Need for Human Intervention Studies in Food and Regulatory Status in the Country and Categorization of Claims and their Substantiation

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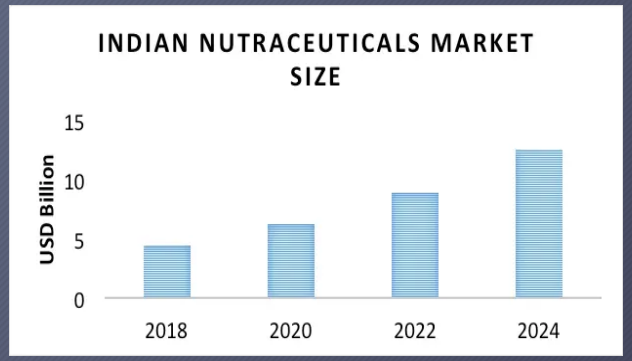
Conflict of Interest Statement

- **Member, FSSAI Scientific Panel on Nutraceuticals and Functional Foods**

- **Member, FSSAI Expert Committee to review matters related to FOPNL**

Introduction

- India is fast emerging as one of the global hubs for health supplements, nutraceuticals, botanicals, medicinal plants and novel foods
- The food supplement sector is growing faster due to multiple innovations compared to earlier times. Nowadays, new molecules, substances and botanicals are included in food supplements
- With globalisation, inter-country trade is regular, which helps to access novel products into the Indian market
- However, these novel products may not be listed under FSSAI regulation



Need for Human Intervention

- FSSAI is the regulatory body that governs all food products and Nutraceuticals-related approvals in India. Getting such products registered and approved as per FSSAI regulations is essential
- The purpose is to provide approvals of Non-Specified Ingredients/Products - for Food Supplements & Nutraceuticals to importers or manufacturers before launching any product into the market. The approval process could take 6-12 months
- The only robust way to evaluate a new food or ingredient is by conducting properly designed human intervention trials
- This evaluation has to be made in consideration of risk versus benefit
- Whenever a application for non specified food is received in FSSAI, it is impossible to determine, the safety and efficacy of the ingredient without a human trial

Regulations for Human Intervention Trials

- There is no way a disease risk reduction claim could be used by a FBO, except through an evidence-based method involving human intervention trials
- Section 16 (2) (i) of FSS act specifies that Food Authority may by regulations specify the manner in which and the procedure subject to which risk analysis, risk assessment, risk communication and risk management shall be undertaken
- Section 16 (3) (c) of FSS act also specifies that the Food Authority shall promote, co-ordinate and issue guidelines for the development of risk assessment methodologies and monitor, conduct and forward messages on the health and nutritional risks of food to the Central Government, State Governments and Commissioners of Food Safety

Regulations for Human Intervention Trials

- Clause 2(20) of FSS (Approval for Non-Specific Food and Food Ingredients) Regulation, 2017 specifies documents on risk assessment or toxicity studies - information to be based on safety/ risk assessment review from published studies (Indexed journals) and safety studies conducted on the ingredient or food product by the applicant adopting OECD guidelines or safety studies as prescribed under D and C Rules, 1945 as amended

- Clause 2(21) of same Regulation specifies Claim support documentation - evidence to support the intended health benefit claims through robust scientific studies including human intervention studies/ clinical studies. Provide supporting published literature (Indexed journals), results of in-vitro and in-vivo studies and studies done on population relevant to India

Regulations for Human Intervention Trials

- Need to develop mechanism for providing regulatory clearance to conduct human intervention studies on novel or other non-specified ingredients / products
- Currently, FSSAI has no mechanism for providing pre-regulatory clearance to FBOs for conducting human intervention studies for generating efficacy and safety data in support of their proposed health claims for novel or other non-specified food
- It is proposed that established guidelines available in CDSCO and ICMR may be examined and suitably modified for the products covered under FSSR
- FSSAI is in the process of framing a protocol for assessment of clinical trials

