

Substantiation of Claims for Value addition in Food products

Dr. V. Sudershan Rao
Deputy Director (retd)
National Institute of Nutrition
Hyderabad

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Out line of Presentation

Introduction to Health claims

Regulatory status – Permitted health claims

Claim substantiation

New EAR and RDA

Driving force for Health Claims

Value addition

Improvement in public health

Reduction in economic burden

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

Health Claims include the following

1. Nutrient function claim
2. Other function claim
3. Reduction of disease risk claim

Nutrient function claim

Describes the physiological role of the nutrient in growth, development and normal functions of the body

Other function claim

Specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet or normal functions or biological activities of the body, which relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health

Reduction of disease risk claims

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

Explanation : Reduction of disease risk means significantly altering major risk factors, for a disease or health related condition as diseases have multiple risk factors and altering one of these risk factors may or may not have a beneficial effect and the presentation of risk reduction claim must ensure, for example, by use of appropriate language and reference to other risk factors, that consumers do not interpret them as prevention claims

Leading cause of deaths in India -2019*

Ischemic heart disease 40.8%

Major risk factors (Modifiable)

Hypertension

Diabetes

Atherogenic dislipidemia

Central obesity

Unhealthy diet

Stress

Smoking

Physical inactivity

*Institute of Health Metrics & Evaluation .[https://doi.org/10.1016/S0140-6736\(20\)30925-9](https://doi.org/10.1016/S0140-6736(20)30925-9)

Health Claims permitted in India

(FSSAI advertisements & claims regulations 2018 and First amendment 2020)

Schedule II A 15 (Edible Oils)

Schedule III 8 (General)

Schedule IV 11 (Fortified Foods)

Prohibited claims.-

No claims shall be made which refer to the suitability of the food for use in the prevention, alleviation, treatment or cure of a disease, disorder or particular physiological condition unless specifically permitted under any other regulations made under Food Safety and Standards Act, 2006 (34 of 2006).

No health claims shall be made for foods that contain nutrients or constituents in quantity that increase the risk of disease or an adverse health-related condition.

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 under these regulations or any other regulations made under the Food Safety and Standards Act, 2006 (34 of 2006).

Health Claim -Disease Risk reduction

Procedure for approval of claim – Information required to be submitted to FSSAI

1. Claim to be made
2. Ingredient/Nutrient/Substance
3. Validated method of Analysis for Ingredient/nutrient /substance
4. Scientific information for **substantiation of claim**
5. How is claim- Clear-meaningful & Help consumer
6. Well designed human intervention trials in case of health claim by or under guidance of established reaserch institutions

Essential components of Health claim

Food & Health relation

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 (Codex)

Evidence provided by well designed human intervention trails - Sufficient

Human observational studies – Not sufficient

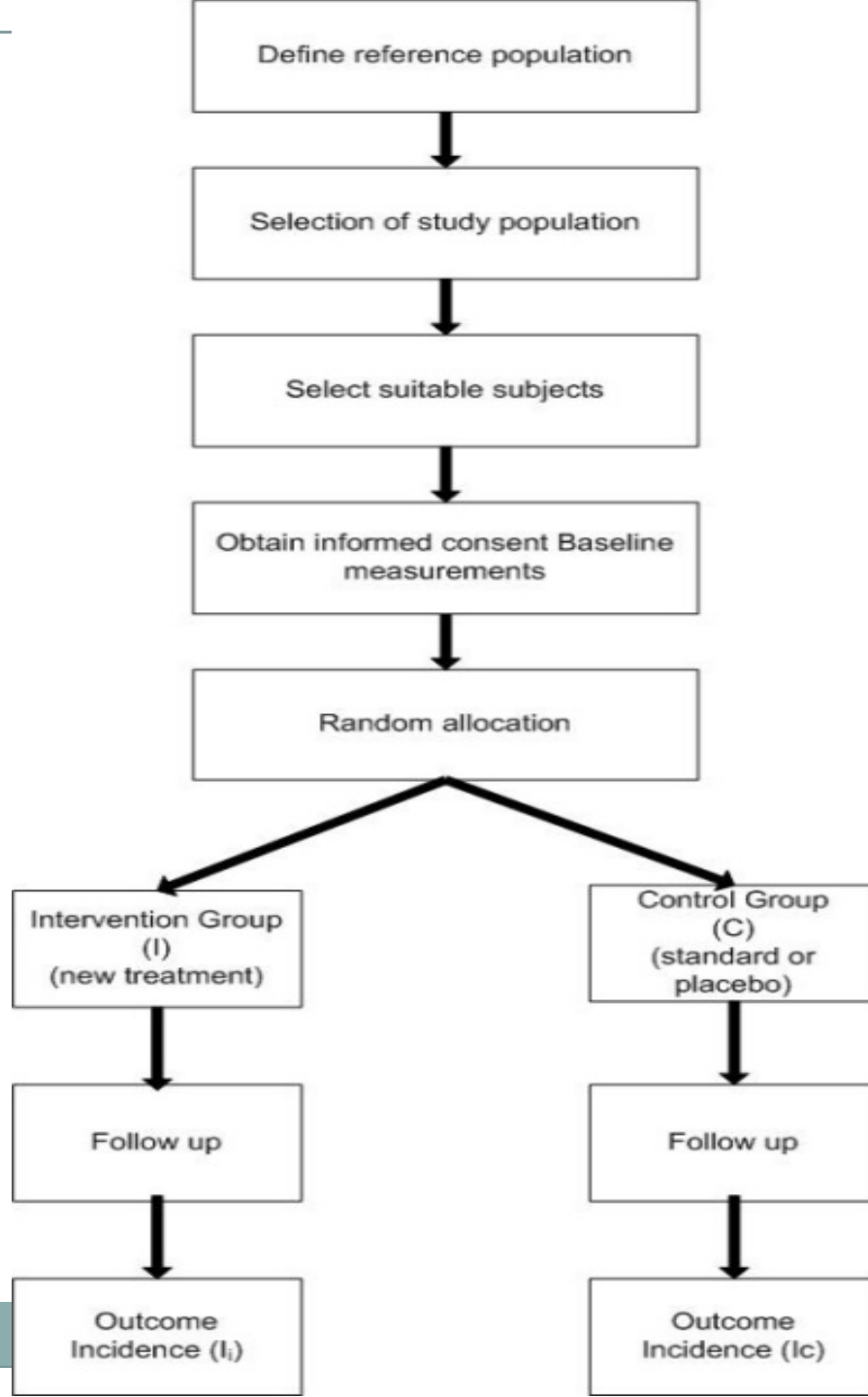
Studies on Animal models, ex vivo, in vivo – Not considered per say

