Functional foods for cholesterol management: A comparison between the United States and Japan

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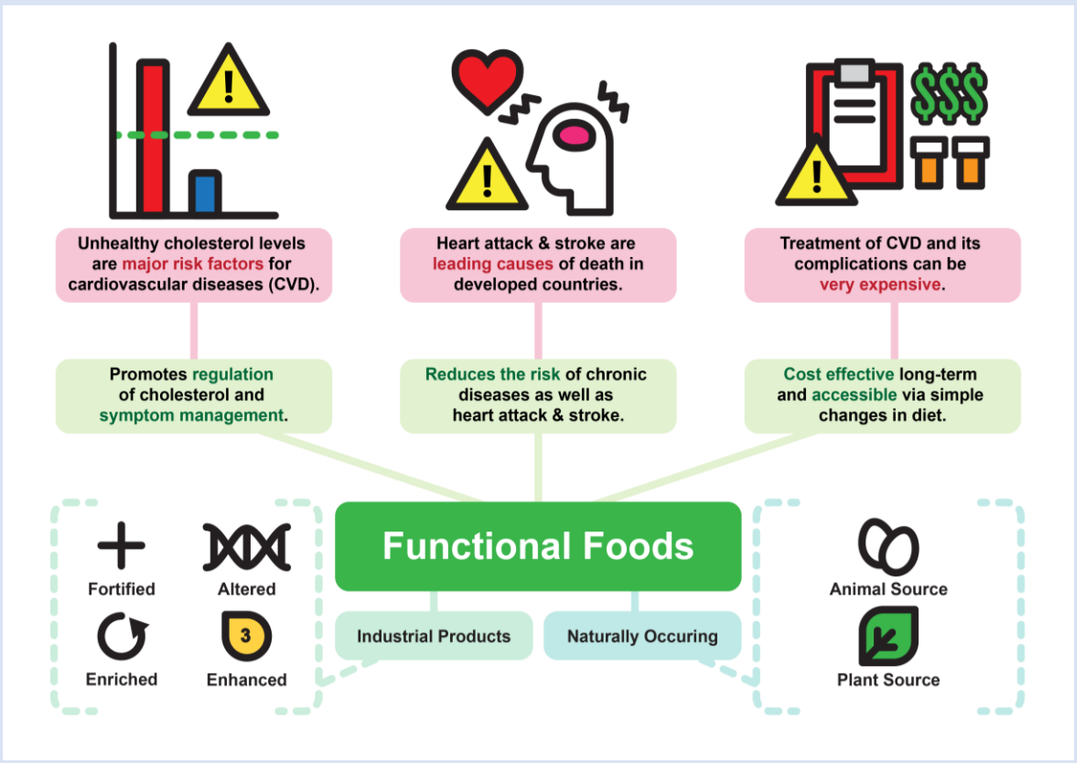
ABSTRACT

Cholesterol management is a cornerstone of cardiovascular disease prevention. Effective management of cholesterol levels can significantly reduce the incidence of cardiovascular events and is a critical component of public health strategies aimed at reducing morbidity and mortality associated with heart disease. Functional foods are known as natural or processed foods containing active compounds in safe, effective amounts, which have been proven to offer health benefits. In recent years, the role of functional foods in managing cholesterol levels has garnered significant attention. These foods offer a promising avenue for non-pharmacological intervention, providing an accessible and natural option for individuals seeking to improve their cholesterol profile through dietary choices. Including functional foods in dietary recommendations reflects a broader shift towards preventive healthcare and personalized nutrition.

This paper aims to provide an in-depth analysis of the emerging role of functional foods in the management of cholesterol, with a dual focus on the United States and Japan. By comparing the prevalence and modifiable risk factors of high cholesterol, regulatory environments, market dynamics, consumer behaviors, and the scientific validity of health claims associated with functional foods, this document seeks to uncover the nuances that shape the acceptance and effectiveness of these foods in each cultural and regulatory context. Through this comparative lens, the paper intends to identify best practices, challenges, and opportunities for the integration of functional foods into dietary strategies for cholesterol management. Ultimately, this analysis is designed to inform stakeholders—including policymakers, health professionals, and food industry players—of the potential for functional foods as a non-pharmacological approach to improving public health outcomes related to cardiovascular disease. The goal is to contribute to the discourse on preventive health care and personalized nutrition, providing a foundation for future research, innovation, and policy development in the global landscape of functional foods and cholesterol management.

Keywords: Cholesterol Management, Functional Foods, FOSHU, Functional Food Definitions, FOSHU Approval Criteria



Graphical Abstract: Functional foods for cholesterol management

INTRODUCTION

Cholesterol, a lipid essential for cellular function and physiological processes, becomes a significant health risk when imbalanced [1]. The distinction between low-density lipoprotein (LDL), often termed "bad" cholesterol due to its role in arterial plaque formation leading to atherosclerosis, and high-density lipoprotein (HDL), known as "good" cholesterol for its capacity to remove cholesterol from the bloodstream, is crucial in assessing cardiovascular risk [1]. High cholesterol, particularly characterized by elevated LDL and reduced HDL levels, poses a significant health risk [2]. An imbalance in cholesterol levels is a major risk factor for the development of heart disease and stroke by causing plaque buildup in arteries, which are the leading causes of death in developed countries [3-4]. This condition, often undetected until advanced stages, underscores the importance of regular cholesterol monitoring from a young age [2].

The United States and Japan are the world's leading functional food markets, followed by Asia Pacific and Europe [5]. In the early 1980s, the Japanese scientific academic community pioneered the definition and introduction of the “functional food” concept [6]. While in the United States, the term "functional foods" lacks a legal definition, serving more as a marketing term than one with regulatory significance [7]. Functional foods, sometimes vaguely defined, are recognized for offering health benefits beyond mere nutrition (Table 1). This encompasses a broad range of products, from naturally healthful items like fish, beans, whole grains, and nuts to those enhanced with additional nutrients, dietary fibers, phytochemicals, or probiotics aimed at boosting health or preventing diseases [8]. The Academy of Nutrition and Dietetics acknowledges the inclusion of most healthy and fortified foods under this category, with a few exceptions, such as sugar-sweetened beverages and alcoholic drinks, suggesting a need for a more precise and encompassing definition that highlights the inclusion of substances or live microorganisms at concentrations safe and effective enough for health enhancement or disease prevention [8]. The Functional Food Center has been crucial in characterizing functional foods as those with active ingredients that, at appropriate doses, offer proven benefits against chronic diseases [9-10]. This definition underscores the importance of functional foods in promoting optimal health and reducing the risk of chronic diseases through dietary interventions.

Table 1. Functional Food Definitions

Selected Functional Foods Definitions	Organizations	Country	Year
“Food that has physiological functions, including regulation of biorhythms, the nervous system, the immune system, and bodily defense beyond nutrient functions [6].	Ministry of Education, Science and Culture (ad hoc national project)	Japan	1984

Selected Functional Foods Definitions	Organizations	Country	Year
"A functional food is similar in appearance to, or may be, a conventional food, is consumed as part of a usual diet, and is demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions" [11].	Health Canada	Canada	1998
"Foods and food components that provide a health benefit beyond basic nutrition (for the intended population). These substances provide essential nutrients often beyond quantities necessary for normal maintenance, growth, and development, and/or other biologically active components that impart health benefits or desirable physiological effects" [12].	Institute of Food Technologists	United States	2004
"Natural or processed foods that contain biologically active compounds, which, in defined, effective, non-toxic amounts, provide a clinically proven and documented health benefit utilizing specific biomarkers, to promote optimal health and reduce the risk of chronic/viral diseases and manage their symptoms" [10].	Functional Food Center	United States	2021

METHODOLOGY

This white paper employs a comprehensive literature review to assess the role of functional foods in cholesterol management, focusing on a comparative analysis between the United States and Japan. The methodology encompasses an extensive examination of secondary data sources, including peer-reviewed journal articles, census data, government publications, and relevant websites. The objective is to synthesize existing knowledge on the high cholesterol conditions as well as efficacy, acceptance, and regulatory frameworks of functional foods in these two countries, thereby identifying gaps and opportunities for future research and policy development.

Research Questions: The foundation of the research begins with several pivotal questions designed to navigate the search and analysis:

(1) What are the prevalence rates and primary modifiable risk factors for high cholesterol in the United States and Japan, and how do these factors inform the need for cholesterol management through dietary interventions?

