

Understanding Nutrition Claims

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Seminar on Nutrient and Health Claims
on Food Products

8, Nov, 2017 at Hotel Courtyard
Marriot, Andheri (E) Mumbai



KNOW YOUR SPEAKER



- ▶ Postgraduate with >20 years Techno-Commercial Experience.
- ▶ Native of Himalaya Foothills – Dehradun, Uttarakhand.
- ▶ Key Competencies :
 - Regulatory Affairs, QMS & FSMS, QA/Quality Control/Sensory
 - Manufacturing & Operations
 - Certified QMS/FSMS/ISO 14000 LA Courses – DNV/BVQI
 - Members to Indian Delegation in Various CODEX Committees.
 - Members of BIS FAD 10, FAD 15, FAD 16 FAD 24 and FAD 28 committees.



Regulatory Affairs



Enduring Value

Regulatory Affairs



refreshing India
QA/QC/RSA/
Manufacturing



QA/QC/QMS/
FSMS/Manufacturing



Microbiologist/Chemist/QMS

What is a 'Nutrition Claim' ?

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

Nutrition Claims??



- A method of conveying information about foodstuffs to the consumer.
- To ensure fair comparisons between the products marketed
- Helping consumers choose the right food



How consumers gets the claim information?



Education



Media & Advertisements

(Print, digital, social, POS, Prescriptions)



Food Product label

Nutrition Claims

Nutrient Content claim

Nutrient content claim that describes the level of a nutrient contained in a food.
Eg. Source of; high in; rich in; low in etc.



Hi fibre
Dietary fibre value -6g/100g

Nutrient Comparative claim

Nutritive comparative claim is a claim that compares the nutrient levels and/ or energy value of two or more foods.
Eg. Reduced, less than, fewer, increased, more than etc.



Reduced sugar compared to original kellogg's fruit loops

Nutrient Function claim

Nutrient Function claim is that which describes the physiological role of the nutrient in growth, development and normal function of the body.
Eg. Calcium builds strong bones



Calcium for healthy bones

What constitutes a nutrient content claim?



- When a nutrient content claim that is approved/listed or a synonymous claim is made, the conditions specified in the national/international legislation for that claim, should apply.
- A claim to the effect that a food is free of salt can be made, provided the food meets the conditions for free of sodium as approved by national/international legislation.
- Where a food is by its nature low in or free of the nutrient that is the subject of the claim, the term describing the level of the nutrient should not immediately precede the name of the food but should be in the form “a low (naming the nutrient) food” or “a (naming the nutrient)-free food”.

“a low sodium food” or Cholesterol free food

“ Transfat free”, “High Fibre”, “High protein”



What constitutes a nutrient comparative claim?



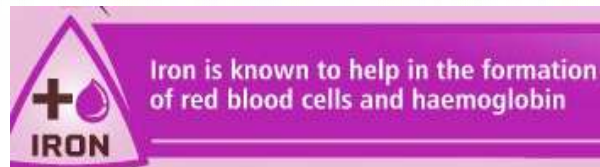
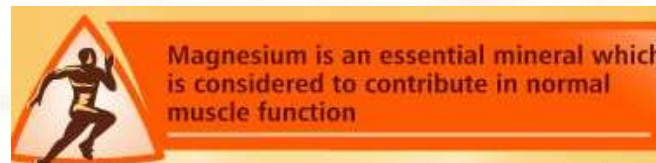
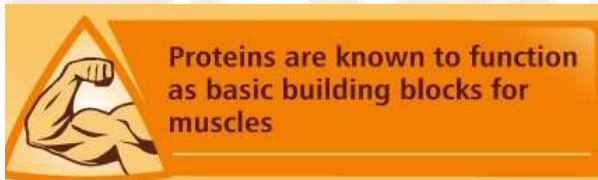
When a Nutrient comparative claim is made, the food shall be **different versions of the same food or similar food being compared** and shall be clearly identified.

- For comparative claims about energy or macronutrients and sodium, the comparison should be based on a relative difference of at least 25% in the energy value or the nutrient content respectively between the compared foods and a minimum absolute difference in the energy value or nutrient content equivalent to the figure defined as “low” or as a “source” in the Table to these Guidelines.
- For comparative claims about micronutrients other than sodium the comparison should be based on a difference of at least 10% of the NRV (Nutrient Reference value) between the compared foods.
- A statement of the amount of difference in the energy value or nutrient content should be given. **The following information should appear in close proximity to the comparative claim.**
 - **The amount of difference related to the same quantity, expressed as a percentage, fraction, or an absolute amount. Full details of the comparison should be given.**
 - **Eg: “25% less fat than the regular product of the same brand”**

What constitutes a nutrient function claim?



