



Disease Risk Reduction Claim

Top 10 causes of death in India (Global burden of disease 2016)

1. Heart disease
2. Chronic Obstructive Pulmonary Disease
3. Diarrhoea
- 4 Stroke
- 5 Lower Respiratory Infection
- 6 Tuberculosis
- 7 Neonatal preterm birth
- 8 Suicides or Self harm
- 9 Road injuries
- 10 Other neo natal infections

Risk factors for Coronary Heart Disease which can be controlled

- High blood cholesterol and triglyceride levels (a type of fat found in the blood)
 - High blood pressure
 - Diabetes and prediabetes
 - Overweight and obesity
 - Smoking
 - Lack of physical activity
 - Unhealthy diet
 - Stress
- Risk factors which cannot be controlled Age, gender and family history of CHD

Codex – Disease risk reduction

Claims relating the consumption of a food or food constituent, in the **context of the total diet**, to the **reduced risk of developing a disease or health-related condition**. Risk reduction means significantly altering a major risk factor(s) for a **disease or health-related condition**. Diseases have multiple risk factors and altering one of these risk factors may or may not have a beneficial effect. The presentation of risk reduction claims must ensure, for example, by use of **appropriate language** and **reference to other risk factors**, that **consumers do not interpret them as prevention claims**.



European Union

'Reduction of disease risk claim' means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease.



US FDA Health claim is Disease Risk Reduction

Health claims describe a relationship between a food substance (a food, food component, or dietary supplement ingredient), and reduced risk of a disease or health-related condition



Australia –New Zealand Health Claim Definition

- **General level health claims** refer to a nutrient or substance in a food, or the food itself, and its effect on health. For example: **calcium for healthy bones and teeth**. They must not refer to a serious disease or to a biomarker of a serious disease.
- **High level health claims** refer to a nutrient or substance in a food and its relationship to a serious disease or to a biomarker of a serious disease. For example: **Diets high in calcium may reduce the risk of osteoporosis in people 65 years and over**. An example of a biomarker health claim is: **Phytosterols may reduce blood cholesterol**.



Canada

Disease Risk Reduction Claims

Statements that link a food to a reduced risk of developing a diet-related disease or condition in the context of the total diet. For example, "[Naming the food or food constituent] may reduce the risk of cardiovascular disease".



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.

*(Functional-----Novel foods) Notification 2016



India

Disease Risk Reduction claims state, suggest or imply that consumption of such food(s) or food constituents , In the context of total diet, reduce the risk factor of developing disease or health condition. Disease Risk Reduction means significantly altering a major risk factor(s), for a disease or health related condition. Diseases may have multiple risk factors and altering one of these risk factors may or may not have beneficial effect.



Name of the country	Pre approved disease risk reduction claims
Australia –New Zealand	13
Canada	5
China	24 health function claims
European Union	14
Indonesia	11
Japan	Product specific
Singapore	5
USA	12

Examples of Authorised claim in Europe

Vitamin D - Helps to reduce the risk of falling associated with postural Instability and muscle weakness. Falling is a risk factor for bone fracture

Condition- Should be used only for Food supplements with 15ug of Vitamin D in Daily portion

Mono and Poly unsaturated fat- Replacing fats with unsaturated fats in the diet has been shown to lower/reduce the blood cholesterol

High cholesterol is a risk factor in the development of coronary heart disease

The claim may be used only for food which is high in unsaturated fatty acids, as referred to in the claim HIGH UNSATURATED FAT as listed in the Annex to Regulation (EC) No 1924/2006.

Sugar Free Chewing gum

Helps to reduce tooth demineralization

Tooth demineralization is a risk factor in the development of dental caries

Condition / consumer information “ beneficial effect is obtained in chewing 2-3g of sugar chewing gum for 20 minutes at least 3 times per day, after meals



USFDA Regulation on Health Claims

Health claims are limited to Disease Risk Reduction

Authorized claims -Significant Scientific Agreement (SSA) among qualified experts that the claim is supported by the totality of publicly available scientific evidence for a substance/disease relationship

Qualified claims- Some scientific evidence, but do not meet the significant scientific agreement standard. To ensure that they are not false or misleading to consumers, qualified health claims must be accompanied by a disclaimer or other qualifying language to accurately communicate the level of scientific evidence supporting the claim.



Examples of US FDA approved health Claims - Disease Risk Reduction Claims

Calcium - Osteoporosis

Dietary Saturated fats and cholesterol - Coronary Heart
Disease

Sodium -Hypertension

Soluble fibre -Coronary Heart Disease

Fruits and Vegetables - Cancer



Example of Qualified claims

“Scientific evidence suggests, but does not prove, that whole grains (three servings or 48 grams per day), as part of a low saturated fat, low cholesterol diet, may reduce the risk of diabetes mellitus type 2.”