(2) How do the regulatory frameworks for functional foods in the United States and Japan influence the development, approval, and marketing of products aimed at cholesterol management?

(3) What is the current market landscape for functional foods, especially those aimed at cholesterol management, in the United States and Japan, including popular products, market trends, and consumer behaviors?

(4) What scientific evidence supports the efficacy of functional foods in managing cholesterol, and how is this evidence leveraged within the regulatory and consumer landscapes in the United States and Japan?

Literature Search Strategy: We initiated our research with a systematic search for scholarly articles, reports, and legislative documents relevant to functional foods and cholesterol management in the United States and Japan. Key databases such as PubMed, FFHDJ.com, Google Scholar, and J-STAGE were utilized, alongside government databases such as NHANES (US) and NHNS (Japan), as well as official health organization websites such as CDC, FDA, and MHLW.

Selection Criteria: Inclusion criteria were established to ensure the relevance and quality of sources. No restrictions on publication year were established. Articles and reports published in English within the last 10 years received priority, focusing on empirical studies, reviews, and official guidelines related to cholesterol management through dietary means.

Data Extraction and Analysis: Key information extracted from the sources included prevalence and modifiable risk factors for high cholesterol, regulatory approaches for functional foods, evidence of their efficacy in cholesterol management, market trends, and consumer behaviors in the United States and Japan. This process involved translation and synthesis of information from Japanese

sources where necessary. Findings were integrated into comparative narratives as well as systematically compiled into structured tables and figures to facilitate analysis.

PREVALENCE AND MODIFIABLE RISK FACTORS FOR HIGH CHOLESTEROL

JAPAN

Prevalence: Drawing upon data from the Health Japan 21 Analysis and Assessment program, specifically the Physical Status Questionnaire, a critical evaluation of cholesterol levels reveals a discernible upward trend in the prevalence of high serum total cholesterol (≥240mg/dL) from 1989 to 2019 among individuals aged 20 years and over, segmented by gender and age [13]. In 2019, the incidence of high cholesterol in males was recorded at 12.9%, with the 40-49 age group exhibiting the highest rate at 28.4% [13]. For females, the rate stood at 22.4%, with the 50-59 age group witnessing the highest rate at 39.4% [13]. This data marks a significant increase from 2000, where the data for males and females were 11.5% and 16.2%, respectively, underscoring a concerning rise in cholesterol levels over the past two decades [13].

Dietary Intake: The Seven Countries Study in 1957 revealed that Japanese populations exhibited lower fat consumption, reduced serum total cholesterol levels, and decreased rates of coronary heart disease (CHD) compared to populations in the United States, despite Japan's higher smoking rates [14]. Post-World War II, Japan saw a rapid increase in serum total cholesterol levels, correlating with a rise in dietary fat intake from 10% to 25% of total daily energy intake per capita [14]. In addition, the recommended daily vegetable intake, set at 350 grams by the 1998 FAO/WHO guidelines, aims to ensure that individuals receive adequate nutrients and fiber to support overall health and prevent chronic diseases [15]. However, the 2019 Japan National Health and Nutrition Survey (NHNS) highlights a gap between these guidelines and actual consumption patterns in Japan, where the average intake is only 281 grams per person per day, with men consumed an average of 288 grams per day and woman consumed 274 grams [16].

Tobacco Use: Tobacco nicotine adversely affects cardiovascular health by lowering HDL (good) cholesterol levels while increasing LDL (bad) cholesterol and VLDL cholesterol levels, leading to lipid accumulation in arterial walls and elevating atherosclerosis risk [17]. Tobacco usage has been identified as the leading risk factor for death and disability in Japan as of 2019 [18]. With an estimated 18.2 million adults aged 15 and older using tobacco products in 2023, Japan ranks 12th globally and 3rd in the WHO Western Pacific Region in terms of tobacco product users [18]. According to the Japan NHNS conducted during 2018-2019, approximately 16.7% of Japanese adults aged 20 and above, equating to 17.8 million individuals, engaged in the use of combustible cigarettes (CCs) and heated tobacco products (HTPs), with the demographic comprising 12% cigarette smokers and 4.5% HTP users [18]. A notable observation from recent studies is that exclusive users of HTPs tend to have lower HDL cholesterol concentrations compared to non-smokers, however, their HDL-C levels are higher than those found in exclusive cigarette smokers [19]. This suggests that while HTPs may pose a slightly reduced risk to HDL-C levels than traditional cigarettes, they still negatively impact cardiovascular health relative to not smoking at all.

U.S.

Prevalence: Between 2017 and 2020 in the United States, an analysis of adult cholesterol levels revealed significant health challenges: 10% of those aged 20 and older had total cholesterol levels exceeding 240 mg/dL, which refers to high total cholesterol, while approximately 17% had HDL (good) cholesterol levels below 40 mg/dL [20]. The prevalence of elevated cholesterol is also widespread, with around 86 million adults exhibiting total cholesterol levels above 200 mg/dL and nearly 25 million of these surpassing 240 mg/dL [20]. The issue of high cholesterol extends to the younger population as well, affecting about 7% of children and adolescents aged 6 to 19 [20]. The condition is often asymptomatic, leading many to remain unaware of their high cholesterol levels until tested [20]. High cholesterol significantly increases the risk of heart disease and stroke, the leading and fifth leading causes of death, respectively [20]. Racial and ethnic disparities in cholesterol levels are evident, with Non-Hispanic Asian males and Non-Hispanic White females showing the highest prevalence of elevated cholesterol levels within their respective gender groups [20].

Dietary Intake: Among the modifiable risk factors, dietary habits stand out prominently; the intake of foods rich in saturated and trans fats, such as red meats, full-fat

dairy products, margarine, fried, and processed foods, is known to exacerbate cholesterol levels [21]. The 2020-2025 Dietary Guidelines for Americans advise limiting saturated fat to less than 10% of daily caloric intake [22]. However, only one-third of adults aged 20 and older adhere to this guideline, with the remainder consuming an average of 13.9% of their daily calories from saturated fats [22]. Additionally, fiber plays a crucial role in supporting digestive health and reducing cholesterol levels, with sources ranging from grains, cereals, legumes, to fruits and vegetables [23]. The American Heart Association recommends diversifying fiber intake to achieve the advised 25 to 30 grams daily through foods.[23] However, the average fiber consumption among U.S. adults is only around 15 grams a day, falling significantly short of the recommendation [23].

Physical Activity: A sedentary lifestyle not only contributes to weight gain but also correlates with elevated LDL and reduced of HDL levels [21]. In 2020, only about one-quarter of U.S. adults (24.2%) adhered to the 2018 Physical Activity Guidelines, incorporating both aerobic and muscle-strengthening activities, with higher compliance observed in men (28.3%) compared to women (20.4%) [24]. Notably, adherence to these guidelines decreased with advancing age across both genders [24].

Obesity: Obesity significantly worsens health outcomes, as individuals with a body mass index (BMI) exceeding 30 are found to have higher LDL and lower HDL cholesterol levels [21]. Between 1999 and March 2020, the prevalence of obesity in the U.S. increased significantly from 30.5% to 41.9%, with severe obesity rates also rising from 4.7% to 9.2% [25]. This condition, a major public health concern, is linked to severe illnesses such as heart disease, stroke, type 2 diabetes, and certain cancers, leading to preventable premature deaths and nearly $173 billion in annual medical costs in 2019 [25].

REGULATORY FRAMEWORKS FOR FUNCTIONAL FOODS

JAPAN

The Japanese functional foods market is experiencing consistent growth, supported by a structured regulatory framework for Foods with Health Claims (FHC) [26]. This framework encompasses Foods for Specified Health Uses (FOSHU), Foods with Nutrient Function Claims (FNFC), and Foods with Function Claims (FFC) [26]. FOSHU products, requiring Consumer Affairs Agency (CAA) assessment and Ministry of Health, Labor, and Welfare (MHLW) approval, are subject to strict eligibility criteria [27]. FNFC, introduced in 2001, covers foods containing specified vitamins and minerals and allows for more freedom in manufacturing and distribution [27]. The FFC category, launched in April 2015, permits labeling of specific health benefits based on scientific evidence without pre-approval, streamlining the process for introducing functional foods to the market [27].

