

Proposed Approval Mechanism for Health Claims on Foods for Infants and Young Children

Technical Meeting with Trade
8 July 2015

Background

- Under the proposed regulatory framework on nutrition and health claims for formula products and foods for infants and young children (IYC foods) under the age of 36 months, some health claims will be allowed to be made on IYC foods.
- There are merits in establishing-
 - a list of approved claims, and
 - a mechanism to develop the list and relevant claim conditions

Application-based approach

- It is proposed to establish a list of approved health claims by way of application by the trade
- Traders interested in making health claims on their products which are not on the list would need to submit applications to the CFS for consideration
- CFS will maintain a list of approved claims, which will be available to the trade and the public for reference
- Once a claim has been included in the list of approved claims, the applicant and other traders may make the claim on the relevant product as well as products in the same product category, so long as the specified conditions have been fulfilled

“Fast-track” assessment

- To simplify the claims application and assessment procedures, it is proposed to establish a “fast-track” mechanism for certain health claims that have been accepted overseas.
- The claims in concern must have been undergone scientific evaluation and being accepted to be used on IYC foods by an overseas authority recognised by CFS (“recognised authority”)
- However, applications relating to claims that have been rejected by any recognised authority will not be entertained.

The “recognised authority”

- The recognised authority:
 - An official authority which is charged by or part of the government
 - With solid experience and ability on conducting individual scientific assessment of health claims
 - The result of the scientific assessment and the relevant details should be open to public or available upon request

Requirements for “fast-track” application

- Applicant should produce adequate documentary proof that:
 - the claim in question has already been considered to be scientifically substantiated and accepted by a recognised authority
 - relevant claim conditions set by the recognised authority have been fulfilled, e.g.
 - definition or characterisation of the claimed substance;
 - the required amount of the claimed substance in IYC foods;
 - the target population of the claim, etc.
- Such documentation may include but not limited to:
 - the list of accepted claims published by the recognised authority,
 - official evaluation report released by the recognised authority,
 - test report issued by accredited laboratories, etc.
- The applicant should declare that the claim in question, or its equivalent, has not been rejected by any recognised authority to his/her knowledge

Claims that were not assessed overseas

- Traders would need to submit relevant documents on the scientific substantiation of the claims to CFS for detailed evaluation.
- The assessment will mainly base on Codex's recommendation on the substantiation of health claim as provided in Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997).

Codex recommendations on systematic review processes

- According to Codex recommendation, the systematic review of the scientific evidence for health claims takes into account the general principles for substantiation.
- Such a process typically includes the following steps:
 - Identify the proposed relationship between the food or food constituent and the health effect;
 - Identify appropriate valid measurements for the food or food constituent and for the health effect;
 - Identify and categorise all the relevant scientific data;
 - Assess the quality of and interpret each relevant scientific study;
 - 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.

Codex's basic criteria for health claims substantiation

- 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.
- **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.
- 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.

Requirements for detailed assessment

- Applications under this category should provide adequate information for the assessment, including-
 - all scientific data in favour and not in favour that are pertinent to the health claim,
 - laboratory reports on the content of the nutrients/ substances in concern,
 - comprehensive review of the data from relevant human studies, etc.

Application processing time and fee

- In order to conduct such a comprehensive scientific assessment, CFS would need to identify and recruit a pool of experts who have no conflict of interest in this area and are able to provide expert advice on the scientific substantiation of health claims in concern.
- As such, the time required for processing the application would depend on a number of factors such as -
 - successful recruitment of suitable experts,
 - timely submission of adequate supporting documentations from the applicant,
 - time required by the experts to evaluate the claims, etc.
- Application fee calculated on a cost recovery basis will likely apply

Reviewing list of approved claims

- Taking into consideration of advance of science, emergence of significant new evidence and change of overseas regulation in future, CFS will review the list of approved claims on a need basis when such new information has come to CFS's knowledge

~ For Discussion ~