- It describes the physiological role of a nutrient in growth, development and normal functions of the body. *
- It must fulfil several general principles, such as:
 - The claim must be supported by science.
 - **The information about the physiological role of the claimed nutrient must be included in the claim.**
- **Specific Format (Best Practice):**
- “Nutrient A (naming a physiological role of nutrient A in the body in the maintenance of health and promotion of normal growth and development). Food X is a source of/ high in nutrient A.”*
- Example of common nutrient function claims:
 - **“Calcium helps build strong bones”. Milk is a source of Calcium**



*Source - codex

Equivalence claim

- **It's an emerging food marketing tool which is being used of the equivalence claim**
- Equivalence claims are commercial representations that attempt to promote the equality in value, amount and importance of one food attribute to another.
- For example, "contains as much [nutrient] as a [food]" may be made if both reference food and labelled food are a "Good Source" of a nutrient on a per serving basis.
e.g. "Contains as much vitamin C as an 8 ounce glass of orange juice")
- **Theses type of claims to be based on an accepted scientific approach able to withstand the rigors of expert scrutiny and not simply on a manufacturer-derived formula.**

Contains 0% juice

Nutrition Facts
Serving Size 1 bottle (300ml)
Amount Per Serving
Calories 90 Calories from Fat 0
% Daily Value*

Total Fat	0g	0%
Saturated Fat	0g	0%
Trans Fat	0g	0%
Cholesterol	0mg	0%
Sodium	45mg	2%
Total Carbohydrate	35g	12%
Dietary Fiber	14g	56%
Sugars	0g	
Protein	0g	
Vitamin A	0%	Vitamin C 100%
Calcium	0%	Iron 0%

*Percent Daily Values are based on a diet of 2,000 calories. Your Daily Values may be higher or lower depending on your calorie needs.
Calories: 2,000 2,500

Total Fat: Less than 45g 45g
Saturated Fat: Less than 30g 25g
Cholesterol: Less than 300mg 300mg
Sodium: Less than 2,400mg 2,400mg
Total Carb: 300g 375g
Dietary Fiber: 25g 30g

Helps maintain normal cholesterol levels*

Provides as much dietary fiber (14g) as 2-1/2 bowls of high fiber cereal or over 4 apples

No Artificial Flavors
No Preservatives
Excellent source of Vitamin C and Dietary Fiber

SUGGESTED USE:
Enjoy one drink daily. As your body adjusts to increased fiber intake, you may experience changes in bowel habits or minor bloating. Keep bottle tightly closed. Refrigerate after opening. Best when served chilled and when used by date printed on bottle. Do not use if tearing is broken or missing.

INGREDIENTS: Purified Water, Sugar, Fiber Blend (Maltodextrin and Inulin), Natural Flavors, Sodium Citrate, Ascorbic Acid (Vitamin C), Citric Acid, Caramel (Added for Color), Sodium Ascorbate.

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

4 BISCUITS

GLASS OF MILK

1 glass (175 ml) cow's milk
Reference NIN, 2007

*Source (USFDA & ACCC)

How Rigorously a Nutrition claims need to be looked at !



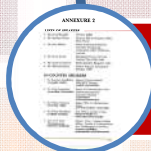
The amount of nutrient involved in a nutrition claim must be declared on the nutrition label.



Product Appropriateness



Approver of claims should look at scientifically validated data or appropriate literature established by recognised scientific authority/ institution considering the study of bioavailability of the substance.



Must be listed in national regulations



Comprehensive analytical data of the said product would be reviewed or validated including statistics.



The stability of the claimed Nutrients should be throughout the shelf life of the product.



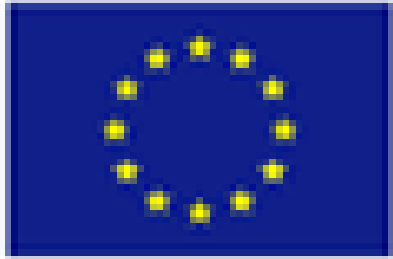
Any modification in the formulation will influence to relook at the claims.