FOSHU: In the face of rising cardiovascular disease rates among an aging population, Japan proactively established the FOSHU regulatory framework in 1991 [28]. This initiative endorsed functional foods aimed at combatting lifestyle-related diseases, reflecting a shift towards health-conscious dietary habits. FOSHU represent a class of functional foods in Japan, legally defined and regulated to assert physiological benefits [29]. Unlike drugs and medical foods that target individuals who are sick, FOSHU is specifically designed to cater not only to individuals aiming for general health maintenance but also to those at the preliminary stages of disease and with sub-optimal health [30]. These products, ranging from fortified beverages to nutraceuticals, are subjected to rigorous scientific scrutiny to affirm their health claims and instill confidence in their effectiveness [29]. A prevalent example is the FOSHU-approved beverages with added dietary fiber, which have been clinically shown to regulate bowel movements and contribute to digestive health [28]. Marked by the official FOSHU seal (Fig. 1), these foods align with Japan's proactive stance on preventive healthcare, offering consumers targeted nutritional interventions for managing conditions like hypercholesterolemia and hypertension [29].

Figure 1. Seal for FOSHU Approval

FOSHU Approval Criteria and Process: To qualify for FOSHU status, products must meet criteria that substantiate the claimed health benefits (Fig 2). A demanding approval process is overseen by the MHLW, involving strict criteria to ensure that no excessive use of certain ingredients, such as salt, occurs, and that the food's quality remains consistent from production to consumption [29]. The evidence must be empirical, derived from well-designed clinical trials, and demonstrate a clear cause-and-effect relationship between the product's consumption and the health outcome. [29-31]. For instance, FOSHU-approved foods containing viscous polysaccharides are required to show quantifiable effects on postprandial blood glucose levels. Moreover, safety assessments, including but not limited to animal toxicity tests, must affirm that the product poses no risk to human health even at intake levels beyond the recommended dosage [29].

This approval process necessitates consultation phases for both effectiveness and safety, engaging the expertise of the Council on Pharmaceutical Affairs and Food Sanitation as well as the Food Safety Commission [29]. Moreover, the framework categorizes FOSHU into regular, qualified, standardized, and disease risk reduction FOSHU, each with tailored benchmarks of evidence and quality control [29]. The FOSHU approval not only underscores a product's health-enhancing capabilities but also signifies its compliance with Japan's stringent food safety and regulatory standards. By ensuring compatibility with product specifications and established quality control methods, the FOSHU seal is a testament to a product's commitment to consumer health and regulatory adherence. The significance of the FOSHU system is manifold, safeguarding public health, guiding consumer choices, and fostering trust in the functional food market. The FOSHU system, while advantageous for ensuring product quality and efficacy, presents significant challenges for manufacturers, including the financial burdens associated with extensive research and development (R&D), clinical trials, and the protracted approval process required to bring a product to market [26].

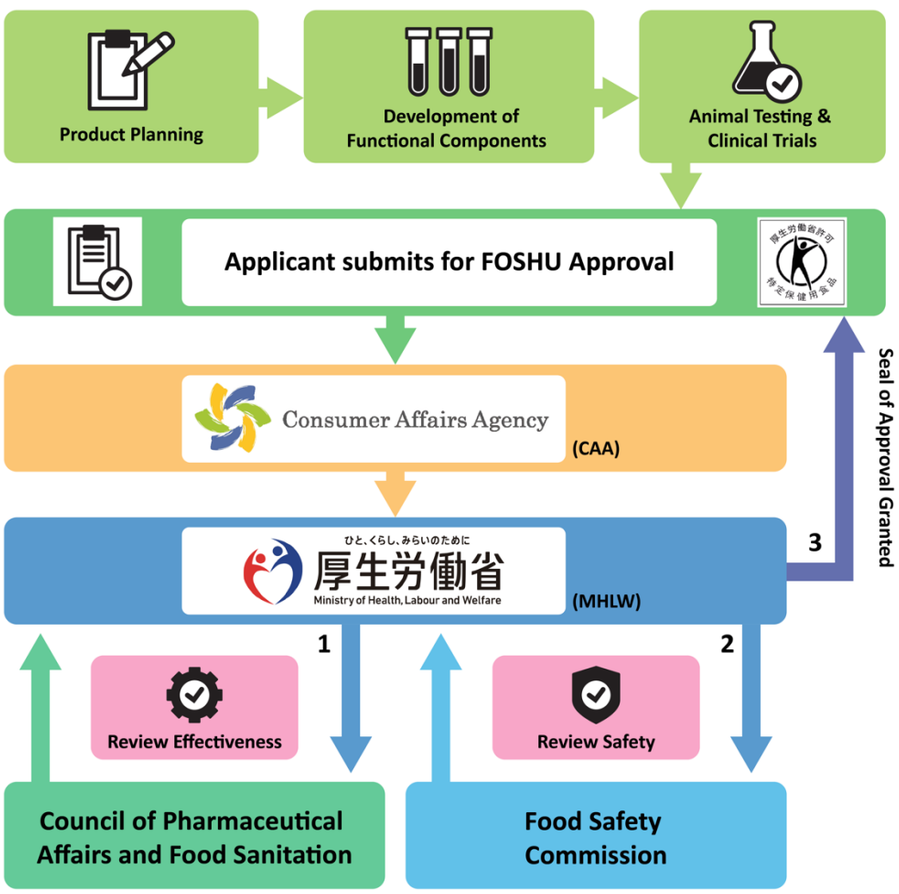


Figure 2. FOSHU Approval Process

U.S.

Unlike Japan's FOSHU system, the U.S. Food and Drug Administration (FDA) does not have a distinct category for functional foods, operating under the assumption that the extant regulatory framework for foods is adequately comprehensive to encompass the spectrum of functional foods, and focusing instead on evaluating health claim petitions relating food components to diseases or health conditions [32-33]. This fundamental difference highlights a gap in the two countries' regulatory approach to functional foods. The FDA's health claim process involves assessing the totality of public evidence and determining significant scientific agreement among experts [32]. However, it lacks a

specific framework for evaluating the comprehensive benefits and safety of functional foods as seen in Japan's FOSHU system.

Functional foods, though not legally defined in U.S. regulations, are generally recognized as foods that offer health benefits beyond basic nutrition, including conventional foods and dietary supplements that are fortified, enriched, or enhanced [8]. Unlike conventional foods, functional foods are distinct for their claims of health benefits, such as enhancing bodily functions or reducing health risks, rather than solely for their nutritional value [33]. The key difference between functional foods and other food categories lies in the health-related claims made about them [33].

In the United States, the regulatory framework for functional foods is managed primarily by the FDA, with additional oversight on advertising from the Federal Trade Commission (FTC) [34]. The FDA's regulatory authority emanates from the Federal Food, Drug, and Cosmetic Act (FFDCA). It is supplemented by the Dietary Supplement Health and Education Act of 1994 (DSHEA), guiding these products' safety, labeling, and marketing [35]. Food label claims regulated by the FDA are divided into three categories: health claims, structure/function claims and nutrient content claims (Fig. 3) [33].

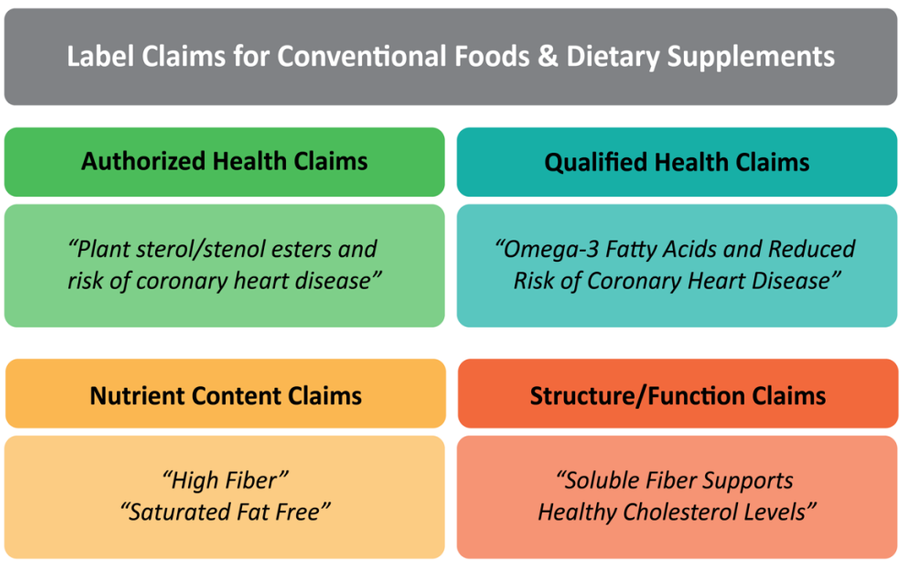


Figure 3. Label Claims by FDA

MARKET OVERVIEW FOR FUNCTIONAL FOODS

JAPAN

FOSHU-Approved Products for Cholesterol Management

The foundational data for this analysis were obtained from the CAA of the Government of Japan, an authoritative source for food labeling and health-related product information. The CAA maintains a comprehensive and up-to-date database of products certified under the FOSHU system. The most recent update, an Excel file listing approved FOSHU items, was dated December 22, 2020. In total, the database lists 1,058 FOSHU-approved products [36]. For each product, the database provides a detailed profile that includes applicant/company name, corporate number, types of food, ingredients involved, permission to display, precautions for ingestion, suggested daily intake, division, permission date, permit number, and sales results in FY4 of Reiwa. The dataset was initially in Japanese. After translation and synthesis of Information, the relevant data were systematically compiled into a structured table format (Table 2; Appendix A). This table was designed to provide a clear, accessible representation of the cholesterol management products approved by the FOSHU system, thereby serving as a critical resource within this white paper for stakeholders seeking to navigate the landscape of health-focused food products in Japan.

