentioned in the approved lists, to be expressed in numerical terms per100g or per 100ml of the product sold and where appropriate per 100g or 100ml of the product ready for use in accordance with the manufacturer's instructions.
- A statement specifying the nutrient(s) which have been reduced, deleted, increased or otherwise modified, relative to the normal requirements, and the rationale for the reduction, deletion, increase or other modifications as the case may be.
- the statement `For the dietary management of ..... where the blank shall be filled in with the diseases, disorders or medical conditions for which the product is intended;
- Information on the origin and the nature of protein and / or protein hydrolysates contained in the product
- Adequate directions for the preparation including the requirement to add other ingredients, for the use of the food and for its storage
- A prominent statement indicating whether the product is or is not intended as the sole source of nutrition shall appear on the label.
- A statement on the rationale for the use of the product and a description of the properties or characteristics that make it useful.
- A statement that the product is intended for a specific age group, as appropriate;
- Where appropriate a statement that the product poses a health hazard when consumed by persons who do not have the condition, disease, disorder or medical state for which the product is intended.
- Where appropriate, a warning that the product is not for parenteral use.
- The declaration of nutrient content shall be numerical. However the use of additional means of presentation should not be prohibited.
- The number of servings or portions contained in the package should be stated.
- Foods for special medical purposes in which the essential characteristic involves a specific modification of the content or the nature of the proteins, fats or carbohydrates shall bear a description of this modification and information on the amino acid, fatty acid or carbohydrate profile, when necessary.
- A prominent statement "USE UNDER MEDICAL ADVICE" shall appear on the label in bold letters in an area separated from other written, printed, or graphic information.
- Any claims made for the foods covered by this standard shall be in accordance with the General Regualtion on labeling, nutritional labeling and Claims.

4. Additives to be used

Additives allowed to be used in these products also need to be specified. The codex list of allowed additives are given in Annexure 8.

5. Restrictions

A food which has not been processed or modified for use as a special nutritional purpose food but is suitable for use in a particular dietary regimen because of its natural composition, shall not be labelled or claimed with any of the above mentioned categories or sub categories or any other equivalent term.

In any case, the nutrition and health claims shall not

- Be false, ambiguous or misleading
- Give rise to doubt about the safety and / or nutritional adequacy of other foods
- Encourage or condone excess consumption of a food
- State, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients for which sufficient quantities of nutrients in general.
- Refer to changes in bodily functions which could give rise to or exploit fear or desire in the consumer either textually or pictorial, graphic or symbolic representation.

c) Dietary Foods for use in Weight management:

~~i.~~i) **Foods in use for weight control** 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.

~~ii.~~ii) **Food specially prepared for slimming purpose** are prepared to supply a minimum amount of carbohydrates and the daily requirements of the essential nutrients in the range of 450-800 kcal which represents the sole source of energy intake.

The foods mentioned above in i) & ii) are foods when presented as “ready-to-eat” or when prepared in conformity with the directions for use are specifically presented as replacements for all or part of the total daily diet. These Include products with reduced caloric content such as those that are low in sugar and/or fat, sugar- or fat-free, or contain sugar and / or fat substitutes.

(this is largely based on the Codex categorisation and standards)

i. Foods for use in weight control:

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

Dietary 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.

1. General Conditions

Energy Content:

A Dietary food presented as a replacement for all meals of the daily diet shall provide not less than 800 kcal (3350 kJ) and not more than 1200 kcal (5020 kJ). The individual portions or servings contained in these products shall provide approximately one third or one fourth of the total energy of the product depending on whether the recommended number of portions or servings per day is 3 or 4 respectively.

A Dietary food presented as a replacement for one or more meals of the daily diet shall provide not less than 200 kcal (835 kJ) and not more than 400 kcal (1670 kJ) per meal. When such products are

presented as a replacement for the major part of the diet the total energy intake shall not exceed 1200 kcal (5020 kJ).

Nutrient Content:

Protein:

A minimum of 25% and a maximum of 50% of the energy available from the food, when ready-to-serve, shall be derived from its protein content. The total amount of protein shall not exceed 125 g per day.

The protein shall be:

of a nutritional quality equivalent to egg or milk protein (the reference protein);

a. where the protein quality is less than the reference protein, the minimum levels should be increased to compensate for the lower protein quality. No protein with a quality of less than 80% of that of the reference protein shall be used in a Dietary food for use in a weight control diet.

