Understanding Labelled Nutritional Information and its Substantiation

PFNDAI “Role of Evolving Food Regulations in Ensuring Ingredients Safety and Transparent Labelling“

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Content

- Nutritional information – Past, present, future
- Substantiation of NIP
- Other nutritional information- Claims (Nutrient content, nutrient function, health claims)
- Substantiation of claims
- Future FSSA initiatives- Claims approval in Epass portal, Guidance on Human Intervention studies

Past

PREVENTION OF FOOD ADULTERATION (7TH AMENDMENT) RULES, 2006

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

NOTIFICATION

New Delhi, the 21st August, 2006

*G.S.R. 491(E).- Whereas certain draft rules further to amend the Prevention of Food

ABC Product	
Nutritional Information (Per 100 g)	
Energy (kcal)	556
Protein (g)	8.4
Carbohydrate (g)	50.3
Of which Sugar (g)	1.1
Fat (g)	35.6
Trans fat (g)	0.0
Saturated fat (g)	16.1

No Specific tolerance given for declared nutrients

Present

PREVENTION OF FOOD ADULTERATION (7TH AMENDMENT) RULES, 2006

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FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA

NOTIFICATION

New Delhi, the 17th November, 2020

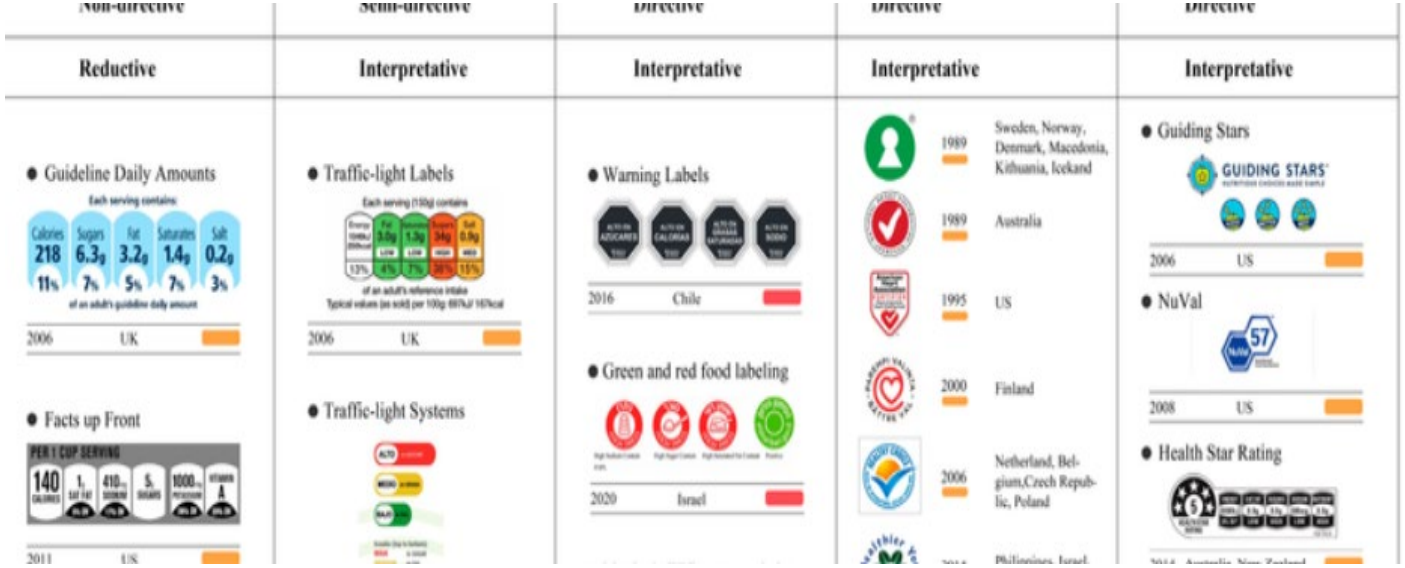
F. No. 1-94/FSSAI/SP(Labelling)/2014(Pt-2).—Whereas the draft of certain regulations, namely, the Food