As of December 2020, analysis from Table 2 indicates a total of 121 FOSHU-approved products aimed at managing cholesterol levels. These products are distinguished by their active ingredients, reflecting a diverse approach to cholesterol management. Here is a detailed categorization:

- Chitosan-Based (52 total): Primarily powdered soft drinks, with Toyo Shinyaku Corporation as a notable manufacturer.
- Soy Protein-Based (20 total): Mainly in soy milk, indicating soy protein's popularity in daily dietary consumption.
- Low-Molecular-Weight Sodium Alginate (17 total): Primarily soft drinks.
- Dietary Fiber (Derived from Psyllium Seed Coat) (10 total): Utilized in powdered jelly drinks.
- Tea Catechins-Based (12 total): Offered as tea-

based beverages.

- Phytosterols-Based (6 total): Found in consume conditioning oils.
- Plant Sterol Esters (2 total) and Vegetable Sterols (1 total): Focused exploration of plant sterols' cholesterol management benefits.
- SMCS (Natural Amino Acids) (1 total): Derived from broccoli and cabbage, representing natural amino acids' innovative use in cholesterol management.

Market Trend and Consumer Behaviors

Following the implementation of FOSHU regulations, the functional food market in Japan witnessed substantial growth between 1997 and 2007, driven by consumer demand, with peak sales of $6.2 billion in 2007 [28]. During this period, half of the health claims focused on improving gastrointestinal health through probiotics, oligosaccharides, and dietary fibers, while about 20% of products aimed at reducing serum triglycerides and another 20% addressed issues like high blood pressure and LDL-cholesterol [28]. Post-2007, the FOSHU market plateaued, leading to the introduction of a new regulatory framework in 2015, inspired by the US's DSHEA, for "Foods with function claims" that encouraged innovation through more lenient health claims and no requirement for government approval [28]. This shift rejuvenated the market, with sales of these new functional foods reaching 1.8 billion USD by 2018, elevating the total functional foods market to an estimated $8 billion USD [28].

The aging Japanese population, particularly those seeking to maintain health, improve sleep, and combat conditions such as locomotive syndrome, has been a key demographic for health products [27]. Products catering to individuals in their 40s and 50s often emphasize metabolism and weight management alongside a broad range of health and beauty-oriented products [27]. A six-year study by Intage Inc. involving over 10,000 participants revealed gender-specific health preferences in Japan's health food market: men prioritize fatigue recovery, hypertension prevention, and health maintenance, while women seek anti-flatulence, skincare, and nutritional support [27]. Fuji Keizai's analysis confirms that "Intestinal regulation," "Lifestyle disease prevention," and "Nutrient" are leading market segments, with yogurt and functional drinks highly favored for their health benefits [27]. The market for cholesterol management is notably driven by catechin-enriched Green Teas, a trend supported by a significant 183.5 million USD market size for catechin products in 2018, with all major manufacturers offering versions of this product to cater to the growing consumer demand [27].

Supermarkets, holding 35% of the market share, emerge as the primary distribution channels for health-related foods, closely followed by convenience stores and drugstores, with 22% and 13% shares respectively [27]. This distribution strategy is strategically leveraged by top food manufacturers to maximize the reach of their health-related product lines [27].

The Foods with Function Claims (FFC) registration process, recognized for its relative ease and affordability compared to FOSHU, has significantly increased the volume of companies and products marketing health food products [26-27]. Despite this growth, there remains a challenge in consumer awareness and understanding of these health claims [27,37]. A significant gap exists between the labels of FFCs and the substantiated efficacy of their functional substances [37]. The proliferation of various packaging claims has led to consumer confusion, even though FFC products now represent approximately 15% of the total health-related food market [27,37]. Research has suggested that creating a centralized, publicly accessible data repository to provide accurate efficacy information is essential, empowering consumers to make informed decisions and effectively use Functional Health Claims (FHCs) for health improvement [37].

U.S.

Popular Functional Foods for Cholesterol Management

Although the United States lacks a dedicated regulatory category for functional foods such as Japan's FOSHU-approved products specifically for cholesterol management, there is nonetheless a selection of popular and evidence-based food products that have garnered widespread public acceptance and hold a strong presence in the market. The FDA has authorized specific health claims for products that can impact cholesterol levels and thereby reduce the risk of coronary heart disease. Foods that provide soluble fiber from sources like oats, barley, and psyllium are recognized for their role in lowering the risk of heart disease [33]. To make such a claim, a product must specify the amount of soluble fiber per serving and how it fits into the daily dietary intake required for the desired health effect [33]. Additionally, the FDA has identified that a daily intake of 25 grams of soy protein may also reduce the risk of heart disease, with labeling required to state the amount of soy protein per serving of the food product [33]. Lastly, the consumption of 800 milligrams of phytosterols from

foods across two meals each day is acknowledged for its potential in heart disease risk reduction, necessitating clear labeling of phytosterol content per serving [33]. These claims, grounded in scientific evidence, allow certain foods to be marketed with the assurance that they contribute to heart health when included as part of a diet low in saturated fat and cholesterol [33]. Harvard Medical School's recent recommendations on cholesterol-lowering foods align with FDA-authorized health claims, highlighting the benefits of soluble fiber-rich foods like oatmeal and beans, as well as nuts, foods containing polyunsaturated fats, plant sterols, and stanols [38].

***Market Trend and Consumer Behaviors*:** The U.S. functional food market is poised for growth, driven by an increasing demand for nutrient-dense foods among health-conscious consumers facing busy lifestyles and a growing aging population focused on wellness [39]. Health benefits, ingredient sourcing, and dietary claims significantly influence consumer food purchases [40]. Popular functional food products for cholesterol management are closely tied to FDA health claims, including ingredients like omega-3 fatty acids, soluble fiber, plant sterols, and soy proteins (Table 3). The industry is responding by enriching food and beverage offerings with essential nutrients such as fibers, vitamins, and omega-3 fatty acids, with dairy products and functional desserts leading the innovation [39]. This trend has been further amplified by the COVID-19 pandemic, which has significantly elevated consumer interest in products purported to enhance immunity and offer protection against diseases [39]. Specifically, a significant portion of consumers are increasingly using food and beverages as tools to manage or address health conditions, with particular emphasis on heart health [40]. The American Heart Association (AHA) and the American Diabetes Association (ADA) report that over 122 million U.S. adults suffer from hypertension, 94 million have high cholesterol, and 37 million, including children, live with diabetes, with an additional 114 million adults having prediabetes [40]. This health crisis has fueled a significant demand for foods and beverages with heart health claims, leading to an 11% sales increase to $3.4 billion in 2021 [40]. This trend is paralleled by concerns over conditions such as diabetes, obesity, and a range of physical and mental health issues, driving demand for foods rich in anti-inflammatory ingredients, antioxidants, and other nutrients that support overall metabolic health and wellness [40].

Table 3. Functional foods targeting high cholesterol and cardiovascular disease: Japan and US.

