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# DRAFT EAST AFRICAN STANDARD

## Scientific substantiation of health claims—Guidelines

## EAST AFRICAN COMMUNITY



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# Foreword

Development of the East African Standards has been necessitated by the need for harmonizing requirements governing quality of products and services in the East African Community. It is envisaged that through harmonized standardization, trade barriers that are encountered when goods and services are exchanged within the Community will be removed.

The Community has established an East African Standards Committee (EASC) mandated to develop and issue East African Standards (EAS). The Committee is composed of representatives of the National Standards Bodies in Partner States, together with the representatives from the public and private sector organizations in the community.

East African Standards are developed through Technical Committees that are representative of key stakeholders including government, academia, consumer groups, private sector and other interested parties. Draft East African Standards are circulated to stakeholders through the National Standards Bodies in the Partner States. The comments received are discussed and incorporated before finalization of standards, in accordance with the Principles and procedures for development of East African Standards.

East African Standards are subject to review, to keep pace with technological advances. Users of the East African Standards are therefore expected to ensure that they always have the latest versions of the standards they are implementing.

The committee responsible for this document is Technical Committee EASC/TC 018, *Nutrition and Foods for Special Dietary Uses*.

Attention is drawn to the possibility that some of the elements of this document may be subject of patent rights. EAC shall not be held responsible for identifying any or all such patent rights.

# Introduction

High quality human intervention studies are the prime evidence needed to substantiate claims but there is recognition that, in some cases, only observational studies may be available. Animal and in vitro studies will also be evaluated as part of the totality of the evidence. It has been suggested that the recommendations should include re-evaluation of claims after a certain time period, or if new evidence calls into question the scientific validity underpinning the claims. Setting out a common approach for the substantiation of health claims is an important step in the use of health claims around the world. There is a need to reflect emerging as well as consensus science. The substantiating evidence should be proportionate to the claim.

All health claims must be substantiated by evidence that is relevant to the claims. Evidence may be based on finished products. If such evidence is not available, evidence based on ingredients may be used.

This guideline will help in the implementation of EAS 804 and EAS 805.

# Scientific substantiation of health claims—Guidelines

## 1 Scope

**1.1** These guidelines provide basis for evaluation of health claims with a view of substantiating health claims. It applies to health claims specified in EAS 805.

**1.2** These guidelines cover types of health claims, criteria and process for the substantiation of health claims, consideration of the evidence, specific safety concerns, complaint, feedback to Food Business Operators, communication and re-evaluation of health claims

**1.3** These guidelines include consideration of safety in the evaluation of proposed health claims, but are not intended for the complete evaluation of the safety and the quality of a food, for which relevant provisions are laid out by other Regional Standards and Guidelines or general rules of existing national legislations.

**1.4** These guidelines should be read in conjunction with the Working Principles for Risk Analysis for Food Safety for Application by Governments (CXG 62: 2007)

**1.5** These guidelines are not applicable to foods and their health claims intended for population of 36 months old and below.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EAS 804, *Claims on foods — General requirements*

EAS 805, *Use of nutrition and health claims — Requirements*

CXG 62-2007*, Working Principles for Risk Analysis for Food Safety for Application by Governments*

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

**3.1**
**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:

**3.1.1**
**nutrient function claims**
a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body.

 

Example: “Nutrient A (naming a physiological role of nutrient A in the body in the maintenance of health and promotion of normal growth and development). Food X is a source of/ high in nutrient A.”

**3.1.2**
**other function claims**
These claims concern specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health.

Examples: “Substance A (naming the effect of substance A on improving or modifying a physiological function or biological activity associated with health). Food Y contains x grams of substance A.”

**3.1.3**
**reduction of disease risk claims**
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.

Examples: “A healthy diet low in nutrient or substance A may reduce the risk of disease D. Food X is low in nutrient or substance A.” “A healthful diet rich in nutrient or substance A may reduce the risk of disease D. Food X is high in nutrient or substance A.”

**3.2**
**food or food constituent**
refers to energy, nutrients, related substances, ingredients, and any other feature of a food, a whole food, or a category of foods on which the health claim is based. The category of food is included in the definition because the category itself may be assigned a common property of some of the individual foods making it up.

