Validation of health benefits of functional foods prior to making health claims

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Essentials of a claim

Clear

Accurate

Based on scientific evidence

Definition of Health Claim

"Health Claim" means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health

Essential components of Health claim

(a) Nutraceutical ingredients; and
(b) A health related benefits.

The health claims may include the following types, but not limited to.-

i) ingredients (nutrient or nutritional) function claims
(ii) enhanced function claims
(iii) disease risk reduction claims (deleted)
(iv) health maintenance claims
(v) immunity claims – increased resistance (excluding vaccines
(vi) anti-ageing claims.

Requirements of under regulations for the Health Claim

Adequate level of documentation and Valid proof

1. Claim that led to nutrients

2 Scientific literature - official traditional texts post market data/ consumer studies /cohort or retroactive studies based on eating pattern and health benefits epidemiological international and national data, and other well documented data

3 Consensual, congruent and concurrent validity studies

4 Health promotive and disease risk reduction based on proof from literature and human data of efficacy and safety of the nutrient

5. Controlled clinical trials for efficacy and safety data along with nutraepidemiological data

6. Qualified structure function claims for specific organ or function which are comprehensible to consumer

7. For structure-function claims, a case-to-case basis consumer information for specific age or gender or vulnerable population.

For Product led Health claim

Valid data and suitable statistical design proving the benefit for disease risk reduction, that is, human intervention studies

- Ingredient, that is, nutrient or nutritional
- The product compatibility for the proposed claim benefit and suitable qualifiers such as heart healthy claim on polyunsaturated fatty acids
- “Shown” - single human intervention study shows significant benefit
- “Proven“ more than one human intervention studies or epidemiological evidence on Indian population have been provided

Example of Health claims

"For good health and immunity, physically active and mentally alert "

Composition

It is a combination of Vitamins, minerals and Amino acids with Ginseng Extract powder.

level for all nutrients are within RDA as prescribed by ICMR.

The amount of ginseng is supported by various dietary supplements available in USA & UK.

Safety All nutrients and Ginseng are approved by FSSAI

Scientific evidence Documentation and Valid proof for the claim

Process for the substantiation of health claims (Codex)

a)Identify the proposed relationship between the food or food constituent and the health effect
b)Identify appropriate valid measurements for the food or food constituent and for the health effect;
c)Identify and categories all the relevant scientific data;
d)Assess the quality of and interpret each relevant scientific study
e)Evaluate the totality of the available relevant scientific data, weigh the evidence across studies and determine if, and under what circumstances, a claimed relationship is substantiated.

