CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 1/13 **NFSDU/41 CRD 20**

Original language only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Forty-first Session

Dusseldorf, Germany
24 – 29 November 2019

PROPOSAL FOR NEW WORK ON ESTABLISHING HARMONIZED GUIDELINES FOR THE QUALIFICATION OF NUTRITION AND HEALTH CLAIMED FOOD

Prepared by Republic of Korea

Background

The Codex Alimentarius Commission established the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) to provide guidance for applying all foods for which nutrition and health claims are made in food labelling and advertising.

The guidance provides definitions, the conditions and recommendations for the scientific demonstration of health claims. This guideline has helped many members to elaborate their own policies on nutrition and health claimed(NHC) food.

However, there is a limitation that CAC/GL 23-1997 does not clearly recount who and how to assess and justify foods with nutrition and health claims. In addition, since Nutrition and Health Claimed(NHC) foods contain certain functional ingredients, an appropriate assessment of safety should be applied.

Considering that the guidelines do not provide specific details, the Republic of Korea believes that Codex need to make additional efforts for the purpose of ensuring fair trade and consumer protection related with the nutrition or health claimed foods.

Introduction

1. The Purpose and Scope of the Standard

- The Purpose of this work is to develop international documents on “guidelines on functional ingredients, standard and specification of dietary supplements” based on measurable characteristics, specific safety and quality criteria and any other factors to protect consumer’s health and fair trade.
- The scope of the proposal, applies exclusively on the development of the guidelines on functional raw ingredients, its standard and specification of dietary supplements.
- The scope of the document will include data verification procedure, quality criteria of functional raw ingredient and methods of evaluation, and the requirements for the good manufacturing practices such as production, contaminants, hygiene, safety test, scientific evidences, methods of analysis and sampling, import and export inspection and nutritional values.

2. Relevance and Timeliness

As life expectancy is extended around the world, the duration of disease is increasing and public interests in health continues to rise. As a result, the consumption of foods with specific benefits for nutrition and health is increasing rapidly, and survey[1] shows that the global dietary supplement market is growing at 136 Billion USD.

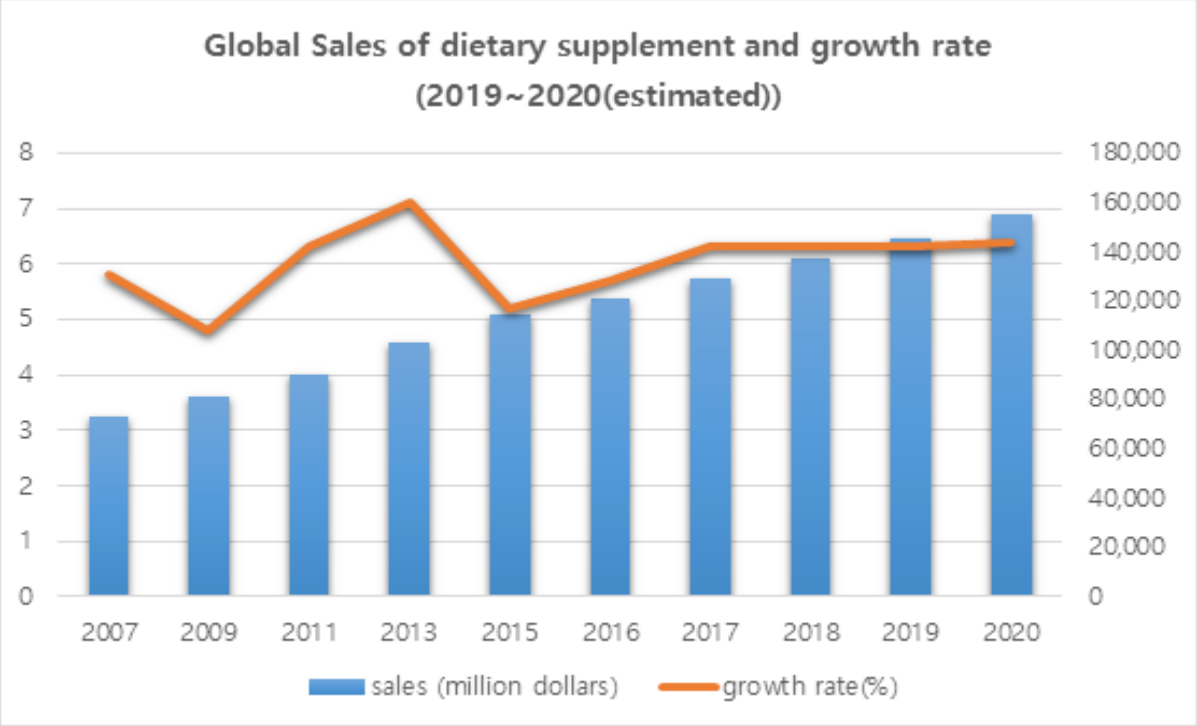
Based on related studies, the US and EU have taken recognition of the fact that dietary supplementation can potentially reduce national medical costs, and evaluated that consumption of health functional foods contributes to improving the welfare of the aged population.