Essential amino acids may be added to improve protein quality only in amounts necessary for this purpose. Only L-forms of amino acids shall be used, except that DL-methionine may be used.

Fat and linoleate: Not more than 30% of the energy available from the food shall be derived from fat including not less than 3% of the energy available derived from linoleic acid (in the form of a glyceride).

Vitamins and minerals

For a Dietary food represented as a replacement for all meals per day, at least 100% of the amounts of vitamins and minerals specified in Annexure 3 (RDA) shall be present in the daily intake.

For a Dietary food represented as a replacement for a single meal, the amounts of vitamins and minerals shall be reduced below the amounts specified above to provide a minimum of 33% or 25% of these amounts, depending on whether the recommended number of servings per day is 3 or 4 respectively.

Ingredients and Additives

Dietary foods for weight control shall be prepared from protein constituents of animals and/or plants which have been proved suitable for human consumption and from other suitable ingredients necessary to achieve the essential composition of the product.

The codex list of approved additives is given in Annexure 8. Codex also allows all Table 3 Additives to be used in these products.

2. Labelling:

Besides general provisions laid down for the labeling except nutritional labeling, these foods shall comply with the following provisions

i. The label and labeling shall not make any reference to the rate or amount of weight loss which may result from the use of the food or to a reduction in the sense of hunger or an increase in the sense of satiety.

~~ii.~~ The label or labeling should make reference to the importance of maintaining an adequate daily fluid intake when dietary foods for weight control are used.

~~iii.~~ If the food provides a daily intake of sugar alcohols in excess of 20 g per day, there shall be a statement on the label to the effect that the food may have a laxative effect.

~~iv.~~ The label and labeling shall carry a statement to the effect that the food may be useful in weight control only as part of an energy-controlled diet.

~~v.~~ For those products presented as replacements of the total daily diet, the label shall contain a prominent statement recommending that, if the food is used for more than six weeks, medical advice should be sought.

~~vi.~~ The average quantity of each nutrient and /or their components if any, added to be expressed in numerical terms per100g or per 100ml of the product sold and where appropriate per 100g or 100ml of the product ready for use in accordance with the manufacturer's instructions.

~~vii.~~ A statement specifying the nutrient(s) which have been reduced, deleted, increased or otherwise modified, relative to the normal requirements, and the rationale for the reduction, deletion, increase or other modifications as the case may be.

~~(c)~~ Adequate directions for the preparation including the requirement to add other ingredients, for the use of the food and for its storage

~~(d)~~ A prominent statement indicating whether the product is or is not intended as the sole source of nutrition shall appear on the label.

~~(e)~~ A complete statement concerning adequate precautions, known side effects, contraindications, and product-drug interactions, as applicable.

~~(f)~~ A statement of the rationale for the use of the product and a description of the properties or characteristics that make it useful.

~~(g)~~ A statement that the product is intended for a specific age group, as appropriate;

~~(h)~~ Where appropriate a statement that the product poses a health hazard when consumed by persons who do not have the condition, medical state for which the product is intended

~~(i)Reference to the importance of maintaining adequate daily fluid intake.~~

~~(j)~~ A statement that the product should not be used by pregnant, nursing and lactating women or by infants, children, adolescents and elderly, except when medically indicated.

~~ii.Dietary foods for slimming purposes~~ Formula Foods For use in very Low energy Diet for Weight Reduction

1. General Conditions

Energy Content

A Dietary food for very low energy diets shall provide when prepared according to instructions a daily energy intake of 450-800 kcal as the only source of energy.

Nutrient Content

~~k.~~i. Protein

Not less than 50 g protein with a nutritional quality equivalent to a protein-digestibility-corrected amino acid score of 1 shall be present in the recommended daily intake of energy.

Essential amino acids may be added to improve protein quality only in amounts necessary for this

purpose. Only L-forms of amino acids shall be used, except that DL-methionine may be used.

~~iii.~~ii. **Fats**

Very low energy diets shall provide not less than 3 g of linoleic acid and less than 0.5 g alpha-linolenic acid in the recommended daily intake with the linoleic acid/alpha -linolenic acid ratio between 5 and 15.

~~iv.~~iii. **Carbohydrates**

Very low energy diets shall provide not less than 50 g of available carbohydrates in the recommended daily intake of energy.

~~v.~~iv. **Vitamins and Minerals**

Very low energy diets shall provide 100% of the recommended daily intakes for vitamins and minerals. Other essential nutrients not specified in Annexure 5 may also be included.