ABC Product			
Nutritional Information	Per 100 g	Per Serve	%RDA Contribution Per Serve
Energy (kcal)	556	83	4
Protein (g)	8.4	1.3	-
Carbohydrate (g)	50.3	7.5	-
Sugars (g)	1.1	0.2	-
Added Sugar (g)	0.1	0.01	0.02
Total fat (g)	35.6	5.3	8
Trans fat (g)	0.0	0.0	0
Saturated fat (g)	16.1	2.4	11
Cholesterol (mg)	0.0	0.0	-
Sodium (mg)	991	149	7
One Serving = 15 g. Number of servings in the Package = 2 *(for a 30 g pack)*			

The tolerance of maximum minus 10 percent of the value for that nutrient declared.

- ✓ Mandatory per serve declaration
- ✓ Include amount of food in gram for reference beside the serving measure and number of servings in package
- ✓ Clear definitions of nutrients
- ✓ Calculation method – energy, protein
- ✓ NIP may additionally be provided on Barcode / Global trade identification number (GTIN)

Future

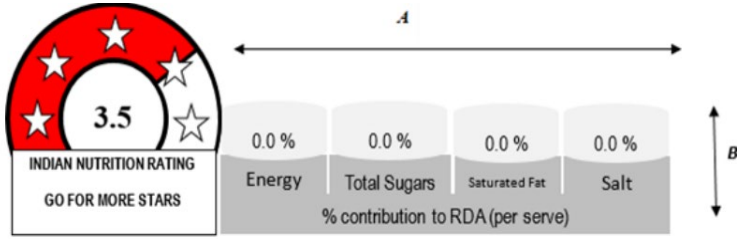


FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA

NOTIFICATION

New Delhi, the 13th September, 2022

F. No. Std./SP-08/T(FoPNL-N-01).—The following draft of certain regulations to further amend the Food



Interpretative Nutritional information labeling for quick on-the-go decisions.

Substantiation and best practices

Labels are subject to post-market surveillance. Manufacturers need to back up nutrient label claims with rigorous, standardized scientific evidence

Core Components of Nutrition Labelling

- **Serving Size:** The standard portion on which the label's data is based.

Manipulation of serving sizes to make calorie and fat counts appear smaller. Keep documentation to demonstrate that the serving size taken is realistic and in line with consumer use.

- **Energy (Calories):** The total energy per serving.

Calculation of Energy: The amount of energy to be listed should be calculated by using the following conversion factors:

(A) Carbohydrates	4 kcal/g
(B) Polyols except Erythritol	2 kcal/g
(C) Erythritol	0kcal/g
(D) Protein	4 kcal/g
(E) Fat	9 kcal/g
(F) Alcohol (Ethanol)	7 kcal/g
(G) Organic acid	3 kcal/g
(H)Dietary fibre	2kcal/g

Substantiation and best practices

- **Core Nutrients:** Mandatory declarations of total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrates, total sugars, added sugars and protein. Further for oils- MUFA, PUFA, omega 3 and 6.
- **Other Nutrients:** claimed to be enriched nutrients (minerals, proteins, vitamins, amino acids or enzymes)

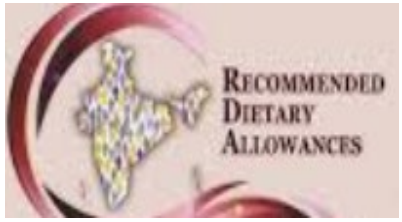
Food safety officers or independent testing bodies periodically test products to verify that the actual nutrient values match the declared values on the label.

Hence, Manufacturers should maintain periodical analytical test records to verify the label claims. Use FSSAI manuals/ internationally validated methods in in-house/ third party laboratory.