Criteria for Substantiation

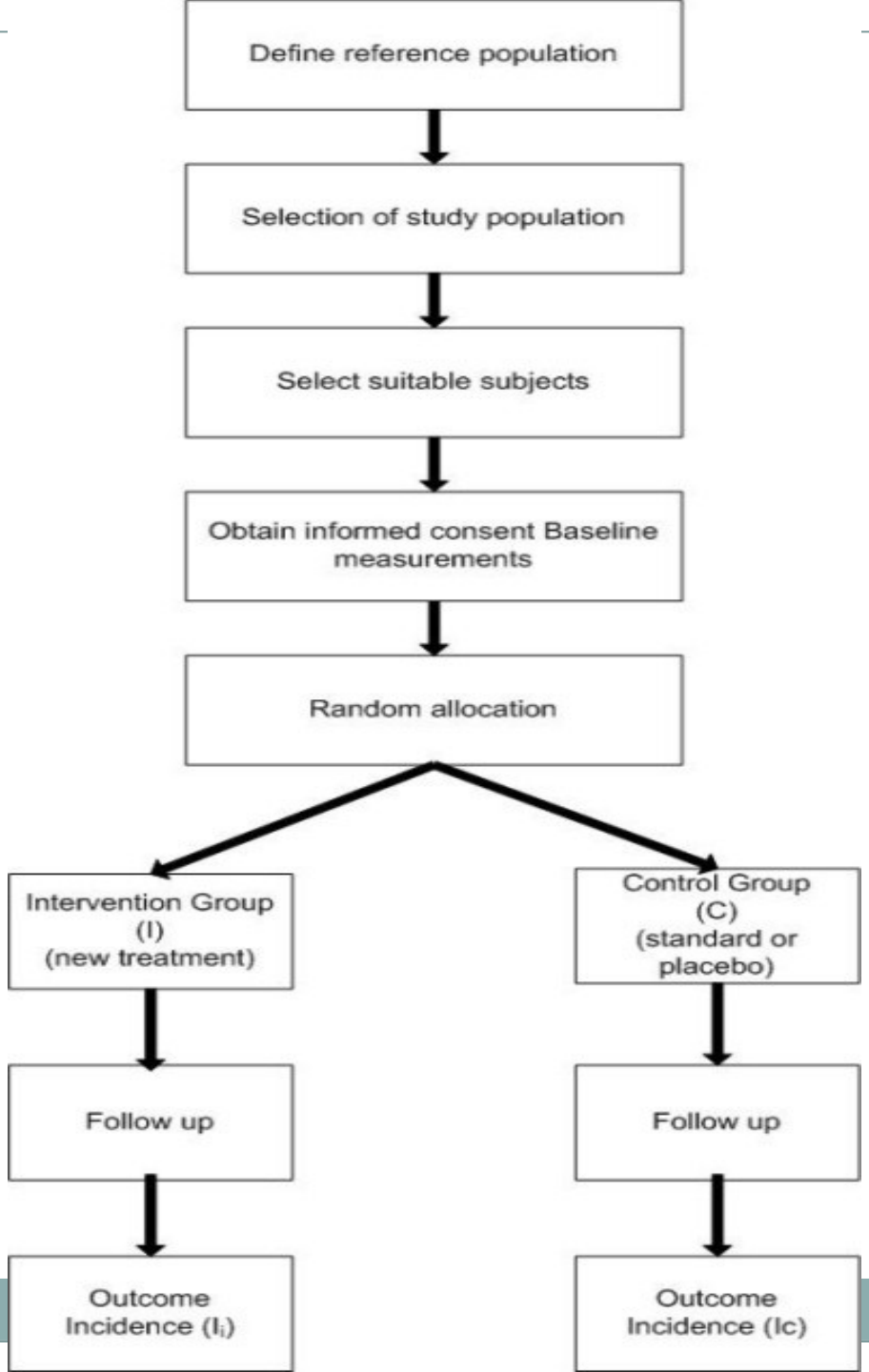
1.Well Designed human clinical trails

2. Observational studies are not sufficient

3. Ex vivo, In vitro animal studies can support but not sufficient

What is well designed Human intervention trial ?

The randomized controlled trial is considered as the most rigorous method of determining whether a cause-effect relationship exists between an intervention and outcome
The strength of the RCT lies in the process of randomization that is unique


Define reference population
Selection of study population
Select suitable subjects
Obtain informed consent Baseline measurements
Random allocation
Intervention Group (I) (new treatment)
Control Group (C) (standard or placebo)
Follow up
Follow up
Outcome Incidence (I_i)
Outcome Incidence (Ic)

Strengths of a randomized controlled trial

- Strongest evidence of any epidemiological study design that a given intervention has a postulated effectiveness and is safe.

- A RCT provides the best type of epidemiological study from which to draw conclusions on causality.

- Randomisation provides a powerful tool for controlling for confounding, even by factors that may be unknown or difficult to measure. Therefore, if well designed and conducted, a RCT minimizes the possibility that any observed association is due to confounding.

- **Clear temporal sequence - exposure clearly precedes outcome.**
- **Provides a strong basis for statistical inference.**

- **Enables blinding and therefore minimizes bias.**

- **Can measure disease incidence and multiple outcomes**

- **Large randomized clinical trails are the best design for detecting small to moderate effects that may be clinically important**

- Weaknesses of RCT

- Ethical constraints - for example, it is not always possible or ethical to manipulate exposure at random.
- Expensive and time consuming.

An example of how scientific review is done to substantiate a health claim

Essential components of systemic review

1 Food or property of food, the health effect- proposed relationship

2 Search strategy used to capture the scientific evidence

3 A final list of studies based on the inclusion and exclusion criteria. Studies in humans are essential.

A relationship between a food or property of food and the health effect cannot be established from animal and in vitro studies alone.

Key information in each included study

(a) Study reference
(b) Study design
(c) Objectives
(d) Sample size in the study groups and loss to follow-up or non-response
(e) Participant characteristics
(f) Method used to measure the food or property of food including amount to be consumed
(g) Confounders measured
(h) Method used to measure the health effect
(i) Study results, including effect size and statistical significance
(j) Adverse effects.

An assessment of the quality of each included study based on consideration of, as a minimum:

(a) A clearly stated hypothesis
(b) Minimisation of bias
(c) Adequate control for confounding
(d) The study participants' background diets and other relevant lifestyle factors
(e) Study duration and follow-up adequate to demonstrate the health effect
(f) The statistical power to test the hypothesis.