Health claims –Substantiation

Well designed human clinical trials

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



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.
- Randomization 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.

Weaknesses of RCT

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

Expensive and time consuming.

Europe Union

Generally accepted scientific evidence of beneficial physiological effect in humans

US & Canada

Significant scientific agreement

Australia & New Zealand

Established food-health relationship based on the totality and weight of evidence

EU – Requirements of claim substantiation

Food/Constituent is defined & characterised

Claim –based-essentiality of nutrients defined – beneficial physiological effect for target population – Can be measured

In vivo in humans

Food/Constituent to required for normal body function- cannot be synthesised/ or in amount which is required – It must be obtained from dietary source

Cause & effect – relation ship – consumption & effect in target group- strength, consistency , specificity, dose, response, biological plausibility of relationship

Quantity of food/constituent- pattern of consumption – reasonably achieved as part of balanced diet

Significant Scientific Agreement

Extent of Agreement among qualified expert in the field – lies very close to consensus

1. Identifying studies to that evaluate the substance/disease relationship
2. Intervention studies
- 3 Observational studies
- 4 Research synthesis studies
- 5 Animal & invitro studies
- 6 Identifying surrogate endpoints of disease risk
- 7 Evaluating human studies
- 8 Assessing the methodological quality of studies
- 9 Evaluating the totality of scientific evidence

Authorised Claims

Qualified health claims

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

Essential components of systemic review (Australia-New Zealand)

- 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 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) there is a consistent association between the food or property of food and the health effect across all high quality studies
- (b) there is a 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) the proposed relationship between the food or property of food and the health effect is biologically plausible
- (d) the amount of the food or property of food to achieve the health effect can be consumed as part of a normal diet of the Australian and New Zealand populations.

A conclusion based on the results of the studies that includes:

- (a) whether a causal relationship has been established between the food or property of food and the health effect based on the totality and weight of evidence; and
- (b) where there is a causal relationship between the food or property of food and the health effect:
 - (i) the amount of the food or property of food required to achieve the health effect
 - (ii) whether the amount of the food or property of food to achieve the health effect is likely to be consumed in the diet of the Australian and New Zealand populations or by the target population group, where relevant.

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 ANZ populations

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 Several published clinical studies support the safety of active ingredients

Scientific evidence Needed

FSSAI - Claim veracity

Carona pandemic – Immunity claims

Khakhra

Haldi

Chyawanprash

Flavoured ice cream

Immuno bread

Advertising Standards Council of India

Recent Cases of Health claims ASCI's Consumer Complaints Council Rulings (31st August, 2019 F&B News)

Rice Variety & Low GI

The advertiser's claims on their product packaging read Helps sugar level and weight management and This keeps the entire family healthier and is suitable for diabetics, were misleading by omission.

The CCC observed that the advertised rice (BPT 5204) has a low Glycaemic Index (GI). However, the CCC also noted that if this low GI rice is consumed in more than adequate quantities, the overall glycaemic load may still be high, and such rice cannot be eaten by diabetics in excess.

The CCC noted that this rice would be suitable for diabetics only if portion sizes are controlled as well as all other lifestyle changes and pharmacotherapy are adhered to and this rice is part of an overall low GI diet.

Suo moto surveillance by ASCI 170 of which 4 advertisements for Food 0/4

European Union – Health Claim approval rate

Overall	10%
Category wise	
Dietary fibre	7/46
Beta glucans	5/12
Antioxidant/Oxidative damage	8/200

(Trends in Food science & Technology 2016)

Balanced Diet – Health claims

Part of general principles of claim

Claims shall not encourage or condone excess consumption of a particular food.

Claims shall not state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients as required by the body.

Where the claim benefit is related to or dependent on the method of preparation of the food the same shall be provided on the label.

Claims shall specify the number of servings of the food per day for the claimed benefit.

Nutrient Requirement for Indians RDAs & EARs - (A Report of expert group of ICMR-NIN , 2020)

Definition of Reference adult Man & Woman

Age range 18-39years (18-29 years)

Body weight Man 65kg (60kg)

Woman 55kg

Energy requirement (Kcal) – Sedentary worker

Adult man 2110 (2320)

Adult woman 1660(1900)

Estimated Average Intake - Median of nutrient intake

Recommended Dietary Allowances - 97.5th Percentile

TUL - Tolerable Upper Limits

To Conclude

Substantiation is basic requirement of making a health claim

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

Consider Indian balanced diet and RDAs for health claim



Thank you for your attention