

## Guideline for Submitting a claim Evaluation Request

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# of Health and Nutrition Claims





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# Introduction



The Saudi Food and Drug Authority has approved the Saudi Technical Regulation No. 2333 SFDA.FD “Requirements for Health and Nutrition Claims”, which aims to use health and nutrition claims on food products based on scientific evidence. Health and nutrition claims are one of the methods used by food companies for marketing. The food sector at the Saudi Food and Drug Authority is pleased to announce the process of submitting evaluation request of a health and nutrition claim to be used in the market.

## Health and Nutrition Claims:

### what is a claim?

Any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics.

## What is the Health Claim?

Any claim that states, suggests, or implies that a relationship exists between a food category, a food or one of its constituents and health, this includes the following:

Any Claim that states, suggests, or implies that a relationship between food category and/or food component exists with health.

1- "**Functional claims**": which relate to growth and development of body functions.

2- "**Disease Risk Reduction Claims**": Related to reducing the risk factors for disease progression.

## What is the Nutrition Claim?

Any claim that states, suggests, or implies that a food has particular nutritional properties including but not limited to the content of energy, protein, fat and carbohydrates, as well as the content of vitamins and minerals.

## What is Claim Evaluation?

The process of scientific evaluation of health and nutrition claims submitted by food manufacturers and other applicants for proofing a claim. A submitted claim must be based on scientific evidence that will be reviewed and evaluated for the effectiveness of the food group or one of its components.



## Regulation of Claims



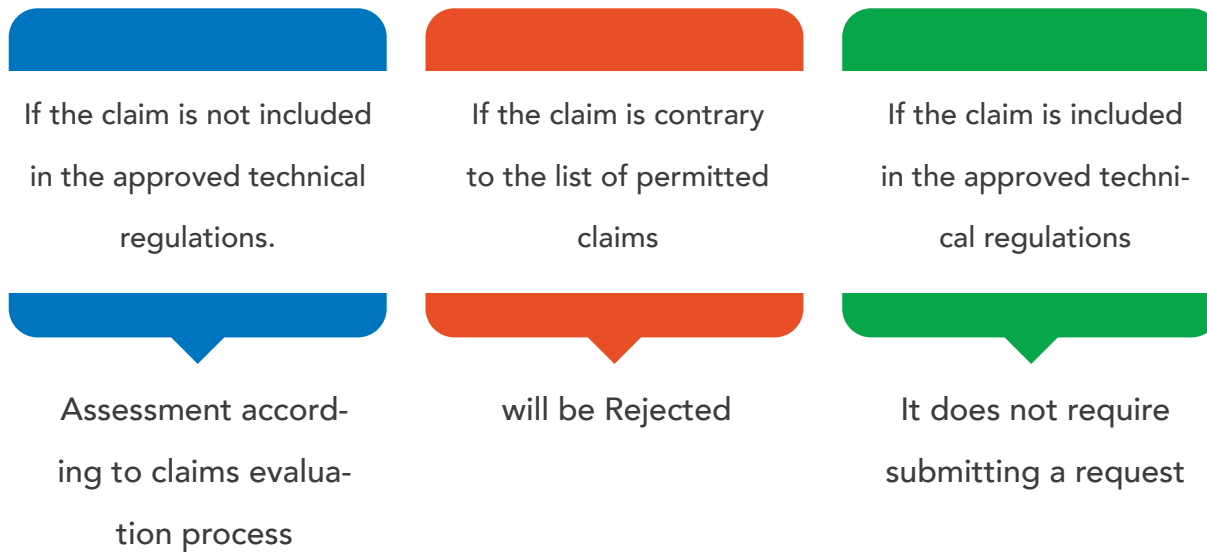
The procedure for regulating health and nutrition claim on food products is subject to the Saudi Technical Regulation No. 2333 SFDA.FD "Requirements for Health and Nutrition Claims", and the relevant technical regulations issued by the Saudi Food and Drug Authority. However, if there is a claim that is not covered by SFDA's technical regulations and specifications, a request must be made to evaluate the claim submitted to the Saudi Food and Drug Authority.