An assessment of the results of the studies as a group by considering whether:

(a) Consistent association between the food or property of food and the health effect across all high quality studies
(b) Causal association between the consumption of the food or property of food and the health effect that is independent of other factors (with most weight given to well-designed experimental studies in humans)
(c) Relationship between the food or property of food and the healt effect is biologically plausible
(d) Amount of the food or property of food to achieve the health effect can be consumed as part of a normal diet of the Indian population

Decision Tree approach for establishing Food Health Relationship

Formulate FRH

Formulate Literature Search Strategy

Identify & categorise studies (Y/N)

Are there any human studies (Y/N)

A well designed experimental, cohort, case control studies (Y/N)

Assess and interpret evidence ,are the studies likely to be of sufficient quality to allow a subsequent assessment of the totality of evidence? (Y/N)

Assess totality of evidence consistent association? Causal relationship independent of other factors? (Y/N)

Food-health relationship likely to be established under identified circumstances (Y/N)

Consider amount of food/property of food required to achieve the health effect in context of Indian population

Current status of Health Claims as per Food Safety & Standards (Advertising and Claims) Regulation, 2018 with amendments up to October, 2021

Where Approval for health claim required

For health claims where scientific support does not exist, or if a novel ingredient is to be introduced, there shall be a prior approval of the Authority which shall be based on adequate scientific evidence

List of Claims permitted for Edible Oils

Claims for 19 edible oils

Type of claims – Type of fatty acids and other bioactive compounds

ex:Mustard oil – Contains Omega-3 polyunsaturated fatty acid
Alpha Linolenic acid in an essential fatty acid
that contributes to the maintenance of normal
blood cholesterol
Contains Tocopherols which are natural antioxidants

Rice bran oil - Oryznol has antioxidant property and reduces highblood cholesterol

Health claims permitted for fortified food

11 Nutrients - fortification

Ex: Vitamin A- Vitamin A helps against night blindness

Iron - Fights Anaemia

Nutrient Food Health Relationships- Approved by FSSAI

1.Calcium or Calcium & Vitamin D- Osteoporosis

2. Sodium –Hypertension

3. Saturated fat – Blood Cholesterol

4. Potassium – Risk of high blood pressure

5. Alpha-Linolenic acid (ALA) - blood cholesterol

6. Soluble dietary fibre – Blood cholesterol

7. Phytosterols or stanols- Blood cholesterol

8. Betaglucons (Oats, Barley) – Blood glucose

General principles for query or challenge.-The food business operator shall-

(i)Prepare and make available the comprehensive product information, safety and claims support data and shall periodically get it reviewed and scrutinised by a scientist or expert with relevant qualifications and experience;

(ii) Attach the scientific view of the reviewer on claims and its veracity along with the qualification and experience of the reviewer as an essential part of the document;

(iii) Clarify, in case of a technical query from the Food Authority or on a public complaint lodged with the Food Authority, and assist the Food Authority to examine or authorise an appropriate expert group to review the case; and

(iv) Alter or modify or stop claim when directed by the Food Authority which shall be based on the opinion of an expert group.

A recently launched health drink

Ex: Product led Health Claim

Diabetes Management- Nutrition Health Drink

Clinically "proven "to manage blood sugar spikes

It helps diabetics patients manage weight as it provides up to 3 hours of satiety and includes only about 85 kcal in one serving.

It controls spikes in blood sugar in patients with diabetes

Oats

Coronary artery disease

Colorectal cancer

Blood Pressure

✓***Blood Glucose***

at least 4g beta-glucans for each 30g of available carbohydrates in the quantified portion o statement that it is taken as part of the meal.

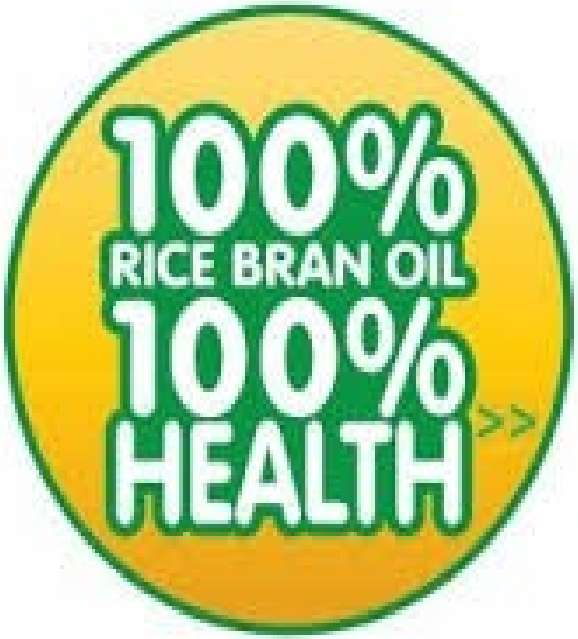
Soluble Dietary Fibre and blood cholesterol

Barely, Oats and Millets and Mixtures

Minimum 1g per serving

Statement that the beneficial effect is obtained with daily intake of 3g of soluble dietary fibre.

Oryzanol



Helps in Lowering cholesterol

Effect On Hypertension

Anti-Diabetic effect

Protective Effect on Liver

Anti – carcinogenic effect + 11

Oryzanol content varies from 0.2-0.5% = 200-500 mg/100g

60-150mg/day at the rate of 30g/day oil

300mg/day 8 week RCT study

To Conclude

Substantiation is basic requirement of making a health claim

Observational studies or studies in animal models or in vivo and intro studies are not sufficient for substantiation of a health claim.


Thank you for your attention