**3.3**
**health effect**
refers to a health outcome as defined in clause 3.1.1 to 3.1.2

## 4 Types of health claims

a) Nutrient function claims

b) Other function claims

c) Reduction of disease risk claims

## 5 Criteria for the substantiation of health claims

**5.1** The following criteria are applicable to the three types of health claims:

a) Health claims should primarily be based on evidence provided by well-designed human intervention studies. Human observational studies are not generally sufficient per se to substantiate a health claim but where relevant they may contribute to the totality of evidence. Animal model studies, ex vivo or in vitro data may be provided as supporting knowledge base for the relationship between the food or food constituent and the health effect but cannot be considered as sufficient per se to substantiate any type of health claim.

b) The totality of the evidence, including unpublished data where appropriate, should be identified and reviewed, including: evidence to support the claimed effect; evidence that contradicts the claimed effect; and evidence that is ambiguous or unclear.

 

c) Evidence based on human studies should demonstrate a consistent association between the food or food constituent and the health effect, with little or no evidence to the contrary.

**5.2** Although a high quality of scientific evidence should always be maintained, substantiation may take into account specific situations and alternate processes, such as:

a) 'Nutrient function' claims may be substantiated based on generally accepted authoritative statements by recognised expert scientific bodies that have been verified and validated over time.

b) Some Health claims, such as those involving a relationship between a food category and a health effect, may be substantiated based on observational evidence such as epidemiological studies. Such studies should provide a consistent body of evidence from a number of well-designed studies. Evidence-based dietary guidelines and authoritative statements prepared or endorsed by a competent authoritative body and meeting the same high scientific standards may also be used.

## 6 Process for the substantiation of health claims

The systematic review of the scientific evidence for health claims by competent national authorities takes into account the general principles for substantiation. Such a process typically includes the following steps:

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 categorise 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.

f) Documentation of the outcome of the substantiation process

g) Communication to the food business operator (FBO) and/or the public as appropriate after notification to the FBO

## 7 Consideration of the evidence

**7.1** The scientific studies considered relevant for the substantiation of health claim are those addressing the relationship between the food or food constituent and the health effect. In case of a claimed health effect that cannot be measured directly, relevant validated biomarkers may be used (e.g. plasma cholesterol concentrations for cardiovascular disease risk).

**7.2** The scientific data should provide adequate characterization of the food or food constituent considered as responsible for the health effect. Where applicable, the characterization includes a summary of the studies undertaken on production conditions, batch-to-batch variability, analytical procedures, results and conclusions of the stability studies, and the conclusions with respect to storage conditions and shelf-life.

**7.3** The relevant data and rationale that the constituent for which the health claim is made is in a form that is available to be used by the human body should be provided where applicable. If absorption is not necessary to produce the claimed effect (e.g. plant sterols, fibres, lactic acid bacteria), the relevant data and rationale that the constituent reaches the target site or mediates the effect are provided. All available data on factors (e.g. forms of the constituents) that could affect the absorption or utilisation in the body of the constituent for which the health claim is made should also be provided.

**7.4** The methodological quality of each type of study should be assessed, including study design and statistical analysis.

 

a) The design of human intervention studies should notably include an appropriate control group, characterize the study groups' background diet and other relevant aspects of lifestyle, be of an adequate duration, take account of the level of consumption of the food or food constituent that can be reasonably achieved in a balanced diet, and assess the influence of the food matrix and total dietary context on the health effect.

b) Statistical analysis of the data should be conducted with methods recognized as appropriate for such studies by the scientific community and with proper interpretation of statistical significance.

**7.5** Studies should be excluded from further review and not included in the relevant scientific data if they do not use appropriate measurements for the food or food constituent and health effect, have major design flaws, or are not applicable to the targeted population for a health claim.

**7.6** By taking into account the totality of the available relevant scientific data and by weighing the evidence, the systematic review should demonstrate the extent to which:

a) the claimed effect of the food or food constituent is beneficial for human health;

b) a cause and effect relationship is established between consumption of the food or food constituent and the claimed effect in humans such as the strength, consistency, specificity, dose-response, where appropriate, and biological plausibility of the relationship;

c) the quantity of the food or food constituent and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet as relevant for the target population for which the claim is intended;

d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

**7.7** Based on this evaluation and the substantiation criteria, competent national authorities can determine if, and under what circumstances, a claimed relationship is substantiated

## 8 Specific safety concerns

**8.1** When the claim is about a food or food constituent, the amount should not expose the consumer to health risks and the known interactions among constituents should be considered as per the competent authorities or any other peer reviewed and published research findings.

**8.2** The expected level of consumption should not exceed relevant upper levels of intake for food constituents.

**8.3** The exposure assessment should be based on an evaluation of the distribution of usual total daily intakes for the general populationand, where relevant, those for vulnerable population groups. It should account for the possibility of cumulative intake from all dietary sources, and of nutritional imbalance due to changes in dietary patterns in response to information to consumers that lays emphasis on the food or food constituent.