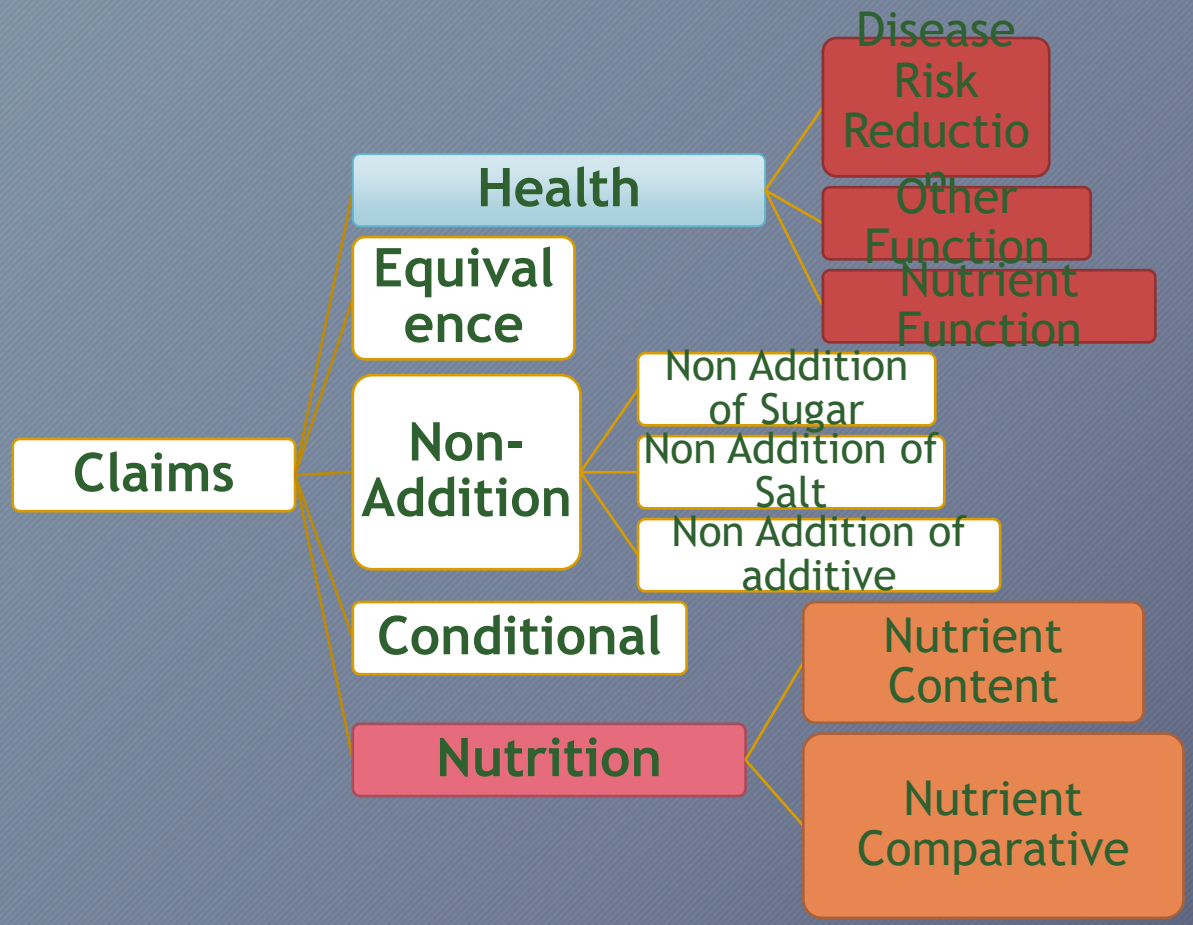
Approval of Claims

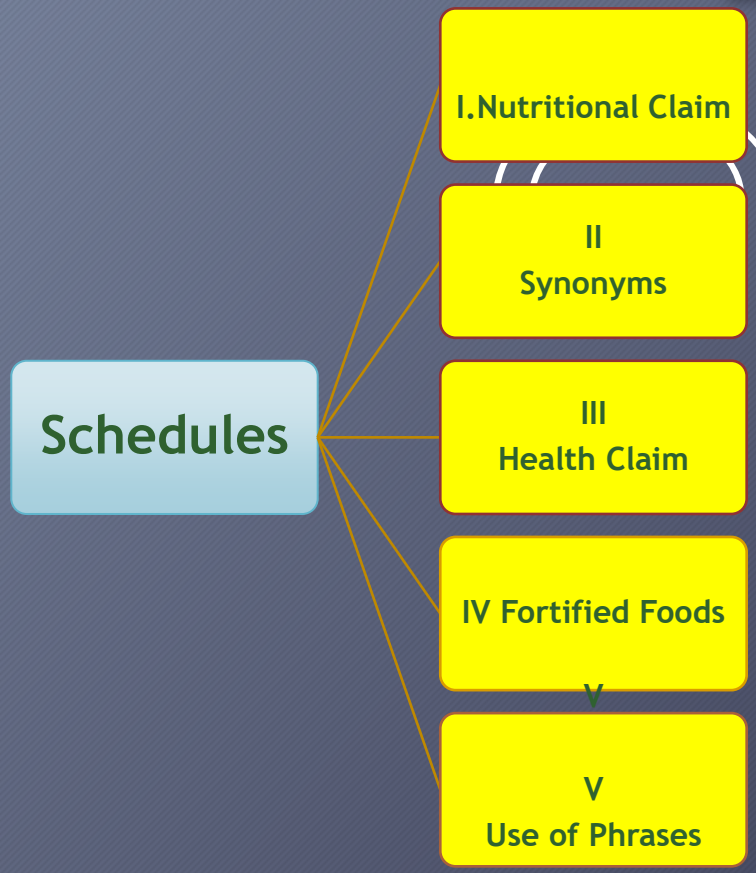
- Many claims, listed in various schedules of these regulations with related criteria, are permitted to be made by FBOs without the need for seeking prior approval from the food regulator

- However, other types of claims not standardised under these regulations may require approval from the Food Authority and should be supported with sound scientific basis

- With a detailed procedure for approval of claims included in these regulations, FBOs may seek prior approval from FSSAI for reduction of disease risk claims other than those specified in these regulations

Claim Categorisation





Nutrition Claims

Any representation which states, suggests or implies that a food has particular **nutritional properties** including but not limited to the energy value and to the content of protein, fat, carbohydrate as well as content of vitamins, minerals and other permitted listed nutrients

Nutrient Content

Directly or indirectly describes the level of a nutrient in a food

Shall be made according to conditions of Schedule –I

Flexibility of wordings allowed as per Schedule II

E.g. High in Calcium, Rich in Fibre

Nutrient content claims for food products falling under health supplement categories shall be governed by Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016

Nutrient Comparative

Compares the nutrient or energy value of two or more (similar or different versions of the same food) foods

The identity of the food being compared and the amount of difference (percent, fraction or absolute amount) to be given in close proximity to the claim

Nutrient Content Claims

Nutrient content claim is related to the content of the nutrient in the product

- High, Rich, Source , Low, Free etc.
- The conditions for nutrition content claims are described in Schedule I of the regulation. Few examples :