Health

Food

Indian & Global Scenario Nutrition claims





Food Safety and Standards - Relevant Provisions

(d) “claim” means any representation which states, suggests, or implies that a food has particular qualities relating to its origin, nutritional properties, nature, processing, composition or otherwise;

**Chapter -2 (FSS Act)
Section 3(d)**

(zf) “misbranded food” means an article of food –

Chapter -2 (FSS Act)

(A) if it is purported, or is represented to be, or is being – **Section 3(zf)**

(i) offered or promoted for sale with false, misleading or deceptive claims either;

Penalties for misbranded food	Extends to Rs. 3 lakhs
Penalties for misleading advertisements	Extends to Rs. 10 lakhs
Penalties for false information	Extend to three months of imprisonment & Rs.2lakh fine

Chapter –IX (FSS Act)- Offences and Penalties

3. Nutritional information – Nutritional Information or nutritional facts per 100 gm or 100ml or per serving of the product shall be given on the label containing the following:—

- (i) energy value in kcal;
- (ii) the amounts of protein, carbohydrate (specify quantity of sugar) and fat in gram (g) or ml;
- (iii) the amount of any other nutrient for which a nutrition or health claim is made:

Provided that where a claim is made regarding the amount or type of fatty acids or the amount of cholesterol, the amount of saturated fatty acids, monounsaturated fatty acids and polyunsaturated fatty acids in gram (g) and cholesterol in milligram (mg) shall be declared, and the amount of trans fatty acid in gram (g) shall be declared in addition to the other requirement stipulated above:

**Chapter -2 (Packaging and Labelling)
Section 2.2.2.3 Nutrition information**

(i) “Health claims” means any representation that states, suggests or implies that a relationship exists between a food or a constituent of that food and health and include nutrition claims which describe the physiological role of the nutrient in growth, development and normal functions of the body, other functional claims concerning specific beneficial effect of the consumption of food or its constituents, in the context of the total diet, on normal functions or biological activities of the body and such claims relate to a positive contribution to health or to the improvement of function or to modifying or preserving health, or disease, risk reduction claim relating to the consumption of a food or food constituents, in the context of the total diet, to the reduced risk of developing a disease or health related condition;

(ii) “Nutrition claim” means any representation which states, suggests or implies that a food has particular nutritional properties which are not limited to the energy value but include protein, fat carbohydrates, vitamins and minerals;

**Chapter -2 (Packaging and Labelling)
Section 2.2.2.3**

A brief look in to Nutrient content claim & Nutrient Comparative claim - Global

Nutrient/ Component	Claim	Codex	EU	USFDA	FSANZ
Protein	Source	10% of NRV per 100 g (solids) 5% of NRV per 100 ml (liquids) or 5% of NRV per 100 kcal (12% of NRV per 1 MJ) or 10% of NRV per serving	at least 12 % of the energy value of the food is provided by protein	The food provides 10% more of the Daily Value for a given nutrient than the comparison food	The food contains at least 10 g of protein/ servings
Saturated fat	Free	Not more than 0.1 g per 100 g (solids) 0.1 g per 100 ml (liquids)	The sum of saturated fat and trans-fatty acids does not exceed 0,1 g of saturated fat per 100 g or 100 ml.	< 0.5 grams of saturated fat and 0.5 grams of trans-fatty acids per serving	The food contains no detectable *saturated fatty acids; and (b) the food contains no detectable *trans fatty acids
Dietary fibre	High	Not less than 6 g per 100 g or 3 g per 100 kcal or 20 % of daily reference value per serving	At least 6 g of fibre per 100 g or at least 3 g of fibre per 100 kcal	5 grams or more fiber per serving	A serving of the food contains at least 7 g of *dietary fibre. (Excellent source)
Cholesterol	Low	Less than 0.02 g per 100 g (solids) 0.01 g per 100 ml (liquids) less than:1.5 g saturated fat per 100 g (solids) 0.75 g saturated fat per 100 ml (liquids) and 10% of energy from saturated fat	Not mentioned	20 mg or less cholesterol per serving and 2 grams or less saturated fat per serving	The food contains no more cholesterol than: (a) 10 mg/100 mL for liquid food; or (b) 20 mg/100 g for solid food.

