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Perspective Regulatory Framework on Health Claim of Tea-Mini Review

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ABSTRACT

Tea is a popular beverage with potential health benefits for those who consume it regularly. Tea products with health claims require scientific evidence based on clinical trials with generally accepted scientific data and newly developed scientific data. Tea products have been labelled FOSHU in Japan, claiming to reduce body fat and cardiovascular risk. In The USA, health claims on tea cannot be recommended and categorized as Qualified Health Claims. In Europe, health claims for tea still required further research to provide accepted scientific data. This review aims to explain the position of tea products based on the perspective of the regulatory framework of food health claims in the different official agencies in the United States, Europe, and Japan.

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Introduction

Tea is a popular beverage after water that is consumed in the world. International tea Committee (ITC) (2021) reported that the world's total tea production in 2020 reached 6.20 MT, whereas China, India, Kenya, Turkey, Sri Lanka, Vietnam, and Indonesia have the most significant tea production. Global consumption increased from 5,510 MT in 2017 to 5,879 MT in 2020, with the most significant tea consumption by countries in 2020 being China, India, Turkey, Pakistan, and Russia. Nowadays, tea is not only consumed as a hot drink. Tea has been developed to be more practical as a ready-to-drink beverage and has been widely used in food, pharmaceutical, and cosmetic products (Hajra and Yang, 2015; Prawira-Atmaja and Rohdiana, 2018).

Tea is rich in a flavonoid compound that constituent up to 30% (dry weight). Flavanol and flavonol are the main classes of flavonoid found in tea (Wang, Provan and Helliwell, 2000). Catechin, flavonol class, is the main bioactive compound in green tea. Theaflavin and thearubigin are the primary oxidation catechin product and are only found in black tea products (Engelhardt, 2010). These compounds contribute to tea's characteristic, such as color and taste. Another bioactive compound found in tea is L-theanine. Theanine is a non-proteinic amino acid unique to tea with health effects primarily related to cognitive performance, emotional status, and sleep quality (Türközü and Şanlier, 2017). Tea also contains bioactive compounds like caffeine, vitamin, and minerals (Da Silva Pinto, 2013).

The study to support the health benefits of tea has increased in recent years. The study reported using animal models and human studies to get a complete mechanism in reducing diseases for more detail on comprehensive reviews such as consumption tea and disease correlation (Sanlier,

Gokcen and Altuğ, 2018). Bioactive polyphenol in green tea, Epigallocatechin gallate (EGCG), is an excellent natural product that should be used to discover and develop potential drug leads Due to its association with chemoprevention. EGCG is an inhibitor of the phosphatidylinositol 3-kinase/protein kinase B/mammalian target of the rapamycin signaling cascade, acting upon major axis points within cancer survival pathways (Tauber, Schweiker, and Levonis, 2020). Tea polyphenol is a potential natural active ingredient to inhibit amylase and amyloglucosidase for the treatment of diabetes (Zhang et al., 2018). Black tea has the health benefit of preventing diarrhea, High BP, digestive problems, blood circulation, tooth decay, and keeping high-density lipoprotein (HDL) at a low-level concentration (Naveed et al., 2018). Green tea consumption 1-3 cups per day had a reduced risk of myocardial infarction and stroke compared to those who did not consume green tea. Routinely consumption of green tea is associated with a lower risk of CVD, stroke risk, cerebral infarction, and intracerebral hemorrhage (Pang et al., 2016).

Although many studies have reported the health benefit of tea, there is still a problem for researchers to determine the right amount and frequency of consumption tea to provide health effects when consumed as usual (Williamson and Holst, 2008; Bo' et al., 2019). Thus, tea products cannot claim as healthy food on their product. It is packaging when released in the market. It is due to non-fulfillment with the country's regulation (lack of scientific evidence). This condition makes consumers confused because of different comprehension of regulations and scientific evidence of food products with health claims.

The present paper aimed to review the health claims of tea on the regulatory framework. We examine regulations widely used as references, such as regulations in Europe, The United States, and Japan.