➢ "Rich in Protein" - product should contain of 20% of RDA value of Protein in 100 g of food (if the food is solid) or 10% RDA in 100 ml (in case of liquid food)

➢ "Low Fat" – Not more than 3 g per 100 g product (Solid Food) and 1.5 g per 100 ml (for liquid food)

➢ "Sugar Free" – Not more than 0.5 g of Sugars per 100 g or 100 ml

➢ "Low in sodium" – Not more than 0.12 g of sodium per 100 g for solids or 100 ml for liquids

Permitted Synonyms

Synonyms that can be used as per the regulation

SCHEDULE – II

[See regulation 5(3)]

Synonyms which may be used for claims defined in these regulations

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

Nutrient Comparative claim – Example

Claim Statement: Product Y contains Upto 10X more Protein than Product X

	Product X	Product Y
Protein(g)	1.1g	11g

- Relative Difference of the claimed parameter between the compared food should be at least 25% in the energy value or nutrient value. Therefore; 11-1.1/11= 90%

- Minimum absolute difference equivalent to the figure defined as ‘low ‘ or ‘source’ as per schedule I for claims about energy, sodium and macro nutrients
  As per Schedule I, source of protein is 10% RDA i.e. 6g
  the relative difference between Product X and Y is 11-1.1.= 9.9g
- Relative difference of at least 10% of RDA for claims about micro nutrients other than sodium.
- The Foods that are compared must be same or similar or Identifiable

Therefore, this claims meets the requirement and is in compliance

Non Addition Claims

- The claim “No added Sugars” is permitted only under the following conditions (Section 6.1)

  - No mono or/and disaccharides are added to the product including corn syrup, honey, etc.
  - The product should not contain ingredients that contain added mono and disaccharides – Example- ingredient like Jam, Syrup
  - The product should not contain ingredients that is added instead of sugar – Example – Fruit juice concentrate, Fruit paste