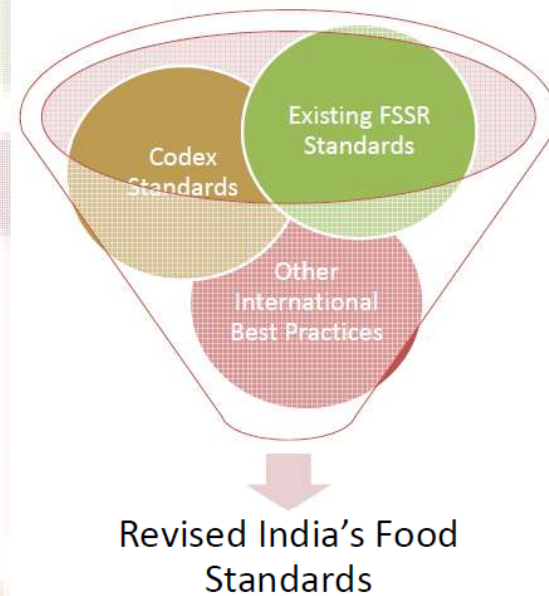
A brief look in to Nutrient content claim & Nutrient Comparative claim - Global

Nutrient/ Component	Claim	Codex	EU	USFDA	FSANZ
Nutrient (Protein, Fat, Carbohydrate Salt)	Reduced	Energy/ Nutrient content between compared foods must differ by at least 25%. Minimum absolute difference in the energy value or nutrient content > or = the value required for claim as “ source” or “low”.	The reduction content must differ by at least 30% compared to similar products. For sodium, or the equivalent value for salt, where a 25 % difference shall be acceptable.	At least 25% less of a given nutrient or calories than the comparison food	At least 25% less nutrient content/ energy than the reference food.
Fat	Free	Not more than 0.5 g per 100 g (solids) or 100 ml (liquids)	Not more than 0.5 g per 100 g (solids) or 100 ml (liquids)	Not more than 0.5 g of fat per reference amount customarily consumed and per serving,	The food contains no more fat than: (a) 3 g/100 g for solid food or (b) 1.5 g/100 mL for liquid food
Sugar	Free	Not more than 0.5 g per 100 g (solids) or 0.5 g per 100 ml (liquids)	Not more than 0.5 g per 100 g (solids) or 0.5 g per 100 ml (liquids)	< 0.5 grams of sugar per serving	The food contains no more sugars than: (a) 5 g/100 g for solid food ; or (b) 2.5 g/100 mL for liquid food.
Sodium	low	Not more than 120mg per 100 g of food	Not more than 120mg or the equivalent value for salt, per 100 g or per 100 ml	Not more than 140 mg or less per serving of food	The food contains no more sodium than: (a) 120 mg/100 g for solid food or (b) 120 mg/100 mL for liquid food
Energy	Low	Not more than (a) 40 kcal per 100 g (solids) or (b) 20 kcal per 100 ml (liquids)	Not more than (a) 40 kcal per 100 g (solids) or (b) 20 kcal per 100 ml (liquids)	Not more than 40 calories or less per serving	The *average energy content of the food is no more than: (a) 40.6kcal/100 g for solid food or (b) 19.1 kcal/100 mL for liquid food;

Claim Guidelines is under development in FSSAI, one of the best practice mentioned above may be considered

How the claims will be regulated in India? – Moving forward

FSSAI is in the process of harmonizing the FSS Standards with the best practices across the world including Codex and other latest development in food science.



FSSAI has also signed a MOU with Advertising Standards Council of India (ASCI) to curb the menace on [misleading advertisements](#)



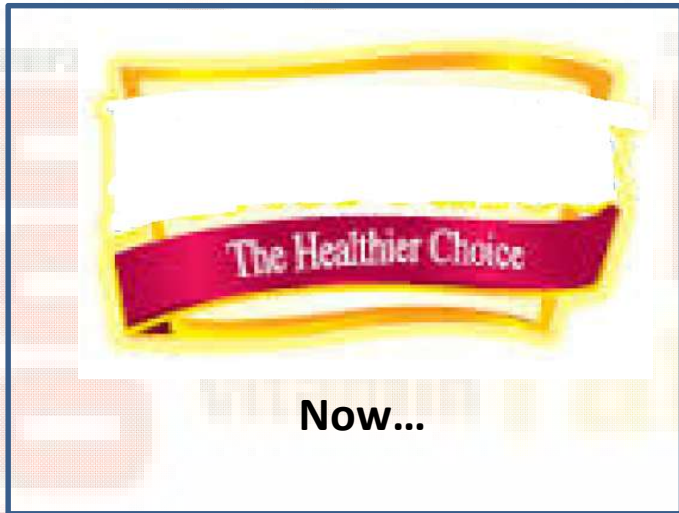
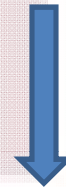
Live Example of a comparative claim..... litigation.....