Table 1. Definition for health claim by international regulation

Official ins/agency	Country/area	Definition	Type of health claim	Claim approval	References
Codex Alimentarius	International	"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."	Nutrient function claim, other function claims, and reduction of disease risk claims	"Based on current relevant scientific substantiation."	(Codex Alimentarius, 2013)
Ministry of Health, Labour and Welfare	Japan	No specific definition-"FHC refer to foods that comply with the specifications and standards established by the Minister of Health, Labor and Welfare and are labeled with certain nutritional or health functions."	Since 2015 there are three types of food with a health claim (FHC): Food for specified health uses (FOSHU), food with nutrient function claim (FNFC), and Food with function claim (FFC)	FOSHU: scientific evidence requirement under current licensing examination procedures FFC: The industry is responsible for providing scientific evidence of food safety based on scientific review	(Maeda-Yamamoto, 2017; Tanemura, Hamadate and Urushihara, 2017; Iwatani and Yamamoto, 2019)
The European Parliament and the Council of the European Union	European union	"Health claim" means any claim that states, suggests, or implies that a relationship exists between a food category, a food, or one of its constituents and health	Function claim (article 13.1 and 13.5), reduction of disease risk claim and claim growth and development children (article 14)	Based on generally accepted scientific data and newly developed scientific data	(The European Parliament and the Council of the European Union 2006)
Food and Drug Administration (FDA)	United State	"Health claim means any claim made on the label or in the labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" references, written statements (e.g. a brand name including a term such as "heart"), symbols (e.g. a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition."	"Health claims are limited to claims about disease risk reduction, and Cannot be claimed about the diagnosis, cure, mitigation, or treatment of Disease."	Health claims require a Significant Scientific Agreement (SSA). When the claim did not meet the SSA A standard can be categorized as a "Qualified Health Claim."	(FDA, 2013)

İns: Institution

The Health Claim Definition

Codex Alimentarius CAC/GL1-1979 revised 1991 and amended 2009 defines claim as "any representation which states, suggests or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality" (Codex Alimentarius, 2009). The European Parliament and the Council of the European Union, (2006) defines claim means that "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."

Japan is the first leading country for developing regulations on food claims with the term "functional food" in 1984 (Arai, 2000). This concept was then integrated by The Japanese Ministry of Health, Welfare, and Labor (MHWL), in 1991, into Food for Specified Health Uses (FOSHU) replaced the term "functional food" (Arai, 2000). MHWL, in 2001, enacted a regulation system by introducing a new term called "Food with Health Claim" (FHC). This regulation system includes the existing FOSHU and a new system called "Food with Nutrient Function Claim" (FNFC) (Shimizu, 2003).

In February 2005, the concept of FOSHU was altered to make them more accessible industry applied their product and distributed them in marketplaces (Lalor and Wall, 2011).

The existing FOSHU was broadened into four categories: Ordinary FOSHU, Standardized FOSHU, Qualified FOSHU, and the new health claim "Reduction of disease risk" (Nagata and Yamada, 2008; Yamada et al., 2008).

The new regulation system was introduced in April 2015 (Figure 1). MHWL added new categories in FHC known as "Food with Function Claims" (FFC) (Kamioka et al., 2017; Tanemura, Hamadate and Urushihara, 2017). The FFC system is more flexible than FOSHU because the industry producer can evaluate and describe scientific evidence of health food benefits with a flexible protocol or based on available scientific (Maeda-Yamamoto, 2017; Iwatani and Yamamoto, 2019).

The concept of regulation of nutrition and health claims has been widely adopted in many countries. However, there are differences in the application of regulations in each country. Studied by de Boer & Bast (2015) on review of legislation on nutrition and health claim from 28 countries found three differences were discerned, i.e.: (i) types of nutrition and health claim; (ii) the approval procedure of claim; and (iii) the use of emerging scientific

In Table 1. We summarize the definition of health claims from several regulatory references such as Codex Alimentarius, FDA, Japan, and the European Union. The industry producer or distributor shall refer to the regulation in the country when applying health claims in their product.

Health claims must be supported by a comprehensive study based on generally accepted scientific data and newly developed scientific data. United States permitted a health claim that is suggested but supported by less scientific evidence known as "Qualified Health Claim" (QHC) (Lalor and Wall, 2011; FDA, 2013).