- **%RDA:** Indicates how much a nutrient contributes to a total daily 2,000-calorie diet.

Manufacturers are required to maintain extensive records of their testing and calculations for %RDA declaration per serve.

product and per serve percentage (%) contribution to Recommended Dietary Allowance calculated on the basis of 2000kcal energy, 67 g total fat, 22 g saturated fat, 2 g trans fat, 50 g added sugar and 2000 mg of sodium (5 g salt) requirement for average adult per day, shall be given on the label containing the following: —



Other nutritional information- Nutrient claims and substantiation

Nutrition Claims - any representation stating/suggesting/implying - food has particular nutritional properties

- **Nutrient Content claims** - directly or indirectly describes the level of a nutrient contained in a food.
- **Nutrient Comparative Claim** - compares the nutrient levels or energy value of two or more similar foods
- **Equivalence claims** -attempt to promote the equality in value, amount and importance of one food attribute to another
- **Conditional Claims-** Where a food is by its nature is high or low or free of a specific nutrient 'natural or naturally' in the claim statement.

10.	Sugars	Low	The product contains not more than **5 g** of sugars per 100 g for solids or **2.5 g** of sugars per 100 ml for liquids.
		Free	The product contains not more than **0.5 g** of sugars per 100 g for solids or 100 ml for liquids.
11.	Protein	Source	10% of RDA per 100 g for solids 5% of RDA per 100 ml for liquids or 5% of RDA per 100 kcal
		Rich / High	20% of RDA per 100 g for solids 10% of RDA per 100 ml for liquids or 10% of RDA per 100 kcal
12.	Vitamin(s) and/or Mineral(s)	Source	The food provides at least **15%** of RDA of the vitamin/mineral per 100g for solids or **7.5%** of RDA of the vitamin/mineral per 100 ml for liquids

Free	Low	Reduced	High	Increased	Source
Zero, No, Without, Negligible Source	Little, few (for calories), contains a small amount of, low source of, Lite, Light	Lower, **Lesser**, fewer (for calories),	More, Rich	, **Higher,** Enhanced	Provides, Contains

parameter between the compared foods is-

[3][(a) at least thirty per cent. in the energy value or macronutrients content;

(b) at least ten per cent. of the recommended dietary allowances per 100 g or 100 ml, for claims about micronutrients other than sodium;

(c) at least twenty-five per cent. in case of sodium, or the equivalent value for salt:

Provided that in case of salt when sold as such, then ten per cent. difference shall be acceptable.]

[3][(6) The equivalence claims in the form of phrases such as "contains the same amount of [nutrient] as a [food]" and "as much [nutrient] as a [food]" may be used on the label or in the labeling of foods, provided that the amount of the nutrient in the reference food is enough to qualify that food as a "source" of that nutrient, and the labeled food, on per 100 g or 100 ml, is an equivalent source of that nutrient, or where the food nutrient is at the same level as the naturally occurring reference food nutrient, the same shall be indicated on the label and through nutritional information (e.g., "as much fibre as an apple," and "contains the same amount of vitamin C as ….. glass of orange juice.").]

9. Conditional Claims.- (1) a claim may be made where a food is by its nature high or low or free of a specific nutrient provided the name of the nutrient or substance is preceded by the words 'natural or naturally' in the claim statement.

Explanation: "a naturally low (naming a nutrient or substance) food" or "a naturally (naming the nutrient or the substance) free food".

Other nutritional information- Nutrient claims and substantiation

Health Claims - any representation stating/suggesting/implying – cause effect relationship

- **Nutrient function claims** - describes the physiological role of nutrient in growth, development and normal function on body
- **Other function Claim** – special beneficial effect on health improvement
- **Disease risk reduction claim**- describes that consumption of food reduces the risk of a health condition
- **Product led claims-** health benefit attributed to the food product.