Country	Functional Food Substances
Japan (FOSHU-approved)	Chitosan
	Soy Protein
	Low-Molecular-Weight Sodium Alginate
	Dietary Fiber (Psyllium Seed Coat)
	Tea Catechins
	Phytosterols
	Plant Sterol Esters/ Vegetable Sterols
	SMCS (Natural Amino Acids)
US (Authorized Health Claims by FDA)	Fruits, Vegetables, Grain Products that contain fiber
	Beta (β) glucan soluble fiber from the whole oat and barley sources
	Psyllium husk
	Plant Sterol/Stanol Esters
	Soy Protein
US (Qualified Health Claims by FDA)	Cocoa Flavanols in High Flavanol Cocoa Powder
	Oleic Acid
	Folic Acid, Vitamin B6, and Vitamin B12
	Nuts (Macadamia Nuts, Walnuts)
	Omega-3 Fatty Acids
	Unsaturated Fatty Acids (Soybean oil, Corn oil, Unsaturated fatty acid from canola oil, monounsaturated fatty acids)

Scientific Evidence for Functional Foods: In the table 5 provided scientific information for popular functional food components for lowering cholesterol in Japan and United States.

Table 4. Scientific evidence for popular functional food compounds for lowering cholesterol: Japan and US.

Country	Active Ingredients /Substances	Mechanism of Action	Food Sources	Example Functional Foods Products	Representative Study (Human subjects)	Key Findings
Japan	**Chitosan**	Chitosan binds to lipids in the small intestine, reducing their absorption and lowering serum cholesterol levels [41].	Uncommon in foods as it's extracted from crustacean shells	Chitosan-based powdered soft drinks	**(1) Bokura et al., 2003** [41] A double-blind, placebo-controlled trial involved 90 women with mild to moderate hypercholesterolemia, assessing the impact of chitosan (1.2 g/day) on cholesterol levels without dietary changes. **(2) Lütjohann et al., 2018** [42] A 12-week, randomized, placebo-controlled, double-blind study with 116 obese adults, assessing the effects of chitosan on cholesterol metabolism. Subjects were advised on dietary improvements and energy expenditure, and the daily chitosan intake was 3200 mg.	(1) Chitosan significantly lowered total cholesterol, with notable reductions in both total and LDL cholesterol in participants over 60 years old, demonstrating a safe and mild effect on cholesterol reduction. (2) In overweight and obese subjects, 12 weeks of chitosan treatment (3 g/day) significantly reduced serum LDL cholesterol levels, without affecting markers of cholesterol absorption, synthesis, and catabolism, suggesting a potential minor decrease in dietary cholesterol absorption.
Japan	**Low-Molecular-Weight Sodium Alginate**	Natural sodium alginate and its lower molecular weight variants AG-5 and AG-10 promote cholesterol excretion and improve glucose tolerance in rats by inhibiting cholesterol and glucose absorption via the gelling action of alginic acid in the stomach, offering potential as dietary fibers for preventing obesity, hypercholesterolemia, and diabetes [43].	Seaweed	LMWSA-based soft drink	**Kobayashi et al., 1997** [44] A controlled trial involving 31 healthy women with a high dietary cholesterol intake showed that consuming 4 g/day of LMWSA for 3 weeks prevented the rise in serum total cholesterol levels that occurred in the control group without LMWSA.	The control group without LMWSA experienced an increase in cholesterol levels from 178 to 186 mg/dL, while the LMWSA group maintained stable cholesterol levels, showing LMWSA's capacity to inhibit cholesterol elevation from high dietary intake, especially in subjects with initial cholesterol levels above 180 mg/dL.
Japan	**Tea Catechins**	Green tea catechins with galloyl moiety inhibit intestinal cholesterol absorption by reducing micellar solubility, thus lowering serum cholesterol [45].	Green Tea	Green tea-infused beverages and health drinks	**Kim et. al., 2011** [46] A systematic review and meta-analysis analyzing randomized controlled trials to assess the effects of green tea catechins (GTCs) on serum lipid levels.	GTCs (145 to 3,000 mg/day for 3 to 24 weeks) significantly reduced total and LDL cholesterol levels but had no significant impact on HDL cholesterol or triglyceride levels.
US	**Omega-3 Fatty Acids**	Omega-3 fatty acids decrease very-low-density lipoprotein (VLDL) synthesis/secretion and enhance TG removal from VLDL/chylomicrons via lipoprotein lipase upregulation [47].	Salmon, Mackerel, Sardines, Flaxseeds, Chia Seeds, Walnuts.	Fortified eggs, yogurt, and milk	**Wang et al., 2023** [48] A meta-analysis of 90 randomized controlled trials including a total of 72,598 participants, which focused on the relationship between omega-3 fatty acid intake, comprising EPA and DHA, and changes in blood lipids.	A linear relationship was observed between omega-3 fatty acid intake and reductions in triglycerides and non-HDL cholesterol, especially prominent in individuals with hyperlipidemia or obesity when consuming doses above 2g/day.
US	**Polyunsaturated fatty acids**	Liver converts polyunsaturated fatty acids into ketone bodies rather than VLDL triglycerides, transporting them for oxidation without producing LDL remnants, unlike saturated fatty acids [49].	Fatty Fish, Plant Oils, Nuts and Seeds.	Plant-based oils, spreads, and dressings	**Telle-Hansen et al., 2022** [50] A randomized controlled crossover study assessed the impact of dietary fat quality on gut microbiota and cholesterol levels in 17 healthy individuals. Participants alternated between diets enriched in saturated fatty acids (SFAs) and polyunsaturated fatty acids (PUFAs) over two three-day periods, with a 1.5-week washout interval.	Switching from SFAs to PUFAs significantly elevated Lachnospiraceae and Bifidobacterium spp. levels in the gut microbiota. This alteration was associated with a decrease in total cholesterol, underscoring the potential of dietary fat quality to modulate cholesterol levels via changes in gut microbiota composition.
US	**Beta-glucan**	Oat β-glucan (OBG) exerts its cholesterol-lowering effects primarily by increasing the viscosity of the gastrointestinal contents, which affects the absorption and	Oat Bran, Rolled Oats, Whole Oat Flour, Oatrim, Whole Grain Barley, Dry	High-fiber cereals and oat-based products	**Whitehead et al., 2014** [51] A meta-analysis of 28 randomized controlled trials, involving a wide demographic including healthy individuals, those with hypercholesterolemia,	Consuming ≥3 g/day of oat β-glucan resulted in significant reductions in LDL and total cholesterol levels by 0.25 mmol/L and 0.30 mmol/L, respectively, without affecting high-density lipoprotein

Country	Active Ingredients /Substances	Mechanism of Action	Food Sources	Example Functional Foods Products	Representative Study (Human subjects)	Key Findings
		metabolism of cholesterol and bile acids [51].	Milled Barley, Barley Betafiber		and subjects with type 2 diabetes, assessed the impact of consuming ≥3 g/day of OBG on serum cholesterol levels. The study synthesized evidence from various interventions ranging from 2 to 12 weeks and involving OBG doses between 3.0 and 12.4 g/day.	cholesterol or triglycerides. The cholesterol-lowering effects were consistent across different doses and durations of OBG intake, with enhanced benefits observed in individuals with higher baseline LDL cholesterol and those with type 2 diabetes.
Both	**Soy Protein**	Soy protein may reduce cholesterol absorption, enhance LDL-receptor activity for faster cholesterol clearance, and alter cholesterol biotransformation in the liver [52].	SeaweedTofu, Soymilk, Edamame, Soy Nuts, Sprouts, Miso, Tempeh, Natto	Meat substitutes, protein bars, and soy milks.	**Blanco et al., 2019** [53] A meta-analysis of 46 trials, including adults with baseline LDL cholesterol levels of 110 to 201 mg/dL, evaluating soy protein (median dose of 25 g/day) compared to non-soy protein over 6 weeks.	Soy protein reduced LDL cholesterol by 4.76 mg/dL and total cholesterol by 6.41 mg/dL, which supported dietary recommendations for increasing plant protein intake as part of a strategy to manage cholesterol levels and reduce cardiovascular disease risk.
Both	**Psyllium husk**	Psyllium fiber from Plantago ovata significantly lowers cholesterol by enhancing bile acid excretion, boosting colonic production of short-chain fatty acids, and influencing cholesterol metabolism [54].	Plantago Ovata	Fiber supplements, cereal, bread.	**Jovanovski et al., 2018** [54] A systematic review and meta-analysis evaluated the impact of psyllium on LDL cholesterol and alternative lipid markers, including non-HDL cholesterol and apolipoprotein B (apoB), across 28 randomized controlled trials (n=1924). The study assessed psyllium's effects in individuals with or without hypercholesterolemia.	Psyllium supplementation, at a median dose of around 10.2 grams per day, significantly lowered LDL cholesterol by 0.33 mmol/L, non-HDL cholesterol by 0.39 mmol/L, and apoB by 0.05 g/L, which suggested that psyllium fiber not only improves conventional lipid markers but also positively affects alternative lipid markers, potentially delaying atherosclerosis and associated CVD risk in individuals with varying cholesterol levels.
Both	**Plant Sterol/Stanol Esters**	Plant sterols/stanols reduce LDL cholesterol by competing with cholesterol for absorption in the digestive system, leading to decreased amount of cholesterol absorbed into the bloodstream [55].	Occur naturally in small amounts in many grains, vegetables, fruits, legumes, nuts, and seeds	Margarine, dairy products, and juices.	**Abumweis et al., 2008** [55] A meta-analysis of 59 randomized clinical trials examining the impact of plant sterol-enriched products on LDL cholesterol, covering publications from 1992 to 2006.	The analysis revealed a significant reduction in LDL cholesterol by an average of 0.31 mmol/L across interventions. Efficacy was enhanced in participants with higher initial LDL levels, with the most significant reductions seen when sterols/stanols were included in fat spreads, mayonnaise, salad dressing, milk, and yogurt compared to other food carriers.