In case the product satisfies the above condition but has inherent mono and disaccharides, the label shall carry the declaration - ‘CONTAINS NATURALLY OCCURRING SUGARS’

Non Addition Claims

- Non Addition of Salt (Sodium Chloride) claim is permitted only under the following conditions (Section 6.2)
  - ✓ No salt is added to the product
  - ✓ The product does not contain any ingredient to which sodium chloride is added – e.g.sauce, salted nuts, pickles

- Non Addition of Additives – claim is permitted only under the following conditions
  - ✓ The additive is not added to the product
  - ✓ The product does not contain any ingredient to which the additive is added
  - ✓ The additive should be permitted in the product

  Example – in milk – "No Added Preservatives" claim is not permitted as the regulation does not permit preservative in milk. Such a claim is possible in fruit beverage as preservatives are permitted in fruit beverages

Schedule – I Nutrient Content Claim

SCHEDULE – I

[See regulation 5 (3) and (4) and regulation 7 (1)(b)]

NUTRITION CLAIMS

A claim that a food containing the nutrient mentioned in column (2) is likely to have the benefits as mentioned in column (3) or has the same meaning for the consumer may be made subject to the conditions as mentioned in column (4) below:

(1)	(2)	(3)	(4)
Sl. No	Nutrient/ component	Claim	Conditions
1.	Energy/Calorie	Low	Not more than 40 kcal# per 100 g for solids 20 kcal per 100 ml for liquids.
		Free	Not more than 4 kcal per 100 ml for liquids.
2.	Fat	Low	Not more than 3 g of fat per 100 g for solids or 1.5 g of fat per 100ml for liquids.
		Free	Not more than 0.5 g of fat per 100 g for solids or 100 ml for liquids.
3.	Cholesterol	Low	Not more than 20 mg cholesterol per 100 g for solids and 1.5 g saturated fat per 100 g for solids or 10 mg per 100 ml for liquids and 0.75 g of saturated fat per 100 ml for liquids and in either case must provide not more than 10% of energy from saturated fat.

Health Claims

Any representation which states, suggests or implies that a relationship exists between a food or a constituent of that food and health

Nutrient Function	*Reduction of Disease Risk*	*Other Function*
Describes the physiological **role of the nutrient** in the growth, development and normal functions of the body	States, suggests or implies that consumption of such food or its constituents **reduce the risk** of developing a disease or health related condition It should significantly alter major risk factors for a disease or health related conditions	Describes the specific beneficial effects of consumption of **the food or its constituents** which relate to positive contribution to health or improvement of a function or to modify or preserving health

Health Claims Substantiation

Health Claim could be

Ingredient Led - Probiotics supports good gut health

Product Led - Product A supports good gut health

- Ingredient led claim 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 recognized by generally accepted scientific review of the data

- Where a claimed health benefit is attributed directly to the product, claim 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

Disease Risk Reduction Claim

Disease Risk Reduction claim -refers to claims that state, suggest or imply that consumption of such foods or food constituents, in the context of total diet, reduce the risk of developing a disease or health related condition.

Example – Diets low in sodium may help in reducing the risk of high blood pressure

- Schedule III contains a positive list of Disease Risk Reduction claims that can be made provided the stated conditions are satisfied
- A DRR claim which is not listed in Schedule III will require prior approval from Food Authority

Disease Risk Reduction Claim – Schedule III

Sl. No.	Nutrient/Food-Health Relationship	Conditions for claim	Claim Statement
1	**Calcium or Calcium and Vitamin D and osteoporosis**	○ the food is a source or high in calcium or in calcium and vitamin D and ○ 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
2	**Sodium and Hypertension**	A food which ○ is low in sodium (0.12g sodium/100g or 100ml) ○ a statement that the beneficial effect is obtained with a low sodium diet.	Diets low in sodium may help in reducing the risk of high blood pressure.
3	**Dietary saturated fat and blood cholesterol level**	○ low saturated fat ○ a statement that the beneficial effect is obtained with a diet low in fat, saturated fat and physical activity	Diets low in saturated fat contributes to the maintenance of normal blood cholesterol levels.
4	**Potassium and risk of high blood pressure**	the food is a good source of potassium and is ○ low in sodium ○ low in total fat and saturated fat.	Diets containing good sources of potassium and low in sodium, fat and saturated fat may help reduce the risk of high blood pressure.
5	**Alpha – linolenic acid (ALA) and blood cholesterol level**	○ the food contains at least 1g of omega-3 fatty acids per 100g or 100ml or 100kcal. ○ statement that the beneficial effect is obtained with daily intake of 2g of ALA	Alpha – linolenic acid (ALA) contributes to the maintenance of normal blood cholesterol levels.