Fortified foods claims as per Schedule IV

(2) Nutrient function claims and other function claims may be made based on current relevant scientific substantiation and to provide sufficient evidence on the type of claimed effect and the relationship to health as recognised by generally accepted scientific review of the data and the scientific substantiation shall be reviewed by food business operator as new knowledge becomes available and claims updated accordingly.

Reduction of disease risk claims

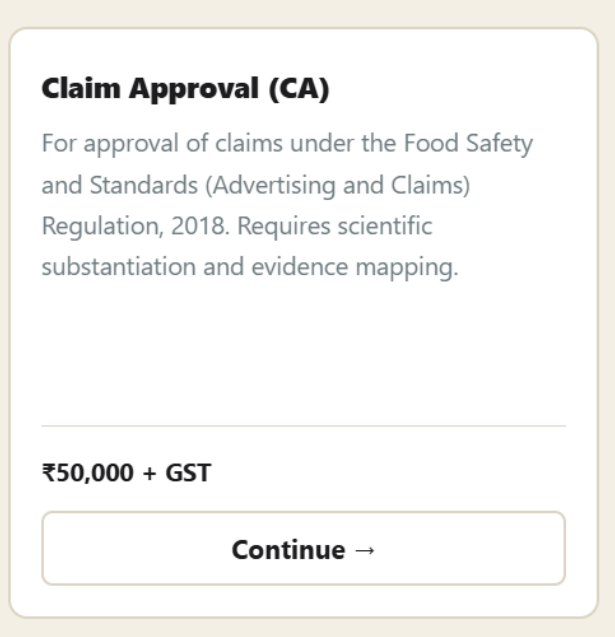
The claim statements provided below may be used on labels and/or advertisements.

SI. No. (1)	Nutrient or Food-Health Relationship (2)	Conditions for claim (3)	Claim Statement (4)
1	Calcium or Calcium and Vitamin D and osteoporosis	(i) The food is a source or high in calcium or in calcium and vitamin D; and (ii) a statement that the beneficial effect is obtained with a daily recommended intake (RDA)	Adequate calcium (or calcium and vitamin D) intake throughout life, through a balanced diet are essential for bone health and to reduce the risk of osteoporosis

11.Approval of claims.- The food business operator or marketer shall seek prior approval from the Food Authority for reduction of disease risk claims other than those that are defined and for which criteria are laid out

(5) Where a claimed health benefit is attributed directly to the product, it shall be based on statistically significant results from well-designed human intervention studies, conducted by or under guidance of established research institutions, in line with the principles of GCP (Good Clinical Practices) and peer reviewed or published in a peer reviewed reputed scientific journal.

Claims approval under Epass portal (www.epass.fssai.gov.in)