DISCUSSION

Prevalence Rates and Primary Modifiable Risk Factors for High Cholesterol: Both Japan and the United States have witnessed a concerning increase in the prevalence of high cholesterol among their populations. While genetic predispositions play a role, the significant influence of modifiable lifestyle factors, such as diet, tobacco use, and physical activity, cannot be overstated. Dietary patterns emerge as the pivotal common factor contributing significantly to high cholesterol conditions in both countries. A study analyzed food intake patterns among Japanese adults and found that adherence to "Westernized" diets, which are characterized by a higher intake of bread, dairy products, butter, margarine, and jam, with a low intake of rice and miso, was associated with higher LDL cholesterol levels [56]. Conversely, traditional Japanese diets, rich in miso, soy sauce, fresh vegetables, fruits, beans, and potatoes, were linked with healthier lipid profiles [56]. Additionally, researchers have conducted the INTERLIPID study that offers a detailed comparative analysis of cardiovascular disease (CVD) risk factors between populations in Japan and Japanese Americans residing in Hawaii, which underlines the significant impact of dietary and lifestyle differences on cholesterol levels and the associated risk of heart disease [57]. The research findings underscore the critical role of dietary habits in the regulation of cholesterol levels. Specifically, the consumption of long-chain n-3 polyunsaturated fatty acids, increased soybean intake, and reduced consumption of saturated fats are identified as key factors contributing to the lower cholesterol levels observed in the Japanese population, in contrast to Japanese Americans who might exhibit a propensity towards Western dietary patterns [57]. Therefore, the strategic use of functional foods not only supports healthier dietary shifts but also provides a proactive approach to managing and preventing high cholesterol, thereby reducing the overall burden of cardiovascular diseases in diverse populations.

Regulatory Frameworks for Functional Foods: The United States and Japan exhibit fundamental differences in their regulatory landscapes for functional foods (Table 5). The regulatory framework for functional foods in Japan is well-established and detailed, primarily through the Foods with Health Claims (FHC) system. This system includes Foods for Specified Health Uses (FOSHU), Foods with Nutrient Function Claims (FNFC), and Foods with Function Claims (FFC), each category serving different purposes and subjected to varying levels of scrutiny. The FOSHU products, which require approval from the Consumer Affairs Agency (CAA) and the Ministry of Health, Labor, and Welfare (MHLW), exemplify Japan's proactive approach to managing public health through diet. These products must demonstrate clear, scientifically validated health benefits and are targeted not only at individuals looking for general health maintenance but also at those at the preliminary stages of disease or with sub-optimal health conditions. This system fosters consumer trust and encourages innovation within the food industry to meet strict regulatory standards.

Conversely, the U.S. lacks a specialized regulatory framework for functional foods, operating instead under the broader umbrella of the Food and Drug Administration (FDA), which oversees all food products and dietary supplements. The FDA does not recognize a distinct category for functional foods; it regulates these products under existing categories of foods and dietary supplements, focusing on evaluating health claims related to food components and diseases. The health claims process requires substantial scientific evidence and consensus among experts, ensuring that claims made about a product are backed by reliable research. However, this system does not necessarily facilitate the introduction of functional foods, as is the case in Japan. The lack of a distinct category for functional foods means that innovations in this area must fit into the existing regulatory structures, which may not always accommodate the unique characteristics and benefits of these products. While this approach ensures that all food products meet high safety standards, it may also slow the introduction of new functional foods that could benefit public health. Overall, as functional foods continue to play a critical role in preventive health and diet management, there is a clear opportunity for the U.S. to reevaluate and potentially refine its regulatory approach to better support the development and dissemination of these beneficial products, thereby aligning more closely with global best practices and enhancing public health outcomes.

Table 5. A Comparative Analysis for FOSHU and FDA

Comparison Elements	Japan (FOSHU)	United States (FDA)
Definition and Characterization of Active Ingredients	Must be chemically, biologically, and physically characterized; mechanism of action is required.	Characterization at a molecular level is not required; mechanism of action is not necessary.
Regulatory Approach	Product-based: each product is evaluated for specific health benefits.	Claim-based: health claims are authorized based on the relationship between the food component and disease.
Scientific Literature Requirements	Requires substantial scientific evidence on efficacy, safety, and other specific health outcomes.	Collects and reviews literature on substance-disease relationships; requires disclaimers for health claims.
Challenges Identified	▪ Guidelines on consumption timing for bioactive compounds are not well-established. ▪ Limited longitudinal research on the effects of functional foods ▪ Need for more comprehensive epidemiological studies to substantiate health claims.	▪ The absence of a designated "Functional Food" category leads to complicated label claims and consumer confusion. ▪ Reliance on manufacturers' intended use for labeling can result in inconsistent product information.

Market Landscape for Functional Foods: The analysis of market trends reveals a growing consumer demand for functional foods in both countries, driven by an increasing awareness of the link between diet and health. The market in Japan is more mature, partly because of the clear regulatory framework and a long history of integrating functional foods into daily diets. As of the latest update, Japan boasts 121 FOSHU-approved products targeting cholesterol management, showing a diversified approach that includes chitosan, soy protein, low-molecular-weight sodium alginate, dietary fibers, tea catechins, and phytosterols. This variety indicates a robust market response to consumer needs and preferences, particularly highlighting the popularity of

beverage-based functional foods, which align with Japan's cultural inclination towards convenient health solutions. The U.S. market for functional foods is also expanding, driven by an aging population and heightened consumer awareness of health and wellness, a trend accelerated by the ongoing COVID-19 pandemic. The demand is particularly strong for products that claim to improve heart health, manage diabetes, and enhance overall metabolic functions, which has led to increased innovation in food products enriched with essential nutrients that address specific health concerns.

However, both markets face challenges in terms of consumer education and the transparency of health claims. The proliferation of products with varied health claims necessitates enhanced consumer understanding, which could be supported by more accessible and comprehensive information regarding the efficacy of these functional foods.

Scientific Evidence and Efficacy of Functional Foods: The effectiveness of functional foods in managing cholesterol is supported by a growing body of scientific evidence. In Japan, products like chitosan and green tea catechins have been shown to significantly reduce cholesterol levels, benefiting from the rigorous testing and approval processes under the FOSHU system. In the U.S., foods containing soluble fiber, soy protein, and plant sterols have received FDA-approved health claims for their cholesterol-lowering properties. Many existing studies, such as those analyzing the effects of plant sterols and stanols, have been conducted over relatively short periods and often under tightly controlled conditions. There is a need for long-term, large-scale studies that examine the long-term safety, efficacy, and health outcomes associated with regular consumption of these functional foods. These studies would help in establishing more definitive guidelines and recommendations for their use in everyday diets.

RECOMMENDATIONS

For Policymakers and Regulators

Establish Clear Definitions and Guidelines: The United States could benefit from defining functional foods more explicitly within its regulatory framework, similar to Japan's FOSHU system. The governmental authorities, such as the FDA, should acknowledge the pioneering work of organizations such as the Functional Food Center, which has proposed robust definitions [58-60] and a clear 17-step regulatory process for functional foods [61-62]. Clear definitions and stringent guidelines would help ensure that health claims made by functional foods are scientifically substantiated, enhancing consumer trust and safety.