Diet Related Claims

Claims like “Healthy Diet” or “Balanced Diet”

- Shall not be based on the selective nutrient
- The nutrients in the food shall comply with the recommendations of ICMR, RDA etc.
- Foods shall not be described as “healthy” or be represented in a manner that implies that a food in and of itself will impart health

Conditional Claims

- When a food naturally satisfies the condition of “source” or “high” or “low” with respect to a particular nutrient, following to be declared:
  Example – Soy milk/Almond milk/Edible vegetable oil does not naturally contain cholesterol. The claim would be – “xxx is naturally cholesterol free”

- Claims containing adjectives such as “natural”, “fresh”, “pure”, “original”, “traditional”, “Authentic”, “Genuine”, “Real”, etc. , when used, to be made accordance with conditions laid down in Schedule V

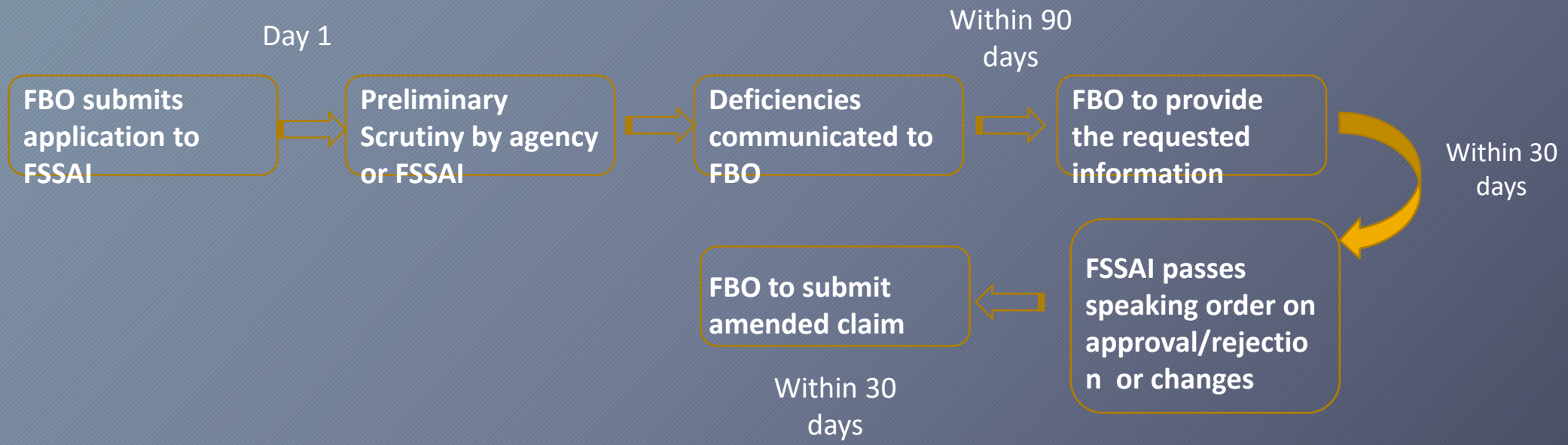
- Claims containing words or phrases like “home-made”, “home cooked”, etc. not to be used

Prohibited Claims

- No claims shall be made around prevention, alleviation, treatment or cure of a disease, disorder or particular physiological conditions
- No label should contain ‘recommended by medical or nutrition or health professionals’ or any words which imply or suggest that the food is recommended, prescribed or approved by medical practitioners or approved for medical purpose
- Don’t claim ‘added nutrients’ if nutrients are merely added as compensation
- FSDU and FSMP to carry a claim only if specifically permitted
- Do not undermine the products of any other manufacturer
- Foods shall not be described as “healthy” or in a manner that implies the food will impart health

