

Nutrient Function claim

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Why Regulate ?



Applicable Regulations

- ▶ Food Safety Standards (Health Supplements- Nutraceuticals) Regulations, 2016
- ▶ DRAFT - Food Safety and Standards (Advertisements and Claims) Regulations, 2017.
- ▶ Food Safety Standards (Fortification of Foods) Regulation, 2017 - Health claims

Definitions

- ▶ Nutrient - not defined
- ▶ Nutrient ingredients - means vitamins, minerals and amino acids specified in schedule I and II of FSS - Nutra Regulation
- ▶ In Nutra Regulation - claims related to nutrient or nutritional ingredients are placed under “Health Claims”
- ▶ Fortification Regulation - places “nutritient function claim” under “health claim”

Definitions - As per Draft Claim Regulation

- ▶ *“Nutrient Function Claim” is that which describes the physiological role of the nutrient in growth, development and normal functions of the body”*
- ▶ *“other Function Claim” that describe the specific beneficial effects of the consumption of food(s) or their constituents, in the context of the total diet or normal functions or biological activities of the body. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health.*
- ▶ Iron - Essential for the formation of Haemoglobin in red blood Cells
- ▶ Reduces tiredness and fatigue

Requirements of Nutrient Function claim

- ▶ Describes or give information on the physiological role of the nutrient in growth, development and normal functioning
- ▶ Claims must help consumers to comprehend the information provided. (Draft Claim)
- ▶ Plain and matter of fact statements
 - ▶ Vitamin D and Calcium are required for proper bone formation
 - ▶ Vitamin B1 is required for carbohydrate metabolism and release of energy
 - ▶ Vitamin A is required for normal vision and prevents night blindness

Requirements of Nutrient Function claim

- ▶ Use of adjectives like “ boosts” or ambiguous words like “ supports”, “Manages” , “Supports in the management of ”etc may not comply with the criteria
- ▶ The nutrient should be a source or high as per Schedule I of Draft Claim regulation

Permitted Nutrition Function claims

- ▶ No Positive list .
- ▶ Can make claims
 - ▶ Which are either permitted or
 - ▶ Criteria for which has been laid down in any regulation under FSS Act (2006)
- ▶ Food articles that are fortified as per Food Safety and Standards (Fortification of Foods) Regulations, 2017 may make health claims as provided

Nutrient - Function Claim in Fortified D Foods

Draft_Claim_Reg_08_11_2017.pdf - Adobe Acrobat Reader DC

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Schedule - IV Health Claims for Fortified Food Articles

SI. No.	Nutrients	Claims
1.	Vitamin A	Helps in preventing Night blindness.
2.	Vitamin D	Supports strong bones.
3.	Vitamin B12	Important for maintaining normal functioning of Nervous system and blood formation.
4.	Folate & Folic acid	Important for foetal development and blood formation.
5.	Iron	Fights Anemia.
6.	Iodine	Required for normal growth, thyroid and brain function.
7.	Zinc	Zinc supports a healthy immune system.
8.	Thiamine	Thiamine is required for normal nerve and heart function.
9.	Riboflavin	Riboflavin is necessary to release the energy from food.

Criteria for making nutrition function claim

- ▶ Nutrition - Function claim is part of health claim (Draft Claim)
- ▶ Available scientific literature including official traditional texts
- ▶ Post market data or consumer studies or cohort or retroactive studies
- ▶ Epidemiological International and National data, and other well documented studies (Nutra Regulation)

Substantiation of Nutrient - Function claim

- ▶ FBO shall
 - ▶ Have a team of scientist or expert, with relevant qualification and experience, who shall periodically review the data on which the claim is based
 - ▶ Produce the document to the Authority when demanded (Nutra Regulation)
- ▶ Prior approval if claim criteria are not met

Nutrition - Function Claim - Market Survey

- ▶ Vitamin B2
 - ▶ Releases energy from food
 - ▶ Release Energy
 - ▶ Riboflavin is necessary to release the energy from food (Fortification)
 - ▶ Riboflavin contributes to normal energy-yielding metabolism (EU)
- ▶ Vitamin D
 - ▶ Maintenance of bone strength
 - ▶ Helps Calcium absorption
 - ▶ Contributes to normal absorption/utilisation of calcium and phosphorus (EU)
 - ▶ Calcium is needed for the maintenance of normal bones (EU)
- ▶ Iron
 - ▶ Healthy Blood
 - ▶ Fights anaemia (Fortification)
 - ▶ Iron contributes to normal formation of red blood cells and haemoglobin (EU)

Nutrition - Function Claim - Market Survey

- ▶ Iodine
 - ▶ Brain Nutrient
 - ▶ For Brain development and its function
 - ▶ Required for normal growth, thyroid and brain function (Fortification)
 - ▶ Contributes to normal cognitive function (EU)
 - ▶ Iodine contributes to the normal production of thyroid hormones and normal thyroid function (EU)
- ▶ Zinc
 - ▶ Boosts immunity
 - ▶ Normal function of immunity
 - ▶ Supports healthy immune system (Fortification)
 - ▶ Zinc contributes to the normal function of the immune system (EU)

Nutrition Function Claim - Comparison

	India	EU	USA
Nomenclature	Nutrition - Function claim	Health Claim	Structure - Function claim
Prior Approval	Yes, if the claim does not comply with the criteria	YES	NO
Conditions with regard to level	YES	YES	YES
Claim wordings	Suggested in case of Fortified	YES	NO

Suggestions

- ▶ ONE NATION ONE CLAIM REGULATION
- ▶ Categorize into “Health Claim” and “Disease Risk Reduction Claim”
- ▶ List of permitted “Health Claim” with suggested wordings for better comprehension by the consumer
- ▶ To permit claims approved by other regulatory bodies along with the conditions

► Thank you.