Regulation on the Health Claim of Tea

In recent decades, research to explore the relationship between tea consumption and its health benefits has been widely reported.The research was conducted on cellular, experimental animals, and humans as experimental objects (Sanlier, Gokcen and Altuğ, 2018; Tang et al., 2019). Although many studies have reported the health benefits of tea, tea products on the market have not put health claims on the label packaging. Health claims must meet regulatory requirements requiring rigorous clinical testing (Gonz, Gil-gonz and Carlos, 2018; Hung and Verbeke, 2019).

In Japan, tea has been approved by the Japanese Consumer Affairs Agency (CAA) as FOSHU and has been widely marketed. The famous product is "Healthy" Green Tea (Kao Corporation, Tokyo); Black oolong tea (Suntory Foods Ltd., Tokyo); Goma- Mugicha (Suntory Foods Ltd., Tokyo); and Tokucha jasmine (Suntory Foods Ltd., Tokyo). Suntory is a significant product innovator of FOSHU with a 50% sharing market of Japan FOSHU beverages (Koe, 2019).

The health claims of tea products include reducing body fat and cardiovascular risk (Nagao, Hase and Tokimitsu, 2007), reducing postprandial plasma glucose concentrations (Takahashi et al., 2019), reducing fat intake (Suntory, 2015), and stimulating lipolytic enzymes to promote body fat loss (Suntory, 2017).

In contrast to Japan, the health claim of tea in the USA and EU still require further research to provide scientific evidence data. Since 2008-2019 EFSA has received requests for health claims for tea products. However, from 8 submissions, EFSA approved health claims related to black tea and improvement of attention (EFSA Panel on Dietetic Products et al. 2018). We reviewed the application on health claims related to tea and tea substances under the EFSA, FDA, and Japan regulatory framework in Table 2.

The main reason EFSA and the FDA rejected the approval decision was the lack of references to provide cause and effect relationship between consumption and clinical study for the scientific substantiation of the claimed effect. The FDA cannot recommend green tea due to the safety and metabolites of green tea and the lack of high-quality and adequately designed studies (Murray et al., 2015). FDA recommended Green tea as a Qualified health claim (QHC) until further research is needed to provide proper scientific evidence (Berhaupt-Glickstein et al., 2014; Berhaupt-Glickstein, Hooker and Hallman, 2019).