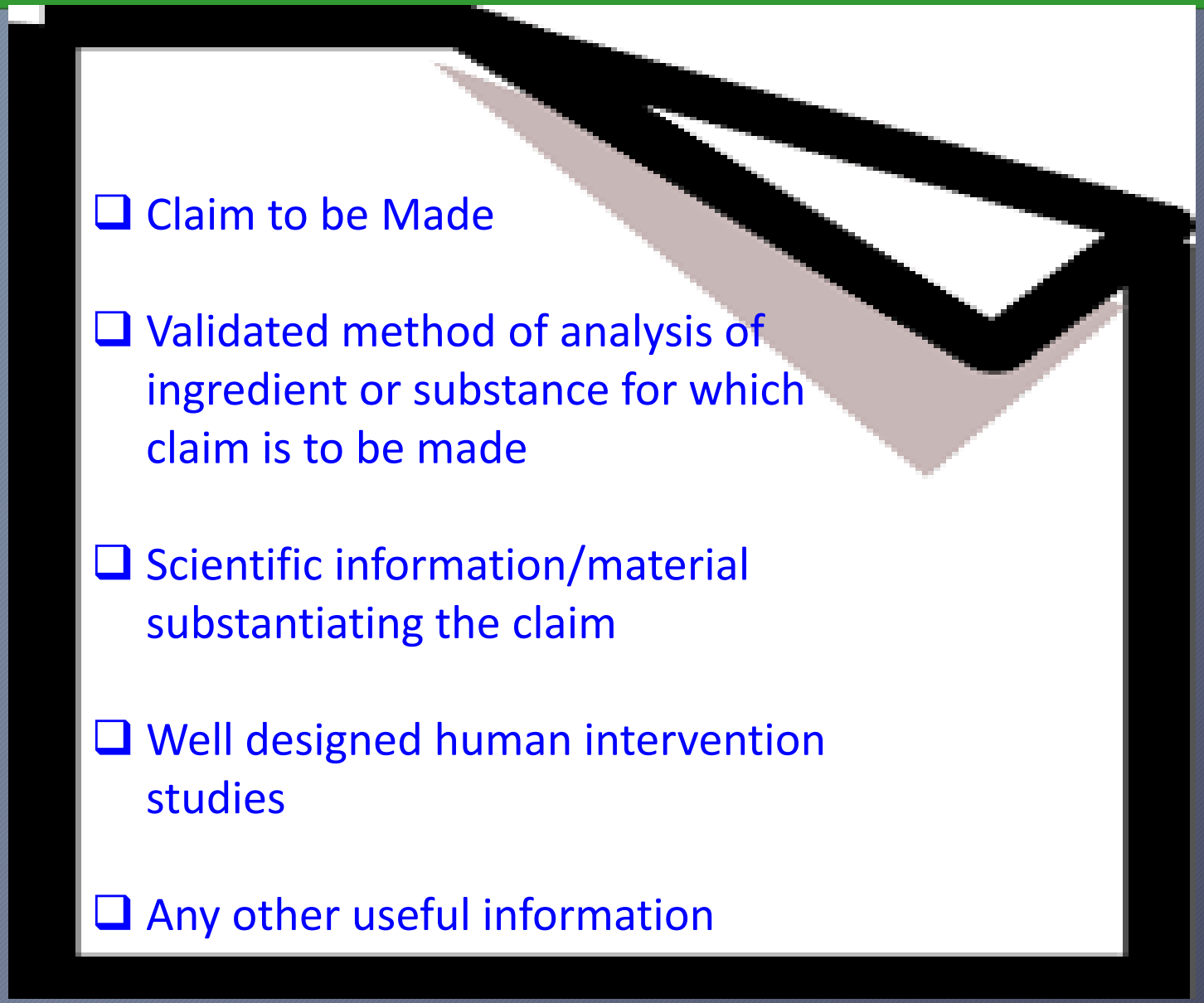
Approval Process For Claims

The FBO shall seek prior approval from the Food Authority **for reduction of disease risk claims** other than those defined in Schedule- III



In case of **Rejection**, the FBO or Marketer **shall not use** the claim in their advertising and marketing communication

