Claim Substantiation

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Essentials of a claim

Clear

Accurate

Based on scientific evidence

Nutritional claims

Nutrient content claim

Nutrient comparative claim

Nutrient function claims

Nutrient function claim

Accepted authoritative statement by recognized expert scientific body, verified and validated overtime

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
(iv) health maintenance claims
(v) immunity claims – increased resistance (excluding vaccines
(vi) anti-ageing claims.

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

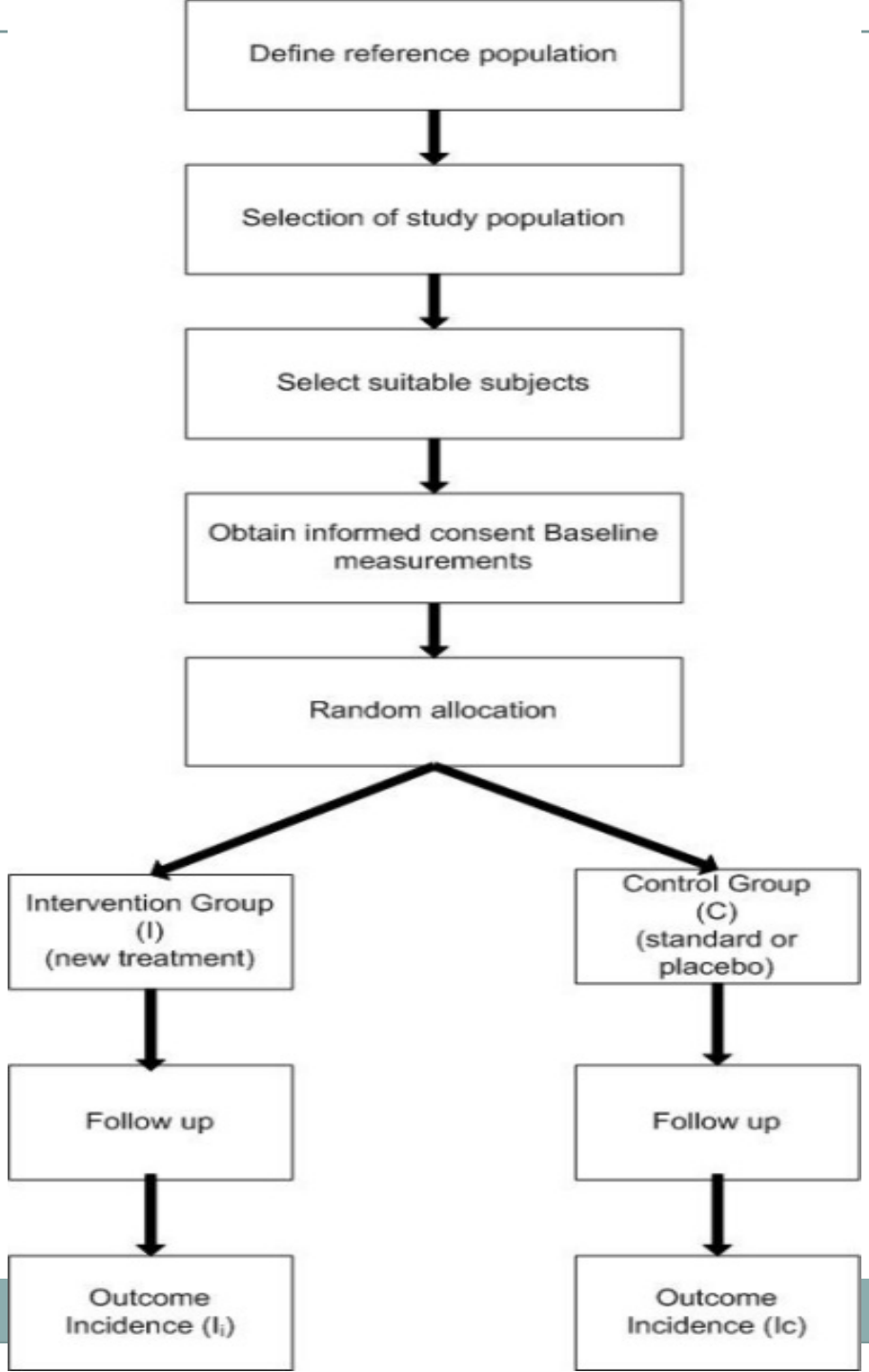
1.Well Designed human clinical trails

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.

- Weaknesses of RCT

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

Product led health claim

Valid data with suitable statistical design

Claims are neutraceutical lead

Product compatibility for proposed claim with suitable qualifiers

“Shown” - one human trial
“Proven” - two human trials

Measurement of claimed health effect

Direct measurement
Validated biomarker
(Plasma cholesterol for cardio vascular diseases)

Plasma cholesterol vs dietary cholesterol

Production condition, batch to batch variability
Analytical procedures, stability studies, storage conditions and shelf life

Study design
Statistical analysis

Food safety concerns

Not expose consumer to health risk and known interactions among other constituents

Should not exceed relevant upper limits

Re-evaluation- Health claims should be reevaluated

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

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 Need for substantial scientific evidence for the claim

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.

6 **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.

8 An existing systematic review may be used if it is updated to include –

(a) the required elements 1 to 6 above for any relevant scientific data not included in the existing systematic review

(b) the required element 7 above incorporating the new relevant scientific data with the conclusions of the existing systematic review.

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

US FDA

Science based evaluation of the strength of evidence to support the claim statement

Methodology quality
Quality of evidence
Number of various types of studies-sample size
Overall consistency of the evidence

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

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.

Oats

Coronary artery disease

Colorectal cancer

Blood Pressure

60 g Oats(un processed) /day has a beneficial effect on lowering the serum cholesterol

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