~~vi.~~v. **Ingredients & Additives**

Very low energy diets shall be prepared from protein constituents of animal and/or plant which have been proved suitable for human consumption and from other suitable ingredients necessary to achieve the essential composition of the product.

The codex list of approved additives is given in Annexure 8. Codex also allows all Table 3 Additives to be used in these products.

2. Labelling

Foods from the above category shall follow the requirements as laid down in General Labelling, nutritional & claim regulation (to be drafted) and shall also carry the following on the label

- ~~(k)~~ The name of the food shall be "Dietary food for slimming purposes and weight reduction" or "Dietary Food for Use in Very Low Energy Diets".
- ~~(l)~~ The average quantity of each nutrient and /or their components if any, added to be expressed in numerical terms per100g or per 100ml of the product sold and where appropriate per 100g or 100ml of the product ready for use in accordance with the manufacturer's instructions.
- ~~(m)~~ A statement specifying the nutrient(s) which have been reduced, deleted, increased or otherwise modified, relative to the normal requirements, and the rationale for the reduction, deletion, increase or other modifications as the case may be.
- ~~(n)~~ Adequate directions for the preparation including the requirement to add other ingredients, for the use of the food and for its storage
- ~~(o)~~ A prominent statement indicating whether the product is or is not intended as the sole source of nutrition shall appear on the label.
- ~~(p)~~ A complete statement concerning adequate precautions, known side effects, contraindications, and product-drug interactions, as applicable.
- ~~(q)~~ A statement of the rationale for the use of the product and a description of the properties or characteristics that make it useful.
- ~~(r)~~ A statement that the product is intended for a specific age group, as appropriate;

(s) Where appropriate a statement that the product poses a health hazard when consumed by persons who do not have the condition, disease, disorder or medical state for which the product is intended.

(t) For those products presented as replacements of the total daily diet, the label shall contain a prominent statement recommending that, if the food is used for more than six weeks, medical advice should be sought.

In addition the following directions should be provided:

(u) The statement "for the dietary management of obesity" shall be declared on the label, in close proximity to the name of the food.

(v) Reference to the importance of maintaining adequate daily fluid intake.

(w) A statement that the product should not be used by pregnant, nursing and lactating women or by infants, children, adolescents and elderly, except when medically indicated.

V. A statement that the product may not be recommended for use for purposes other than the dietary management of obesity

d) Performance Foods & beverages

These are dietetic foods formulated and claimed to provide extra energy and may be designed to meet the specific nutritional requirement of individuals involved in intense and/or prolonged physical activity like sportspersons. They are designed to provide extra energy and/or to replace the fluid and/or nutrients which are lost as a result of high physical activity.

An expert group in FSSA is already deliberating on the requirements and regulatory aspects for this category. Hence it is not deliberated here.

~~A.~~C. Proprietary Foods

Proprietary Food is an existing category under PFA and is defined as:

"Manufacture of Proprietary Food

(1) Proprietary Food means a food which has not been standardised under the PFA Rules 1955 and

(2) In addition to the provisions including labeling requirements specified under these rules, the proprietary foods shall also conform to the following requirements, namely:-

(a) the name of the food and category under which it falls in these rules shall be mentioned on the label;

(b) the proprietary food product shall comply with all other regulatory provisions specified in these rules and in Appendixes".

This category should be retained to allow continuity of the current practices and for bringing innovation in general packaged foods category especially in traditional ethnic foods. Once this regulation comes into force, this category should particularly exclude all Fortified Foods, Food Supplements and FSNU's.

Currently, in absence of these special categories, most of them come under Proprietary and the current definition as given above should continue.

Further,

- These products would be allowed to use additives which are allowed for similar category products.
- In the current regulations a broad based Food category system should be introduced which would help in categorizing most similar products under a category and would allow use of additives and claims etc as per that category.
- Introducing broad based category system and bringing specific provisions for FSNU, FSMP, Food Supplement, Fortified Food etc., would reduce the number of foods getting categorized as proprietary substantially. These foods should follow the restrictions and conditions of the respective categories
- If the product doesn't fall under any standard or any category or intends to use additives not allowed for the particular category, then the product and the use of the said additive should be approved by the Authority.
- If any new ingredient or additive with no history of use in India is to be used in a proprietary product, prior notification and approval from the concerned authority is a must and the procedure for such approval should follow the approval procedure laid down for Novel foods.
- Labelling & Claims Shall be guided by the Regulation for General labelling, Nutritional & other claims

This provision on proprietary foods however, will not form part of this regulation on special types of foods. This section should be inserted at an appropriate place in the FSSA main regulation.