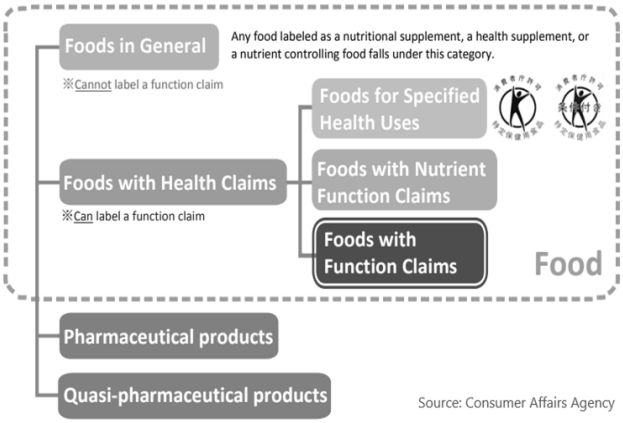

Figure 1. Japan food label with a health claim

Table 2. Health claims of tea regarding regulation in EU, USA, and Japan

C /Area	Tea/tea substances	Claims	Approval decision	Reason decision	Reference
Europe	Black tea	It helps to focus attention and enhances alertness	Rejected	The evidence provided is insufficient to establish a cause and effect relationship between the consumption of black tea from *Camellia sinensis* and 'helps to focus attention.'	(EFSA Panel on Dietetic Products, 2008)
Europe	*Camellia sinensis* (L.) Kuntze (tea), including catechins in green tea and tannins in black tea	Protection of DNA, proteins, and lipids from oxidative damage, reduction of acid production in dental plaque, maintenance of bone, decreasing potentially pathogenic intestinal microorganisms, maintenance of vision, maintenance of normal blood pressure, and maintenance of normal blood cholesterol concentrations	Rejected	Cause and effect relationship has not been established between the consumption of either catechins or tannins in *Camellia sinensis* (L.) to the health claims	(EFSA Panel on Dietetic Products, 2010b)
Europe	*Camellia sinensis* (L.) Kuntze (tea), including catechins from green tea	Maintenance or achievement of normal body weight, increased beta-oxidation of fatty acids leading to a reduction in body fat mass, and maintenance of normal blood glucose concentrations	Rejected	basis of the data presented, the cause and effect relationship has not been established between the consumption of catechins (including EGCG) from green tea (Camellia sinensis (L.) Kuntze) and contribution to the health claims	(EFSA Panel on Dietetic Products, 2010a)
Europe	Epigallocatechin gallate (EGCG) in combination with caffeine	The maintenance or achievement of a normal body weight	Rejected	No references on the effects of epigallocatechin gallate (EGCG) combined with caffeine on body weight have been provided. Cause and effect relationship has not been established between the consumption of epigallocatechin gallate (EGCG) in combination with caffeine and contribution to the maintenance or achievement of a normal body weight	(EFSA Panel on Dietetic Products, 2011b)
Europe	L-theanine from Camellia sinensis (L.) Kuntze (tea)	Improvement of cognitive function, alleviation of psychological stress, maintenance of normal sleep, and reduction of menstrual discomfort	Rejected	Human studies from the scientific substantiation of the claim did not show an effect of L-theanine on the improvement of cognitive function. No references were provided from which conclusions could be drawn for the scientific substantiation of the claim	(EFSA Panel on Dietetic Products, 2011c)

C.: Country

Table 2. Health claims of tea regarding regulation in EU, USA, and Japan

C /Area	Tea/tea substances	Claims	A.d.	Reason decision	Reference
Europe	*Camellia sinensis* (L.) Kuntze (tea), including catechins in green tea	Improvement of endothelium-dependent, maintenance of normal blood pressure, maintenance of normal blood glucose concentrations, maintenance of normal blood LDL-cholesterol concentrations, protection of the skin from UV-induced (including photo-oxidative) damage, protection of DNA from oxidative damage, protection of lipids from oxidative, contribution to normal cognitive function, "cardiovascular system," "invigoration of the body," decreasing potentially pathogenic gastrointestinal microorganisms, "immune health" and "mouth."	Rejected	Lack of references to provide from which conclusions could be drawn for the scientific substantiation of the claimed effect. Cause and effect relationship has not been established between the consumption of catechins (including EGCG) in green tea (Camellia sinensis (L.) Kuntze) on the claimed effect	(EFSA Panel on Dietetic Products, 2011a)
	Black tea	Maintenance of normal endothelium-dependent vasodilation	Rejected	The claimed effect is a beneficial physiological effect. A cause-and-effect relationship has not been established between the consumption of black tea and the maintenance of normal ED vasodilation	(EFSA Panel on Dietetic Products, 2018)
Europe	Black tea	Improvement of attention	Accepted	The Panel considers that its caffeine content can explain the effect of black tea on attention. 2–3 servings of black tea providing at least 75 mg of caffeine in total should be consumed within 90 min	(EFSA Panel on Dietetic Products, 2018)
United State	Green tea	Reduced Risk of Cardiovascular Disease	Rejected	lacking scientific evidence to support qualified health claims in the reduction of several risk factors associated with CVD	(FDA, 2006)
	Green tea	Reduce the risk of breast or prostate cancer	Rejected	lacking scientific evidence for this claim	(FDA, 2011)
Japan	Oolong tea	increases fecal lipid excretion	Accepted as FOSHU	"Polyphenol-enriched oolong tea increased fecal lipid excretion without any side effects; so, it could be acceptable as a daily beverage and be expected to control the absorption of lipids for the healthy people."	(Hsu et al., 2006)

C.: Country, A.d: Approval decision

Conclusion

Research to find out the health benefits of tea has been widely reported. The research was plethora conducted using experimental animals and human objects. The main objective is to determine the relationship between tea's cause and effect consumption on human health as a product with health claims under the regulatory framework. Many health claims on tea were not meet regulatory requirements due to lack of reference to provide cause and effect relationship consumption of tea on the substantiation of the claim.

Further research is needed to fulfil the substance of health claims on tea products based on generally accepted scientific data and newly developed scientific data. It also

requires communication to consumers from official agencies related to scientific evidence to increase understanding of tea products with health claims.

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Conflict of interest

The authors have no conflict of interest

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