Standardized Qualifying Language for Qualified Health Claims.

Scientific Ranking

FDA Category

Appropriate Qualifying Language**

Second Level

B

... "although there is scientific evidence supporting the claim, the evidence is not conclusive."

Third Level

C

"Some scientific evidence suggests ... however, FDA has determined that this evidence is limited and not conclusive."

Fourth Level

D

"Very limited and preliminary scientific research suggests... FDA concludes that there is little

Australia –New Zealand

General Level Health claim

Calcium –required for normal teeth
And bone structure

Base- 200 pre approved food health
health relationships

High level health claim

Reduced risk of osteoporosis

Base -13 pre approved food –
relationships

Type of information required	General Level Health claim		High Level Health claim
Food /property of food	Calcium		Calcium
Specific health effect	Necessary for normal teeth and bone structure		Reduced risk of Osteoporosis
Relevant population	No relevant population is required		Persons over 65 years of age
Dietary context	No additional dietary context is required		Diet high in calcium and adequate vitamin D status
Condition	Meet nutrient content claim		Food contains not less than 290mg of calcium per serving

Disease Risk Reduction Claims as proposed in Draft Regulations

- | | |
|-----------------------------------------------|------------------------|
| 1. Calcium, Calcium & Vitamin D | Osteoporosis |
| 2. Sodium | Hypertension |
| 3. Dietary Saturated fat & Cholesterol | Coronary Heart Disease |
| 4. Potassium | High blood pressure |
| 5. Alpha-Linolenic acid | Lipid profile |
| 6. Betaglucans or Phylum husk (soluble fibre) | Lipid profile |
| 7. Phytosterols/stanols | Lipid Profile |
| 8. Beta glucans (Oats, Barley) | Blood glucose |

Structuring of Health Claims-Disease Risk Reduction

1. Health claims are always stated to be part of diet. It is balanced diet with the food(containing the beneficial nutrient/ingredient) is included in balanced diet leads the food(s) claimed benefit
2. To obtain the claimed benefit two conditions are to be complied with
 - I) A specified amount of nutrient /ingredient per serving of the food
 - ii) A statement that in order to obtain the claimed benefits, daily intake of the nutrient /ingredient should be taken from either the same food or any other food that provides the nutrient/ingredient



Example of conditions for each claim

Food/diseases: Calcium or Calcium & Vitamin D and Osteoporosis

Condition : The food is a source or high in calcium, calcium & Vitamin D

A statement that the beneficial effect is obtained with a recommended daily allowance(RDA)

Claim Statement : Adequate Calcium (Calcium & Vitamin D) intake throughout life, in a balanced diet are essential for bone health and to reduce the risk of osteoporosis



Wording of claims (Canada)

Disease Risk Reduction Claims with Respect to Dental Caries

- (1) "Won't cause cavities."
- (2) "Does not promote tooth decay."
- (3) "Does not promote dental caries."
- (4) "Non-cariogenic."



US FDA provides model(wording) health claims for guidance

- (1) Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.
- (2) Development of hypertension or high blood pressure depends on many factors. [This product] can be part of a low sodium, low salt diet that might reduce the risk of hypertension or high blood pressure.

Example as how the information is provided on approved health claim by USFDA

Sodium & Hypertension

Relationship between sodium and hypertension

What is hypertension >140mm of systolic &> 90mm Hg

Sodium is distinguished from sodium chloride only 39% Sodium

Scientific evidence- High sodium intake is associated with High blood pressure

High blood pressure is a major health concern and is major risk factor mortality from

CHD. Some high risk groups, **but public health concern for all population**

Early management of Blood pressure can reduce the risk of mortality from CHD and stroke

Sodium Essential element 500-2400mg



Specific requirements—(i) *Nature of the claim.* A health claim associating diets low in sodium with reduced risk of high blood pressure may be made on the label or labeling of a food

- (A) The claim states that diets low in sodium “may” or “might” reduce the risk of high blood pressure;
- (B) In specifying the disease, the claim uses the term “high blood pressure”;
- (C) In specifying the nutrient, the claim uses the term “sodium”;
- (D) The claim does not attribute any degree of reduction in risk of high blood pressure to diets low in sodium; and
- (E) The claim indicates that development of high blood pressure depends on many factors.

(ii) **Nature of the food.** The food shall meet all of the nutrient content requirements of for a “low sodium” food.



Example of rejected claim –EU

Isolated soy protein – Protein rich soybean has been shown to lower/reduce blood cholesterol

Lowering blood cholesterol may reduce the risk of coronary heart disease.

Reason - basis of the scientific evidence assessed, this claimed effect for this food has not been substantiated.



To conclude

Diet related Non Communicable Diseases are on increase

More & more products are likely hit the market with Disease Risk Reduction claims

There is a need to understand the essential requirements of making a claim



Thank you for your attention