## The Purpose of the guideline

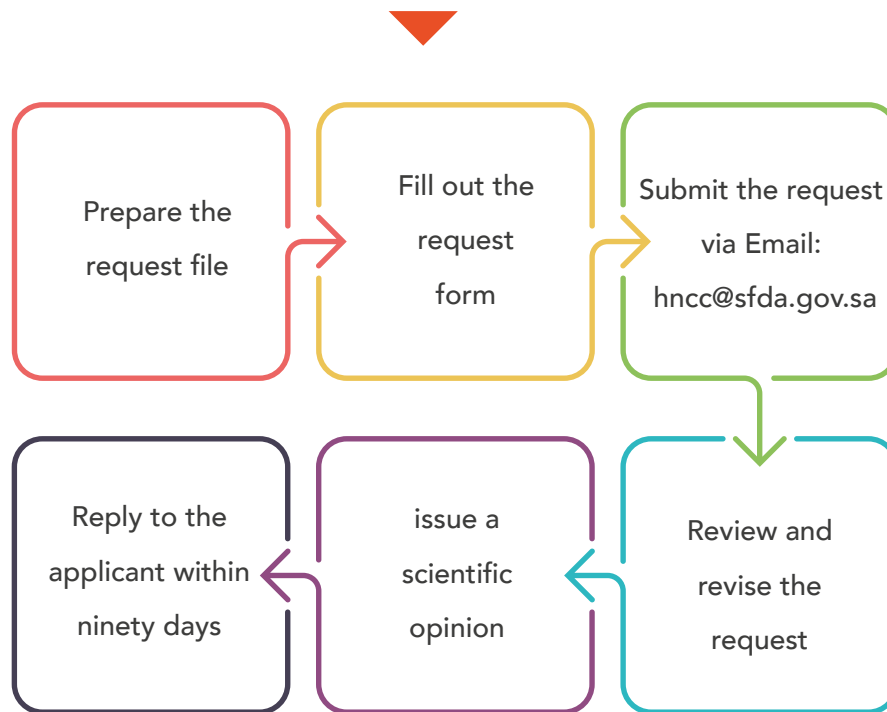


- Clarifying the requirements for accepting claims that are not found in national legislation.
- Clarifying any rejected claims by the Authority.
- Assist applicants to submit health and nutrition claims evaluation requests in an organized and concise manner.
- Facilitating access to scientific information and data required on the application, will help the authority issue scientific opinions effectively and promptly.

# The Mechanism of Claim Acceptance ▼



## The Process of Submitting a Request



## The scope of the committee:

The committee evaluates health and nutrition claims of food products labels, which are under the control of SFDA - food sector, based on the Product Classification Guidelines

## List of not Permitted Claims to be Used on Food



1. Claims that refer to specific percentage or amount of weight loss.
2. Claims that refer to recommendations by individual doctors or health professionals.
3. Claims that suggest health could be affected by not consuming the food.
4. Claims that refer to food, which can be used in preventing, mitigating, treating, or curing a disease, disorder, or a particular physiological condition.
5. Claims stating that food will provide all the adequate amounts of all essential nutrients.
6. Claims implying that a regular or balanced diet of foods cannot supply adequate amounts of nutrients.
7. Claims, which cannot be proven by scientific evidence.
8. Claims that may raise doubts about the safety of food products or can exploit fear to consumers.
9. Meaningless claims, including incomplete comparatives and superlatives.
10. Claims which consist of meanings such as good hygienic practice, wholesomeness, and healthy,
11. Claims made on food intended exclusively for infants and children.



# List of Permitted Claims to be Used on Food



1 . Health (including functional claims) and nutritional claims used on food labels for advertising purposes are permitted if the claim complies with all the necessary requirements (including restrictions & warnings) listed in the national Standards /Technical Regulation list No. SFDA.FD 2333 “Requirements for Health and Nutrition Claims”.

2 . Health and nutritional claims that are not mentioned on the list of unauthorized claims can be permitted if the requirements mentioned in this guide are completed and approved by the Saudi Food and Drug authority. However, the authority has the right to reject any claim if it does not comply with national legislation or in case of insufficient scientific evidence.

# Requirements of Claims evaluation

## Application file should include:

- 1- A wording proposal for any health/ nutrition claim and the specific conditions of use.
  - 2- Characteristics information of the food/ nutrient for which the claim is made for.
  - 3- Information on the Claim effectiveness.
- For function claims, the (specific) function of the body that is the target of the claim has to be specified.
  - A rationale report that the proposed changes in the function will be beneficial physiologically for the target individuals for which the claim is intended to. Also, outcome variables (s) and methods of measurements could be used to assess changes in vivo in humans be provided, together with the outcome variable (s) and methods of measurement which could be used to assess such changes in in vivo in humans.
- 4- All the available scientific data (including data supporting and not supporting, published and unpublished) which are relevant to the health/ nutrition claim. Also, it should be provided in order to demonstrate that the health claim is validated by the totality of the scientific data.

