

# **Brief Communication**



# CODEX Labelling Standard for Reduction of Disease Risk Claim and the Status in Other Countries

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# **ABSTRACT**

In South Korea, health claim is classified into reduction of disease risk claim, physiological function improvement labeling, and nutritional component function labeling, in accordance with the "Labeling Standard of Health Functional Food" under the "Health Functional Food Act." Currently, indications for reducing the risk of disease are allowed only for health functional foods. Only the intake of calcium and vitamin D for the reduction of the risk of osteoporosis, and the intake of xylitol for the reduction of the risk of dental caries are recognized. In this communication, the meaning and current status of reduction of disease risk claim were discussed.

**Keywords:** CODEX Guidelines on Nutrition Labeling; Reduction of Disease Risk Claim; Health Claim; Nutritional Labeling and Education Act

# **DEFINITION OF REDUCTION OF DISEASE RISK CLAIM**

In South Korea, health claim is classified into 3 categories, which are 'reduction of disease risk,' 'physiological function improvement,' and 'nutrient function' in accordance with the "Labeling Standard of Health Functional Food" under the "Health Functional Food Act." Among these, the reduction of disease risk claim is defined as an indication that the consumption of the food through the total diet is related to a reduction in the risk of disease occurrence or health condition.

Disease risk reduction claim was originated from 'health claim system' of the United States. In 1979, the U.S. Department of Health & Human Services (DHHS) presented "Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention," which aims to be achieved by 1990. After that, Healthy People 2000 was published in 1990, which established a national strategy for national health promotion from 1990 to 2000, by expanding the goals and contents.¹ Since then, Healthy People has been continuously updated until the current Healthy People 2030.² This Healthy People policy in the United States was reflected in the Health Claim established by the enactment of the Nutritional Labeling and Education Act (NLEA), and the items set forth in the Health Claim were evaluated and confirmed based on considerable scientific evidence.³

In fact, the case that triggered the enactment of a health claim in the United States began in 1984 with health claims (all bran and several cancers) on Kellogg's cereal products (https://www.nytimes.com/1986/02/19/garden/health-claims-on-food-put-fda-in-a-corner.html). It can be confirmed that the enactment of the NLEA and the establishment of the Health Claim regulation are in line with the nutrition policy of Healthy People, the national health policy of the United States. The U.S. NLEA aims to ensure that consumers receive more scientifically correct information about food. In accordance with the NLEA Act, the Food and Drug Administration (FDA) is required to enact regulations indicating the association between food ingredients and diseases As the U.S. health claim system has developed into the health claim of each country through CODEX, it is believed that it has been established as reduction of disease risk claim; other function claim, and nutrient function labeling. As can be seen from the beginning of the health claim system in the U.S., public health promotion through food labeling has been the top priority for reduction of disease risk claim. Therefore, the reduction of disease risk claim always emphasizes "correct eating habits and lifestyle." There is always a premise that the intake of certain foods does not prevent diseases.

# **CODEX LABELING STANDARD**

CODEX establishes and informs guidelines for the standards of nutrition and health claims in food labeling in accordance with the "Guidelines for use of nutrition and health claims (CAC/GL 23-1997)." This standard applies to the labeling and advertising of food. It is stated that it applies to all foods except for foods for specific purposes. Among nutrition and health claims, health claims are divided into nutrient function claim, other function claim, and reduction of disease risk claim. Reduction of disease risk claim is defined as "claim 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." While further explanations hereafter suggest that reducing risk means significantly altering a major risk factor for a disease or health-related condition, there are several risk factors for a disease, and altering one of these risk factors may or may not have a beneficial effect. Appropriate language should be used when labeling reduction of risk, and caution should be given by mentioning other risk factors so that consumers do not interpret the consumption of certain foods as preventing a disease.

# STATUS OF REDUCTION OF DISEASE RISK CLAIM IN FOREIGN COUNTRIES

### **United States**

Currently, in the United States, the labeling corresponding to the reduction of disease risk claim is considered as health claim. The functionality of foods and food ingredients associated with diseases, such as reducing the incidence of osteoporosis, increasing the incidence of cancer, reducing the incidence of cancer, increasing the incidence of coronary artery and heart disease, decreasing the incidence of coronary artery and heart disease, and reducing the incidence of dental caries are permitted.

In addition to FDA-approved health claims that have reached scientific consensus, health claims approved based on authoritative statements are also approved and labeled. There are also a qualified health claims that classify and approve the scientific evidence base for food

and food ingredients that have not been able to reach scientific consensus but have secured a certain scientific basis. As of May 2021, 37 list of qualified health claims can be identified.

### **European Union**

In 2006, the European Union officially declared the "Regulation of Nutrition and Health Claims for Foods" (Regulation (EC) No 1924/2006), and the health claim system has been in effect since 2007 along with nutrition claims. In Europe, health claims include: Reduction of Disease Risk Claims (Regulation (EC) No 1924/2006, Article 14.1(a)), Children Development and Health Claims (Regulation (EC) No 1924/2006, Article 14.1(b)), and other health claims. Other health claims include general health claims based on generally accepted scientific evidence (Regulation (EC) No 1924/2006, Article 13(1)) and newly developed scientific evidence, or those classified as New Function Health Claims (Regulation (EC) No 1924/2006, Article 13(5)).

# Australia/New Zealand

Health claims in Australia/New Zealand are classified into High level health claims and General level health claims. All health claims can only be made with respect to the foodhealth relationship that has been verified in Food Standards Australia New Zealand (FSANZ)'s Food standards code 1.2.7. It shall be supported by scientific evidence to the same extent, such as prior approval by the FSANZ or self-evidence by the food company. Only products that meet the Nutrient Profiling Scoring Criterion (NPSC) are permitted (e.g., products high in saturated fat, sugar or salt are not allowed to claim health). Among these, high level health claims indicate the relationship between nutrients or substances in food, with a serious disease or a related biomarker. It is said that it should be based on 13 food-health relationships previously approved by FSANZ, so it can be said as reduction of disease risk labeling—Example: "High calcium sourcing may reduce the risk of osteoporosis."

## Japan

In Japan, the functional labeling food system was implemented in 2015, but reduction of disease risk claim has already been permitted and labeled in foods for specific health use before the disease risk reduction effect of the involved ingredient is medically and nutritionally established. As a food for specific health use that recognizes the disease risk reduction claim, this label can be used only for calcium and folic acid.

# REDUCTION OF DISEASE RISK CLAIM IN SOUTH KOREA

As described above, South Korea has the reduction of disease risk claim in accordance with the "Labeling Standard of Health Functional Food" under the "Health Functional Food Act." Currently, indications for reducing the risk of disease are allowed only for health functional foods. Only the intake of calcium and vitamin D for the reduction of the risk of osteoporosis, and the intake of xylitol for the reduction of the risk of dental caries are legally certified. However, as can be seen from the beginning of the system in the U.S., it is judged that the reduction of disease risk claim needs to be adapted to the national nutrition policy for the promotion of public health. It is necessary to review what nutrients the people are lacking, what diseases are problematic, and whether certain food or ingredients can be used to solve and prevent the most problematic, whether to intake certain foods or ingredients, prevent the problematic diseases in the country, and as whether these should be applied only to supplements or all foods equally.

#### **Reduction of Disease Risk Claim**

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