## 9 Feedback to Food Business Operators (FBOs)

Based on provisions given under clause 7 and 8, the FBO should get feedback from the competent national authority in accordance with the existing turn-around time.

## 10 Complaint regarding scientific substantiation of health claims evaluation

FBOs have the rights to appeal on the process and/or results of the evaluation. A submitted complaint should have information and justification on areas that need to be re-evaluated/ re-assessed. The deadline for appealing should be in accordance with existing procedures of complaint handling.

# 11 Communication

## 11.1 General

Effective communication following the verification of health claims is a critical step in safeguarding public health, ensuring transparency, and maintaining consumer trust. Once health claims on food or food constituents have been scientifically evaluated and verified by the relevant authorities, a clear and coordinated dissemination of information should follow through established communication channels and in line with national and international guidelines.

## 11.2 Communication with FBOs

**11.2.1** Where a food or food constituent is found to carry a false or misleading health claim, or poses a food safety concern, the national competent authority should promptly notify the responsible food business operator in writing, outlining the nature of the violation and the supporting evidence. The communication should be clear, **time-bound**, and include reference to applicable standards and enforcement provisions. The authority should offer technical guidance where appropriate, and initiate enforcement measures if compliance is not achieved within the specified timeframe.

**11.2.2** Following the scientific review of submitted evidence, the competent authority should formally notify the business operator of the outcome regarding the validity of the health claim. If the claim is substantiated, the notification should confirm its acceptability for use under specified conditions.

**11.2.3** If the claim is found to be false, misleading, or unsubstantiated, the authority should issue a written directive requiring immediate cessation of the claim's use, along with technical guidance and timelines. The communication should reference the applicable standards and provide an opportunity for the operator to respond or appeal within a defined period.

## 11.3 Communication with public

**11.3.1** In case of lack of corrective actions by the FBO to remove a false or misleading or unsubstantiated health claim within the timelines communicated by the competent authority, the latter should notify the public of the risks linked to the claim and take appropriate actions. The public notification should be done after a thorough evaluation to avoid loss of public trust as well as ensuring fairness and transparency

**11.3.2** The communication should include:

a) Product identification: The name, brand, and labelling details of the recalled food item.

b) Problem description: What went wrong, why the product is being recalled, and how the issue was discovered.

c) Source information: The name and location of the company that produced the food, and a contact point for inquiries.

d) Distribution details: Where the product was sold or is likely to be found, including quantities and affected regions.

e) Consumer actions: What consumers should do if they experience symptoms or suspect illness

**11.3.3** In the event that a previously rejected health claim is subsequently validated through new evidence or re-evaluation, the competent authority should initiate a formal reassessment process. Upon confirmation of the health claims validity, the authority should update the official registry, issue a public correction notice and revise relevant guidance document accordingly. This process should be conducted transparently to ensure scientific, integrity, procedural fairness and public trust.

### 11.4 Communication Channels

Communication after health claim verification should use multiple, audience-appropriate channels to ensure wide and effective dissemination. Key channels include:

a) Official Public Notices: Published on the websites and bulletin boards of the regulatory authorities.

b) Official Gazettes and Regulatory Bulletins: Serve as legal means of announcing approved health claims.

c) Stakeholder Engagements and Workshops: Facilitate information sharing with food business operators' representatives, academia, and consumer protection groups.

d) Press Releases and Media Briefings: Used to inform the general public and the press about newly verified or rejected health claims.

e) Digital Platforms and Social Media: Offer accessible and rapid communication channels for the public and health professionals.

f) Product Labelling and Marketing Communication: Food manufacturers must update product labels and advertising materials according to the verified claim outcomes

### 11.5 Feedback and Monitoring Mechanism

After dissemination, competent authorities should establish feedback mechanisms such as hotlines, email contacts, and consumer surveys to gather public and FBOs input. Continuous monitoring ensures that communicated claims are not misused and that consumer understanding remains accurate over time.

## 12 Re-evaluation of health claims

Health claims should be re-evaluated. Competent national authorities should re-evaluate health claims either periodically or following the emergence of significant new evidence that has the potential to alter previous conclusions about the relationship between the food or food constituent and the health effect.

# Bibliography

[1] *CXG 23-1997 Guidelines for Use of Nutrition and Health Claims, Rev 2013*

[2] *EAS 805: 2023Use of nutrition and health claims —Requirements*

 