~~B.~~D. Novel Foods

~~B.~~A. Definition

Novel food can be defined as

- A food that does not have a history of human consumption ~~in India~~ or
- Any other ingredient or substance used in food, where that substance or the source from which it is derived does not have a history of human consumption as a food ingredient ~~in India~~ or
- Foods and food ingredients consisting of or derived from plants or animals and / or obtained by new technologies or processes where the plant is obtained from traditional breeding processes but has a history of safe use in food.
- Foods and food ingredients which has been produced by a technology not currently in use or being used for the first time, where the process gives rise significant changes in the composition or structure of the foods or food ingredients which affect the nutritional value, metabolism or level of undesirable substances

~~C.~~B. General Regulation

Novel Foods have to be approved for marketing by the Authority and the manufacturer will have to submit an application for approval along with all relevant documents and details as laid down in the regulation.

This regulation shall not apply to:

a) Food additives, flavourings and extraction solvents, vitamins & minerals and food enzymes falling within the scope of separate regulations and in use
b) Any reformulation of food products produced from existing food ingredients by altering the composition, percentage or amounts of food ingredients and additives.
c) a food or food ingredient has been in use exclusively as or in a food supplement or Food for Special Nutritional Uses prior to this regulation come into force, can be placed on the market after this regulation comes into force without being considered as Novel food and there will be no need for further approval

~~D.~~C. Approval Process

A food business operator planning to place novel foods or novel food ingredients in the market for the first time shall submit a request to the Central Authority informing the details of the product, ingredients used, technology and production process involved and proposed claim or declarations to be made on the label along with sufficient scientific data and documents related to safety and efficacy of the food

A model procedure for approval and Safety Assessment is being suggested in Annexure 7. Once approved, the ingredient and the food shall be notified by the Authority as permitted before they may be sold in the market.

~~E.~~D. Labelling

The approval process should also involve approval of any specific claim or declarations intended to be used by the manufacturer.

V. *Suggested structure for the Regulation of Food Fortification and the set of requirements and restrictions:*

Food Fortification is considered as a programme and does not fall under any special category of foods. Generally, a government initiative which is always mandatory in nature. World over this is a known practice where staple foods get fortified to increase the nutrient content of food in a way to increase the nutrition profile of the population or population group. This could be voluntary as well, however, the deficiency or the disease prevalence among population or population group shall be considered as the prime criteria on the basis of which food needs to be fortified.

Food Fortification

The basis of this regulation is the demonstrated need for increasing the intake of a particular nutrient / nutrients which is identified as shortfall nutrient and are essential for the normal growth and development of the population. There may be diverse requirement among the population group due to age, sex, geographical location etc.

A. Definition

"Fortification" **~~"Fortified Foods"~~** ~~are foods manufactured by~~ means addition of one or more essential nutrients to ~~conventional~~ a food~~s of mass consumption~~, whether or not it is normally contained in the food for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the general population or specific population groups. It could be either mandatory or voluntary in nature.

"Nutrient"

"Mandatory fortification" is where government requires the fortification of certain foods in the interests of public health and makes it mandatory for manufacturers to fortify certain foods of mass consumption with identified or listed nutrient or nutrients for preventing or correcting a demonstrated deficiency of one or more nutrients in the general population or specific population group .

"Voluntary fortification" means discretionary fortification of food products by the manufacturer with specific nutrients as per the daily requirement for preventing or correcting a demonstrated deficiency of one or more nutrients in the general population or specific population group.

B. General Regulation for Fortified Foods

Excessive intakes of vitamins and minerals may result in adverse health effects and it is therefore necessary to set maximum amounts for them when they are added to daily use conventional foods. These amounts must ensure that the normal use of the products, under the instructions for use provided by the manufacturer and in the context of a diversified diet, will be safe for the consumer. Therefore those amounts should be total maximum safe levels for the vitamins and minerals present in the food naturally and/or added to the food for whatever purpose, including for technological uses.