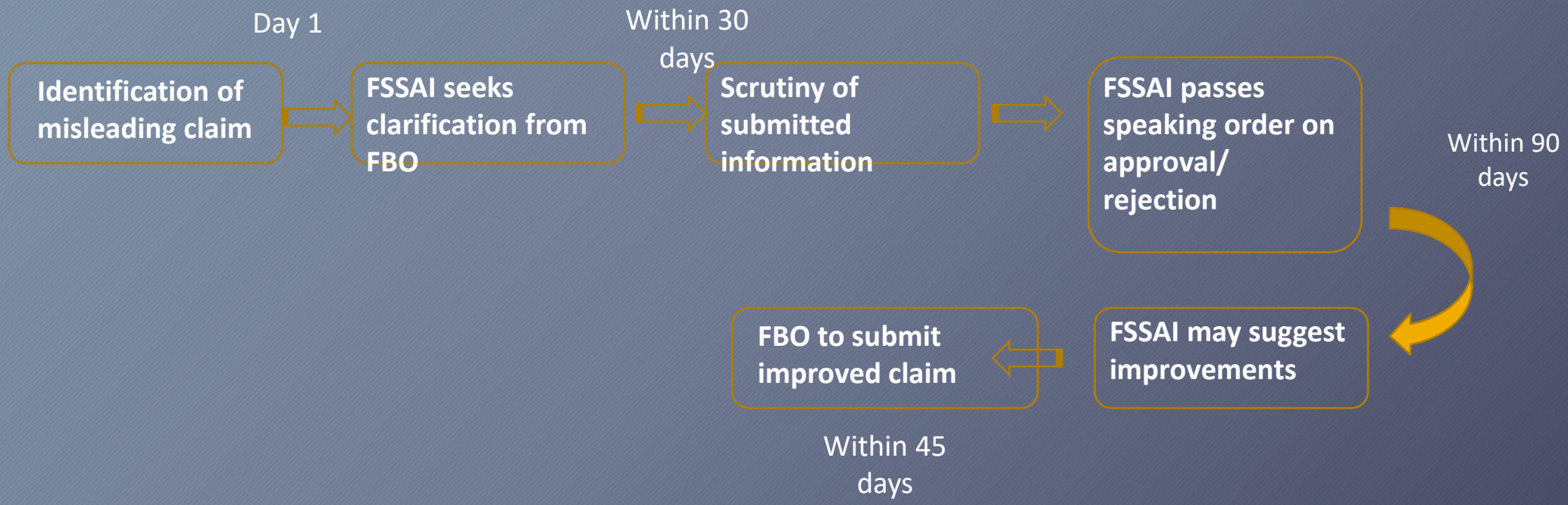
Documentation For Claim Approval



- Claim to be Made
- Validated method of analysis of ingredient or substance for which claim is to be made
- Scientific information/material substantiating the claim
- Well designed human intervention studies
- Any other useful information

Claim Redressal Process

The misleading claims shall be referred to the food authority or the food authority may itself analyse or appoint an agency/panel to **analyse such misleading claims**



Corrective Advertisement: If advertisement is found to be in violation, the food authority may by order require to **stop the advertisement immediately**. FBO to submit corrective advertisement within 30 days to neutralise the effect

Penalty for Misleading Claims / Advertisements

- Any person who advertises or is a party to the publication of any advertisement or claims not complying with this regulation shall be penalized as per section 53 of Food Safety and Standards Act, 2006.

Penalty for misleading advertisement

- Any person who publishes, or is a party to the publication of an advertisement, which falsely describes any food; or is likely to mislead as to the nature or substance or quality of any food or gives false guarantee shall be liable to a penalty which may extend to **ten lakh rupees**

Approval of Non Specified Ingredients/ Products - For Food Supplements & Nutraceuticals in India

Who can Apply ?

Any Indian-based manufacturer, importer, and marketer involved in these products-related businesses can apply for this service.

How to Apply ?

The applicant must follow the following process:

- Prepare the Dossier in the prescribed format with supporting scientific information and other study details.
- Fill out the application Form-I, upload the relevant documents, and pay the online fees of 50,000 rupees, including GST.
- The appointed expert committee by the Food Authority will preliminarily scrutinise the application and data provided. The applicant will be informed in case of any deficiencies within 45days from the date of receipt of the application.
- FBO should submit the required information within 30days from the delivery of the letter.
- On further assessment and as per FORM-II, the Food Authority may either approve or reject the application.
- Once the product is approved, the FBO must conduct and provide post-market surveillance data on relevant safety and efficacy parameters within a year of placing the product in the market.
- If the application is rejected, the FBO can appeal before the CEO within thirty days of receiving the rejection letter.
- In case of rejection by the appellate Authority, FBO may file a review petition before the Chairperson of FSSAI within thirty days from the date of issue of the appellate order.
- And the decision of the Chairperson will be final.

Thank you