

Claims under Food Supplement / Nutraceutical Regulation

Protein Foods & Nutrition
Development Association India

Courtyard of Marriott, Mumbai

8th November, 2017

Claim Regulation – Protect Consumer needs

- From What?
 - Wrong, Misleading claims
- What makes a claim wrong/misleading?
 - Claiming too much – not delivering
 - Not properly substantiated
 - Not enough scientific support
 - Wrongly compared
 - Advertising puffery encroaching into the area of claims

The Conflict

Labelling Regulation

mostly mandatory and specific to product or category

Claim regulation

generally voluntary within a framework

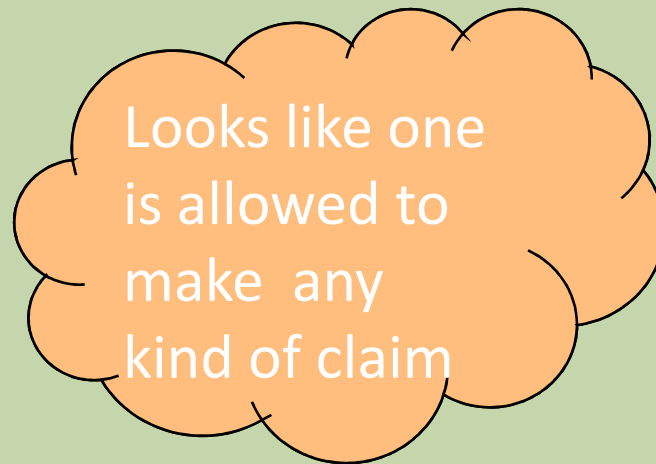
Claims necessary to market a product in the competitive market - may not be always truthfully placed or properly substantiated

End result: regulating too much

Food Claim – as per the Act

As per the definition under FSS Act 2006 -

“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



What the Act says

Food supplements, Nutraceuticals , Foods for special dietary uses and Functional foods are all defined under a general definition in the Act as:

“Foods which are specifically processed or formulated to satisfy particular dietary requirements that exist because of a particular physical or physiological condition or specific diseases and disorders and which are presented as such, wherein the composition of ordinary foods of comparable nature , if such ordinary food exist, and may contain

- 1. minerals, vitamins and proteins or metals or their compounds and amino acids or enzymes*
- 2. other dietary substances, plants or botanicals*
- 3. substances from animal origin etc*

and shall be labelled either as Food Supplement / Nutraceutical / Functional Foods or Food for special dietary uses, as the case may be and can be formulated in the form of powders, granules, tablets, capsules and other dosage forms except parenteral

Specific Prohibition to Claim

22(1)(b)(iii) does not claim to cure or mitigate any specific disease, disorder or condition

(except for certain health benefit or such promotional claims) and

as may be permitted by the regulations made under this Act;

The Regulation further prohibits “implied” claims like prevents bone fragility in post menopausal women

Details under Regulation

FSS Regulation on

Food or Health Supplements, Nutraceuticals, Food for Special Dietary Uses(FSDUs), Food for Special Medical Purposes, Functional Foods & Novel foods, 2016

Clause 2.3 Provides general Conditions for making

- Nutritional claims or
- Health claims

Nutritional Claims

- **Based on Ingredients** (nutrients nutritional) content in the food as allowed and specified in specific Schedules. Example: Contains Calcium
- **Based on Health related benefits** – Example: ‘rich in Calcium and calcium is known to provide bone support’

Ultimately, the claim can be just on the Ingredient, which in general, not so much of a regulatory concern, but claims towards the functional criteria or health effects, may attract regulatory scrutiny

Health Claims

- Health claims in respect of an article of food may include following types

Ingredients function claims

Enhanced Function claims

Disease Risk Reduction Claim or DRR claim

Health Maintenance Claim

Immunity Claims (increased resistance)excludes vaccines

Anti aging Claims

Further allowance - but demands approval

Any other claims in respect to Food that are **not drug claims – may be allowed**

Subject to prior approval from Food Authority

Might create confusion as the regulation provides types of claims which can be made within the framework without any prior approval or intimation

Thus, any such health claims shall be supported by adequate level of substantiation / documentation and valid proof for review by the Food Authority

Conditions for making Health claims

To make any structure –function claim or DRR claim, below points to remember

- Claims should be ingredients led (nutrient or nutritional)
- Based on available scientific literature including official traditional text, post market data, consumer studies or cohort studies (based on eating pattern or health benefits)
- Supported by consensual, congruent and concurrent validity studies

Conditions for DRR Claims

- Health promotive and DRR claims shall be based on valid literature or human data of efficacy and safety of the nutrient / ingredient(Clinical trials)
- Must be supported by nutraepidemiological data

Hence, unless listed, making DRR claims would require proper data support

Conditions for Product Specific Claims

Always needs to be supported by

- Human studies – evidence based data
 - single human intervention study showing significant benefit for claiming 'Shown'
 - more than one successful human intervention studies, or epidemiological evidence on Indian population, provides concurrent validity for claiming 'Proven'

Moreover, the FBO needs to notify the Food Authority before putting the same in the market, submitting necessary documents and a copy of the label

Claim Approval

Limited to

- Claims where scientific support does not exist or
- Claim based on Novel ingredients

To conclude, as per the regulation,

claim Approval is limited to claims made on Novel ingredients, processes or where claim substantiation is missing or inadequate, however, all claims remain open for review by authority at any point of time

For making any health claim, within the framework, needs adequate scientific substantiation ready, so that at any point those can be produced before the authority for review, if asked

Take away

Should move under horizontal standard except specific claim conditions, if any

Regulating food claims

- Right interpretation of the framework
- understanding science and the innovation
- Safety & efficacy data(how much is sufficient)
- Not to be restrictive to trade
- **For Industry**

Decide what to declare – move to self regulation

Thank You