Develop and Support Public Health Initiatives: Promoting public education on lifestyle changes essential for cholesterol management. It's essential to increase awareness about how diet, including functional foods, can positively impact health. Educational initiatives should focus on teaching consumers to navigate health claims and product labels, empowering them to make informed choices. These strategies are crucial for integrating functional foods into everyday health practices and making informed dietary decisions for cholesterol management.

Encourage Research and Development: Comprehensive reviews have highlighted the significant role of bioactive compounds in functional food science [63]. For instance, polyphenols found in green tea have been shown to reduce cholesterol absorption, leading to lower serum cholesterol levels [63]. Additionally, the role of probiotics, such as Lactobacillus strains, in weight management and metabolic health further supports the inclusion of functional foods in dietary interventions [63-64]. Moreover, recent studies incorporating quantum and tempus theories have demonstrated that the precise dosage and timing of bioactive compound intake can significantly influence health outcomes, optimizing the therapeutic potential of functional foods [65]. Governments should foster partnerships between academia, industry, and public health agencies to promote research into functional foods' effectiveness and safety. This could include funding for clinical trials and incentives for companies to pursue rigorous health claim substantiation.

Promote International Collaboration: It is important to foster international cooperation to harmonize standards and regulatory approaches for functional foods across borders. Such collaboration would streamline global trade and ensure that safety and efficacy standards are upheld worldwide, benefiting both consumers and manufacturers.

For Health Professionals

Incorporate Functional Foods into Dietary Guidelines: Physicians, dietitians, and nutritionists should receive specialized training to guide patients on integrating functional foods safely and effectively into their diets for cholesterol management and cardiovascular disease prevention, utilizing evidence from the most recent scientific research.

Prioritize Continuous Professional Development: Regular updates and education on the latest functional foods research are essential for health professionals. This ongoing professional development ensures they can provide their patients with the most effective, scientifically validated dietary recommendations, thus improving the outcomes of health interventions.

For the Food Industry

Invest in Scientific Research: Food industry companies should enhance consumer trust and meet regulatory standards by investing not only in rigorous pre-market scientific research to substantiate health claims of functional food products but also in post-market research, including large-scale epidemiological studies and long-term population monitoring, to ensure ongoing efficacy and safety.

Develop Innovative Products: Companies should proactively innovate to create new functional food products that align with consumer preferences and dietary needs. Focus on enhancing taste, convenience, and health benefits to meet the diverse demands of today's health-conscious consumers.

Enhance Transparent Labeling: Companies should significantly improve product labeling by clearly and comprehensively presenting information about the health benefits of functional foods. This includes detailed descriptions of active ingredients and their specific effects, ensuring consumers can easily understand and trust the product's health claims.

CONCLUSION

This white paper underscores the significant role of functional foods in cholesterol management within the United States and Japan, highlighting the intricate interplay between dietary choices, regulatory frameworks, and consumer behaviors.

The novelty of this paper lies in its comparative analysis of two leading functional food markets, utilizing credible databases and guided by informative research questions. This comprehensive overview integrates functional food theory, FFC's definition, and the detailed steps required to create ideal functional food products, which not only offers a fresh perspective but also paves the way for future innovations in functional food science.

List of Abbreviations: LDL: low-density lipoprotein; HDL: high-density lipoprotein; CHD: coronary heart disease; NHNS: National Health and Nutrition Survey; CCs: combustible cigarettes; HTPs: heated tobacco products; FFC: Functional Food Center; FHC: Foods with Health Claims; FOSHU: Foods for Specified Health Uses; FNFC: Foods with Nutrient Function Claims; FFC: Foods with Function Claims; CAA: Consumer Affairs Agency; MHLW: Ministry of Health, Labor, and Welfare; FDA: Food and Drug Administration; FTC: Federal Trade Commission; FFDCA: Federal Food, Drug, and Cosmetic Act; DSHEA: Dietary Supplement Health and Education Act; FHCs: Functional Health Claims; AHA: American Heart Association; CVD: cardiovascular disease; VLDL: very-low-density lipoprotein; GTCs: green tea catechins; LMWSA: Low-Molecular-Weight Sodium Alginate.

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Appendix A

Table 2. FOSHU-approved products for cholesterol management (https://www.caa.go.jp/policies/policy/food_labeling/foods_for_specified_health_uses)

Product Name	Applicant	Types of foods	Ingredients Involved	Permission to display	Precautions for ingestion	Suggested daily intake
1) Ryokuko Aojiru Chitosan Inn **2)** Asaba Aojiru Cholestrin **3)** Benefit Aojiru **4)** Corescue **5)** Tomorrow's Aojiru every day. **6)** Moisturizing green juice. **7)** Ashitaba Life Support Aojiru. **8)** Asaba Kikubari Aojiru. **9)** Ashitaba Aojiru Good Life. **10)** Chitosan Asaba Juice **11)** Tomorrow is sunny! **12)** Kitosara **13)** Correscap **14)** Choleste Green **15)** Green juice containing chitosan organic tomorrow leaves **16)** Chitosan Asaba Aojiru Hiwa **17)** Ashitaba kind green juice **18)** Chitosan Asaba Hanamaru Aojiru **19)** Chitosan Life **20)** Glossy green juice **21)** Leisurely and colorful **22)** Really green juice **23)** Pure green juice **24)** Green Time **25)** Dolcigard **26)** Tomorrow's life for you tomorrow **27)** Health Management Asaba Aojiru Chitosan **28)** Chitosan × Asaba Life **29)** The bounty of chitosan Asaba **30)** Chitosan barley green juice **31)** Chitosan barley green juice **32)** Mellow green juice with chitosan **33)** Quitokoredaun **34)** Chitosan Support **35)** Chitosan Power **36)** Cholescare Chitosan Aojiru **37)** Perky Chitosan Declaration **38)** Chitosan Life Support Party **39)** Green cheer chitosan barley green juice **40)** Rama Pro Active **41)** Barley green juice for those who are concerned about LDL (bad) cholesterol **42)** Refreshing barley young leaves life every day **43)** Chitosan Aojiru Gold **44)** Health Management Barley Wakaba Aojiru Chitosan **Note: Products (1) to (44) are from Toyo Shinyaku Corporation and have the same**	Toyo Shinyaku Corporation	Powdered soft drinks	chitosan	This product contains chitosan, which suppresses the absorption of cholesterol and lowers blood cholesterol. It is useful for improving the eating habits of those who have high cholesterol levels or are concerned about it. OR This product contains chitosan, which suppresses the absorption of cholesterol and lowers serum cholesterol, especially LDL (bad) cholesterol, so it can help improve the diet of those who are concerned about LDL (bad) cholesterol.	If you take too much or depending on your constitution and physical condition, you may feel a temporary feeling of bloating.	Take 3 bags (9g) per day.