Surendra & Company Vs.
Rajesh Kumar Rai and others
(MP High Court decision on 1st May, 2015)

Rule 49(23) of the Prevention of Food Adulteration Act, 1955,

[(23) The **fat spread** shall not be sold in loose form. It shall be sold in sealed packages weighing not more than 500 gms. **The word "butter" shall not be associated while labelling the product.** The sealed package shall be sold or offered for sale only under AGMARK certification mark bearing the label declaration as provided under rule 42 besides other labelling requirements under these rules.



Held by the MP High Court :

Food packet purchased by the Food Inspector contains the words "Nutralite (Healthier then Butter)". **As per the complaint of the Food Inspector, using the word 'butter' in the labeling of the product is prohibited.** Therefore, it is violation of Section 2(ix)(x) of the Food Adulteration Act and Rule 49(23) of Food Adulteration Rules. Therefore, the word butter used in the label constitute "misbranding".

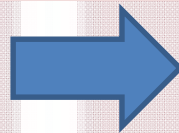
Despite the fact that term will not be associated while labeling product, as has been stated above, the word "butter" has been **used to promote the sale** by labeling it as "healthier than butter"

What makes a sustainable claim ? Industry Perspective !!

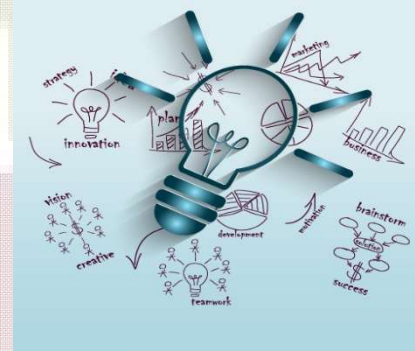


Consumer Benefit

- Consumer confidence
- Affordability
- Product quality
- Reliability



Business interest, Does it make sense to business ?

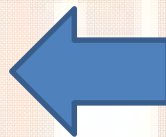


“Magic bullets” generally not convincing

- When discussing food, consumers relate to benefits, not disease
- Dissonance is disturbing
- More label use if: Special diet
Higher income Better nutrition knowledge



- ☑ Understand stability of nutrient in your product
- ☑ Identify relevant studies
- ☑ Classify studies ☑ Rate studies for quality
- ☑ Rate for strength of body of evidence: quantity, consistency, relevance



Role of governance (FSSAI and ASCI)

- Sample picking
- ASCI review
- Verification/substantiation/appropriate
- Testing/ analysis
- Consumer approach

Scientific substantiation through time bound regulatory mechanism

Prohibited Claims



- Claims stating that any given food will provide an adequate source of **all essential nutrients**, except in the case of well defined products for which a Codex standard regulates such claims as admissible claims or where appropriate authorities have accepted the product to be an adequate source of all essential nutrients.
- **Claims implying that a balanced diet or ordinary foods cannot supply adequate amounts of all nutrients.**
- Claims which cannot be substantiated.
- Claims as to the suitability of a food for use in the **prevention, alleviation, treatment or cure of a disease, disorder**, or particular physiological condition unless they are: (a) in accordance with the provisions of Codex standards or guidelines for foods as developed by the Committee on Nutrition and Foods for Special Dietary Uses and follow the principles set forth in these guidelines. or, (b) in the absence of an applicable Codex standard or guideline, permitted under the laws of the country in which the food is distributed.
- Claims which **could give rise to doubt** about the safety of similar food or which could arouse or exploit fear in the consumer (e.g. **causes cancers/carcinogenic (when approved for certain dosage, cholesterol free in a product which is naturally devoid of cholesterol, ????)**).

What's trending ?



- EFSA - Open Public Consultation in relation with the evaluation on the **Regulation on nutrition and health claims made on foods**. Once the evaluation is completed, the European Commission will adopt a Staff Working Document (SWD), drawing on relevant studies and sources of information. The SWD will include a summary of the results of this consultation.
- EFSA has launched a public consultation on its draft scientific opinion on dietary reference values (DRVs) for sodium. In particular, it is seeking feedback on the way it plans to select and use evidence in its assessment.
- EFSA has set dietary reference values for riboflavin (vitamin B2) as part of its review of scientific advice on nutrient intakes.
- EFSA panel renewal 2018 for Nutrition experts
- EFSA to give advice on the intake of sugar added to food.
- Public consultation : follow on formulae with lower protein content
- HFSS – Draft Regulation on Food Safety and Standards (Safe and Wholesome Food – School Children) Regulations, 2017 (**under discussion in FSSAI**)





complied

LABEL AND LABELLING

Thank you





natural

Health

Claim

Low-fat
Low

Nutrition

Fat-free
Salt
Vitamin