5- For claims based on the essentiality of nutrients, scientific data should be provided on the essential mechanistic role in a metabolic function and/or the specific clinical signs and symptoms of deficiency should be provided. The procedure followed to identify the evidence on the essentiality of the nutrients should be depicted.

6- For claims other than those based on the essentiality of nutrients, data from studies in humans addressing the relationship between the consumption of food/constituent and the claimed effect are required for validation. NOTE (Data from animal studies are not accepted).

7- If the claim is considered a "claim based on the essentiality of nutrients", then the priority of the submitted studies should be according to the following sequence:

- Secondary studies: (Meta –analysis, or systematic review) based on interventional studies, including: randomized controlled trials, randomized none controlled trials, or none randomized controlled trials.
- Interventional studies, including: randomized controlled trials, randomized none controlled trials, or none randomized controlled trials.
- Depletion–repletion studies in humans.
- A case report of clinical signs and symptoms of nutritional deficiency in humans.
- Animal studies.
- In vitro studies.

8- If the claim is considered a "claim other than those based on the essentiality of nutrients", then the priority of the submitted studies should be according to the following sequence:

- Secondary studies: (Meta-analysis or Systematic review) are based on interventional studies that include (Randomized controlled trial, Randomized non-controlled trial, and None Randomized controlled trial).
- Interventional studies that include :( Randomized controlled trial, Randomized non-controlled trial, and None Randomized controlled trial).
- Observational studies that include: Cohort . Studies should be arranged according to evidence strength hierarchy as per study design.
- The quality of the report must be enough to allow a complete scientific evaluation by the Saudi Food & Drug authority and it is highly recommended to record the protocols and published the results of the human studies that submitted to substantiate the claims.
- Journal summaries and articles published in newspapers, magazines, newsletters, flyers, books, or book chapters should not be mentioned for consumers or the public.
- Claims must be substantiate by considering the total available scientific data and the weight of evidence, considering the specific conditions of use in particular.
- Evidence should demonstrate the extent to which the food/ingredient has been define and describe.

- Evidence must demonstrate the extent to which the effect of the claim is based on the importance of nutrients, or the effect of the claim has been defined as a physiological effect beneficial to the target group and can be measured in the body.
- Evidence must demonstrate to what extent a food/ingredient is required for (normal human body) function i.e. it contains an essential component and a mechanical role in metabolic function and/or can reverse clinical signs and symptoms of its deficiency and cannot be synthesized by the body, or it cannot be synthesized in quantities sufficient to maintain the normal body function that is the subject of the claim, as it must be obtained from a food source, or a cause-and-effect relationship has been established between food/component consumption and the claimed effect in humans (for the target group under the proposed conditions of use), by considering strength, consistency, specificity, dose-response, and biological acceptability of the relationship.
- Evidence must demonstrate to what extent it is reasonably possible to achieve the amount of food/ingredient and pattern of consumption required to obtain the claimed effect as part of a balanced diet.
- The targeted group for the claim must be identified. A statement directed for groups who should avoid the use of the food/ingredient for which the claim has been made must be clarified. A warning of any food/ingredient that is likely to pose a health hazard if consumed in large numbers; any other restrictions of use; Instructions for rationale preparation and/or use.

- The Saudi Food & Drug authority can use data that is not included in the form if it is consider relevant to the claim. However, the authority should not be require to conduct any additional literature reviews to collect or process data to evaluate the form. The application must be comprehensive and complete, and each application will be consider as an individual case.
- One application form must be prepared for each claim.
- The entire form cannot remain secret; it should have only parts or sections or words, or diagrams or specific data sets that remain secret by the applicant at a minimum and clearly defined. The applicant must provide a detailed and verifiable justification for each part of the file that is allege to be confidential.
- The statement of the claim should be clear and does not misleading to the consumer.
- Giving an approval of any health or nutrition claim on food products labels, does not mean that the product is safe for human consumption .
- Requests must submitted in Arabic language.
- The period of studying the submitted application takes (90) days, starting from the date of acceptance of the application.
- The decision released by the Saudi Food and Drug Authority to accept the claim is not a document that may be used to claim the intellectual ownership rights of the submitted claim. The applicant must contact the competent authorities to obtain the rights.

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