Vitamins and minerals in a form that is bio-available to the human body may be added to foods, whether or not they are usually contained therein, in order to take into account, in particular:

(a) a deficiency of one or more vitamins and/or minerals in the population or specific population groups that can be demonstrated by clinical or sub-clinical evidence of deficiency or indicated by estimated low levels of intake of nutrients; or
(b) the potential to improve the nutritional status of the population or specific population groups and/or correct possible deficiencies in dietary intakes of vitamins or minerals due to changes in dietary habits; or
(c) evolving policies and regulatory initiatives based on acceptable scientific knowledge on the role of vitamins and minerals in nutrition and consequent effects on health.

Provided that addition of extra vitamins or minerals to rectify the loss while processing shall not be considered as fortification.

It is suggested that a list of approved vitamins, minerals and other nutrients along with their forms and quantities need to be listed for this purpose. The suggested approved by EU as given in Annex I & II, may serve as the basis.

The criteria for vitamin formulations and mineral substances need to be set taking into account:

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

(b) Intakes of vitamins and minerals from other dietary sources.

(c) the contribution of individual products to the overall diet of the population in general or of sub-groups of the population;

(d) the nutrient profile of the product established

The addition of a vitamin or a mineral to a food and claimed to be so added shall result in the presence of that vitamin or mineral in the food in at least a significant amount. Australia New Zealand Food law specifies that 15 % of the recommended allowance by 100 g or 100 ml or per package if the package contains only a single portion, should be taken into consideration in deciding what constitutes a significant amount.

C. <u>Approval</u>

Once these lists of approved nutrients and their quantities are specified, no approval, permission or notification from concerned authority should be required for voluntary fortification provided the product complies with the requirements laid down and specific labelling requirements for nutritional and health claim as given in **Annexure 6 (**also based on Codex, EU and USFDA).

Provided that for using any new but known additional nutrients for which safety criteria has been established in food, prior approval will be required from authority and once approved the specific nutrient / nutrients will be added in the existing list of nutrients.

Any new nutrient which has no previous history of safe use shall follow the approval procedure laid down for novel foods.

D. <u>Restriction on Fortification</u>

Generally following type of foods should not be fortified

i) All unprocessed fruits, vegetables, meat, poultry and fish
ii) Products containing more than 1.2% alcohol.
~~iii) Fortification should generally be discouraged in foods having significant fat, salt or sugar content~~

iii) The intake of the food selected as a vehicle should be stable and uniform and the lower and upper levels of intake should be known.
iv) The amount of the essential nutrient added to the food should be sufficient to correct or prevent the deficiency when the food is consumed in normal amounts by the population at risk.
v) The amount of the essential nutrient added should not result in excessive intakes by individuals with a high intake of a fortified food.

~~iv)~~ GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS (CAC/GL 09-1987 (amended 1989, 1991)

E. Labeling & Claims

Labelling of fortified foods shall follow the requirements laid down in General labelling, nutritional and Claims Regulation (to be developed)

For mandatory fortification a declaration on the label stating "fortified with……" (the blank to be filled up by the name of the nutrient) and the quantity of the nutrient added (which will be finalised by the authority) shall be given.

In case of voluntary fortification and claims made to that respect shall be justified and not misleading and, the fortified food shall be labelled as "fortified with……" the blank to be filled up by the name of the nutrient and the quantity of the nutrient added along with the percentage of RDA that will come from per serving of the food.

VI. Inputs required from Experts

Apart from general comments on the content, scope and the regulatory requirements, particular inputs are sought from the experts on the following:

1. Whether the four broad categories and sub categories there-under cover the whole gamut of special types of foods or not(excluding fortification)
2. Suggest and finalise list of vitamins and minerals and their criteria for use as given by Codex (Annex 1, 2, 4 &5). NIN could be contacted for current data available with them.
3. Any special packaging for vitamins & mineral supplements, if required
4. Suggest and finalize list of nutrients other than Vitamins and minerals for India
5. Suggest and finalise list of ingredients from Ayurvedic or Unani origin that can be allowed in special foods
6. Suggest and finalise list of approved claims related to such ingredients
7. Finalise the Annexure 3 on RDAs for India
8. Check whether Annexure 4 on nutritional composition of nutrients for nutritionally complete foods for medical purposes (which is taken from EU regulation) can be adopted as such for India or it requires amendment
9. Data on Safety and efficacy of novel food ingredients, if any

10. Data on need for fortification based on prevalence of deficiencies, diseases or disorders amongst population or population group
11. Suggestion on whether there should be a minimum amount of vitamins / minerals content to claim the product a Health supplement, if so what are those amounts
12. Any suggestion on mandatory / voluntary fortification in India