[1] 2019 Supplement Business Report, Nutrition Business Journal. 2019

Global trade market ranges 121.2 Billion dollars in 2016 whereas it was 72.8 billion in 2007. Global Supplements market shows 5~6% of yearly growth in the last decade (2007~2017, except for 2009) and expected to continue to grow at the consistent level.[2]

Year	2007	2009	2011	2013	2015	2016	2017	2018	2019	2020
Sales	72,798	80,741	90,433	103,175	114,713	121,245	128,966	137,016	145,700	155,096
Growth Rate(%)	5.8	4.8	6.3	7.1	5.2	5.7	6.3	6.3	6.3	6.4

Sales (units in Million USD)



And it is noticeable trend that consumers tend to purchase Nutrition and Health claimed foods directly through e-commerce. In South Korea, Nutrition and Health Claimed foods account for $5.8 Billion out of the $27.5 billion of individual consumer purchases directly from overseas through e-commerce.

However there are possible risks from uncontrolled trade such as a) products uses sub-standard raw materials, b) products manufactured under un-sanitary condition, or c) raw materials did not meet requirements for toxicity test etc.

Safety and functionality of these directly purchased products via e-commerce are not reliable sometimes because there are no practical ways to provide respectable information from different countries that have different methods or procedures for accrediting NHC foods.

The Republic of Korea believes that there is a needs to create internationally harmonized guidelines on functional ingredients, standard, specification and the safety assessment of Nutrition and Health Claimed foods to address these issues.

Objective and fair examination with the CODEX guideline will guarantee to protect the health of the consumer and to ensure fair practices in the international trade.

3. <u>Main aspects to be covered</u>

This document as general requirements covers the following aspects:

[2] Global Supplement Business Report, Nutrition Business Journal. 2017

a. Products definition

b. Composition: including provisions for evaluation on safety, toxicity, and characteristics of raw materials

c. General requirements for products of dietary supplements: including provisions for types of products, ingredients and its amount, manufacturing process, specifications, scientific evidence of safety and nutritional values of the products

d. Quality criteria

4. Assessment against the criteria for the establishment of work priorities

4.1 General criteria

The directive should provide following criteria: manufacturing process, specifications, scientific evidence of safety and Qualification process of the Nutrition and Health Claimed foods.

4.2 Criteria applicable to general subjects

A. The establishment of Definitions: Definitions to be clarified related to NHC(Nutrition and Health Claimed) foods are “nutrient”, “beneficial consistent”, “beneficial effect”, and etc.

B. Scientific vindication of safety: Demonstrating the safety of functional ingredients is very important for public health. Scientific basis to confirm that the raw materials do not harm the human body, such as food intake experience, intake evaluation, toxicity test data and human application tests.

C. Manufacturing: For approved manufacturer, Consideration should be given to the application of good manufacturing practices to maintain the proper content and properties of functional ingredients, or to the application of HACCP to effectively manage hazards.

D. Qualification procedures: It Is necessary to develop objective recognition procedures to help global fair trade and consumer confidence.

Relevance to the Codex Strategic objectives

The proposal is consistent with the Strategic Plan of the Codex Alimentarius Commission 2020~2025, in particular, strategic Goal 3(Codex Standards are widely used for the protection of consumer health and ensuring fair practices in the food trade).

The proposal is in accordance with Objective (3.1) of “Codex standards drive harmonization of global food regulations for the protection of consumer health and ensuring fair practices in the food trade”.

Information on the relation between the proposal and other existing Codex Documents.

a. CAC/GL 23-1997 Guidelines for use of nutritional and health claims

b. CAC/RCP 1-2010 Food hygiene

c. CCPR – Data bases relating to the maximum limits for pesticides residue issued Codex committee on Pesticides Residues in Food

d. CXS 193-2012 General Standard for Contaminants and Toxins in Food and Feed

5. Identification of any requirements for and availability of expert scientific advice.

Technical advice may be required for the preparation of this project document from expertise and third parties in this scope.

6. Identification of any need for technical input to the standard from external bodies

This can be planned for possibly expected to be used as inputs from international organizations such as International Organization for Standardization(ISO), WHO, FAO and other relevant concerned organizations.

7. Proposed timeline DATE ADVANCE and PROCEDURES

If approved by the CCNFSDU41 in 2019, the further work expected to start with eWG in 2020. It is expected to take at least three Committee sessions to be completed.