1. Applicant and product details → 2. Claim and IPR → 3. Scientific study → 4. Payment

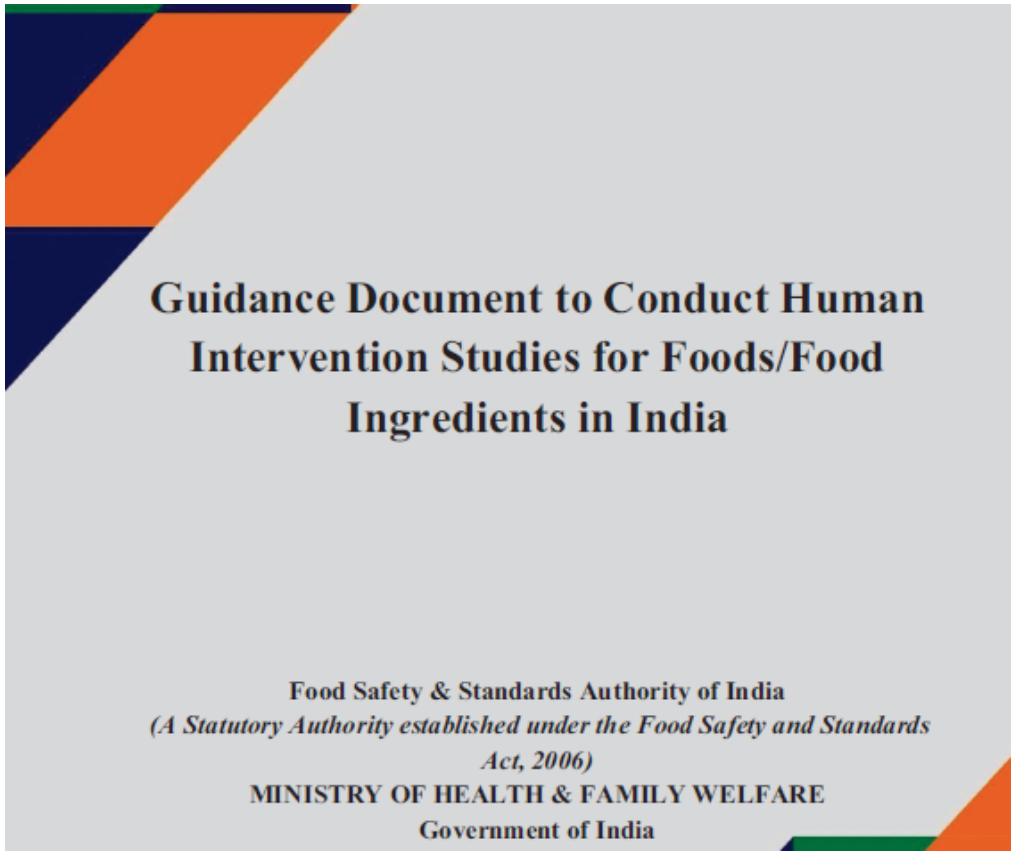
Claim and IPR
Type of Claim Required (on product/ingredient)
Name of the ingredient, nutrient or substance on which the claim is to be made
Claim Statement
Justification of the claim statement - How is the claim clear and meaningful to help consumers comprehend the information on the product - I
Is the Ingredient or product on which claim is intended to be made protected under Intellectual Property Rights/Patented?
Are any claim functions protected by IPR?
IPR supporting documents

Scientific study
Scientific Substantiation - Scientific substantiation supporting documents/materials
Cause-effect relationship studies for "Reduction of Disease Risk" claims
Validated method of analysis for ingredient or substance for which the claim is made
Safety
Additional Information

FSSA Draft Guidance on Human Intervention studies (HIS)

FSSA necessitates HIS in below conditions:

- **Health Claims:** To substantiate claims regarding a product's health benefits, which must be based on statistically significant results from well-designed human studies.
- **Non-Specified Food & Ingredients (NSF&I):** For new ingredients or foods not currently standardized under FSSAI regulations.
- **Functional/Specialty Foods:** For Foods for Special Medical Purposes (FSMP) or Food for Special Dietary Uses (FSDU) or Foods with Probiotics & Prebiotics, Nutraceuticals & Health Supplements, Speciality Foods with Botanicals, to demonstrate efficacy and safety.
- **Novel Products:** when approval is sought for a novel food product/ingredient
- **Processes:** When using a novel, non-traditional method for processing traditional foods.
- **Efficacy Data Generation:** When an existing approved food/ingredient is used with the intent of generating new data to make a specific label claim.



Annexure 1: Decision Tree for deciding the HIS studies

Annexure 2: Format for applying to seek NOC for conducting the HIS in India

Annexure 3: Format for NOC with conditions of NOC

Annexure 4: Format for Undertaking of Principal Investigator(s)

Annexure 5: Format for submission of report of the HIS

Annexure 6: Post-Market Surveillance (PMS) Data Submission Format

Pre-approval activities
Compound identification
research design

FSSA approval for HIS

HIS implementation
Ethics committee approval
Trial design
Dietary intervention type
No of subjects, drop outs

Post implementation activities
Data collation, statistical analysis
Adverse event reporting
Data management

Thank you ☺