bioactive ingredient, chitosan, but are sold under different names.						
45) Chitosan Asaba Aojiru **46)** Asaba Aojiru The Power of Chitosan **Note: Products (45) and (46) are from TKobayashi Pharmaceutical Co., Ltd and have the same bioactive ingredient, chitosan, but are sold under different names.**	Kobayashi Pharmaceutical Co., Ltd	Powdered soft drinks	chitosan	This product contains chitosan, which suppresses the absorption of cholesterol and lowers blood cholesterol. It is useful for improving the eating habits of those who have high cholesterol levels or are concerned about it.	If you take too much or depending on your constitution and physical condition, you may feel a temporary feeling of bloating.	Take 3 bags (9g) per day.
47) Delicious green juice made with Asaba	Art Nature Inc.	Powdered soft drinks	chitosan	This product contains chitosan, which suppresses the absorption of cholesterol and lowers blood cholesterol. It is useful for improving the eating habits of those who have high cholesterol levels or are concerned about it.	If you take too much or depending on your constitution and physical condition, you may feel a temporary feeling of bloating.	Take 3 bags (9g) per day.
48) Ichikawaen's Chitosan Asaba Power	Ichikawaen Corporation	Powdered soft drinks	chitosan	This product contains chitosan, which suppresses the absorption of cholesterol and lowers blood cholesterol. It is useful for improving the eating habits of those who have high cholesterol levels or are concerned about it.	If you take too much or depending on your constitution and physical condition, you may feel a temporary feeling of bloating.	Take 3 bags (9g) per day.
49) Chitosan barley young leaves Hanamaru Aojiru	TAKEI CORPORATION	Powdered soft drinks	chitosan	This product contains chitosan, which suppresses the absorption of cholesterol and lowers blood cholesterol. It is useful for improving the eating habits of those who have high cholesterol levels or are concerned about it.	If you take too much or depending on your constitution and physical condition, you may feel a temporary feeling of bloating.	Take 3 bags (9g) per day.
50) Chitosan Inn	Daichi Chikara Research Institute Co., Ltd.	Powdered drinks	chitosan	This product contains chitosan, which suppresses the absorption of cholesterol and lowers serum cholesterol, especially LDL (bad) cholesterol, so it can help improve the diet of those who are concerned about LDL (bad) cholesterol.	If you take too much or depending on your constitution and physical condition, you may feel a temporary feeling of bloating.	Drink 3 bags (9g) per day.
51) Health Support Food Marine with Chitosan	Kibun Foods Co., Ltd.	Sausages	chitosan	This product contains chitosan, which is a component of crab shell, so it can improve (regulate) blood cholesterol levels while taking high-quality fish protein. It is suitable for people with high cholesterol and those who are worried.	Ingesting a large amount of this product does not cure the disease.	6 bottles: One pack of this product contains 0.7g of chitosan, so 6 bottles per day is a guide. 11 bottles: One pack of this product contains 1.1g of chitosan, so 7~8 bottles per day is a guide.
52) Colechitosan	Makoma Corporation	Biscuits	chitosan	"Colechitosan" helps to improve the diet of those who have high cholesterol or are careful.	Since it contains dietary fiber, please consume it with water as much as possible.	Please consume 12.5~25.0g (1~2 bags) per day as a biscuit.
53) Soybean karaage	Fuji Oil Corporation	Sausages	Soy protein	This product is made from isolated soy protein and is designed to make it easy to ingest soy protein, which has the function of lowering blood cholesterol, so it is useful for improving the diet of those who are concerned about cholesterol.	N/A	Please take 1 bag (20g) of this product per day.
54) Nomu yogurt made with soy milk	Fuji Oil Corporation	Fermented soy milk	Soy protein	This product is made from soy milk and is designed to make it easy to ingest soy protein, which has the function of lowering serum cholesterol, so it is useful for improving the diet of those who are concerned about cholesterol.	Consuming large amounts does not cure diseases or improve health.	1) internal capacity 125 ml Please consume 2 bottles (250ml) per day. Ingredients: soy protein 7.8 g/day 2) capacity: 200 ml Please consume 1 bottle (200ml) per day. Ingredients soy protein 6.2g/day 3) capacity: 500 ml Please consume 200 to 250ml per day. Involved ingredients soy protein 6.2 to 7.8 g/day
55) Hi! Prepared soy milk	Fuji Oil Corporation	Prepared soy milk	Soy protein	This product is made from soy milk and is designed to make it easy to ingest soy protein, which has the function of lowering serum cholesterol, so it is useful for improving the diet of those who are concerned about cholesterol.	Consuming large amounts does not cure diseases or improve health.	Take 1 bottle (200 ml) per day. Ingredient "Soybean protein" 6.0 g / day
56) Health Declaration Healthyburg	Marudai Foods Co., Ltd.	Hamburger	Soy protein	This product is designed to prevent the absorption of cholesterol derived from meals. It helps to improve the diet of those who are concerned about serum cholesterol.	Consuming large amounts does not cure diseases or improve health.	Aim for 80g per day.
57) Health Declaration Healthy Ball	Marudai Foods Co., Ltd.	meatball	Soy protein	This product contains soy protein, which works to inhibit the absorption of cholesterol, and helps improve the diet of those with high serum cholesterol.	Consuming large amounts does not cure diseases or improve health.	Take 1 bag (90g) as a guide.

58) Extra-thick soy milk **59)** Thick Prepared Soy Milk **60)** Soy milk made from Hokkaido's soybeans **Note: Products (58) to (60) are from Kikkoman Corporation and have the same bioactive ingredient, soy protein, but are sold under different names.**	Kikkoman Corporation	Prepared soy milk	Soy protein	This product is made from soy milk and is designed to make it easy to ingest soy protein, which has the function of lowering serum cholesterol, so it is useful for improving the diet of those who are concerned about cholesterol.	Ingestion of this product does not cure diseases or improve health by ingestion of large amounts.	200ml: Drink 1 bottle (200ml) per day. 1000ml: Drink 200ml per day.
61) Prepared soy milk from domestic soybeans **62)** Domestic soybean 100% ✆ prepared soy milk **Note: Products (61) and (62) are from MARUSAN-AI CO., LTD. and have the same bioactive ingredient, soy protein, but are sold under different names.**	MARUSAN-AI CO., LTD.	Prepared soy milk	Soy protein	This product is made from soy milk and is designed to make it easy to ingest soy protein, which has the function of lowering serum cholesterol, so it is useful for improving the diet of those who are concerned about cholesterol.	Consuming large amounts does not cure diseases or improve health.	General use (200ml): Take 1 bottle (200ml) per day. Ingredient "Soy protein" 7.0g/day For home delivery (200ml): Please consume 1 bottle (200ml) per day. Ingredient "Soy protein" 7.0g/day General use (1000ml): Take 200ml per day. Ingredient "Soy protein" 7.0g/day
63) Prepared soy milk using domestic soybeans	Yakult Corporation	Prepared soy milk	Soy protein	This product is made from soy milk and is designed to make it easy to ingest soy protein, which has the function of lowering serum cholesterol, so it is useful for improving the diet of those who are concerned about cholesterol.	Consuming large amounts does not cure diseases or improve health.	Take 1 piece (200 ml) per day.
64) Soup made from soybeans (corn potage flavor) **65)** Soup made from soybeans (spicy flavor) **Note: Products (64) and (65) are from Meiji Corporation and have the same bioactive ingredient, soy protein, but are sold under different** flavors/**names.**	Meiji Corporation	Dried soup	Soy protein	This product is made from soy protein, which has the function of lowering serum cholesterol, and is designed to be easy to ingest, so it is a food suitable for those with high cholesterol.	Consuming large amounts does not cure diseases or improve health.	Take 1 bag (15g) per day.
66) Plain yogurt made with soy milk. **67)** Yogurt made with soy milk Plain A. **68)** Yogurt made with soy milk, aloe. **69)** Yogurt made with soy milk, aloe A. **70)** Yogurt made with soy milk, blueberry. **71)** Yogurt made with soy milk, blueberry A **Note: Products (66) to (71) are from POKKA SAPPORO Food & Beverage Co., Ltd. and have the same bioactive ingredient, soy protein, but are sold under different** flavors/**names.**	POKKA SAPPORO Food & Beverage Co., Ltd.	Fermented soy milk	Soy protein	This product is made from soy milk and is designed to make it easy to ingest soy protein, which has the function of lowering serum cholesterol, so it is useful for improving the diet of those who are concerned about cholesterol.	Consuming large amounts does not cure diseases or improve health.	Take 2 pieces (220g) per day.
72) Deliciously prepared soy milk	POKKA SAPPORO Food & Beverage Co., Ltd.	Fermented soy milk	Soy protein	This product is made from soy milk and is designed to make it easy to ingest soy protein, which has the function of lowering serum cholesterol, so it is useful for improving the diet of those who are concerned about cholesterol.	Consuming large amounts does not cure diseases or improve health.	Take 1 bottle (200 ml) per day. Ingredient involved "soy protein" 6.0 g / day.
73) Korekut **74)** Korecut Light **75)** Korekut Light Lychee **76)** Korecut Muscat **77)** Korekut Lemon **78)** Korecut Alpha **79)** Korecut Zero **80)** Korecut Mango **81)** Koresmart	Kaigen Pharma Corporation	soft drink	Low-molecular-weight sodium alginate	The product "Korecut" is designed to be easy to drink by containing water-soluble dietary fiber (low-molecular-weight sodium alginate), which makes it difficult to absorb cholesterol and regulates the condition of the stomach. It is a beverage that is suitable for those who have high cholesterol, those who are concerned about their stomach condition, and those who want to improve the eating habits of modern people, who tend to be deficient in dietary fiber.	You may drink too much, or your stomach may become loose depending on your constitution and physical condition.	Drink 150g of 150g (4g of low-molecular-weight sodium alginate) per day.

Note: Products (73) to (81) are from Kaigen Pharma Corporation and have the same bioactive ingredient, low-molecular-weight sodium alginate, but are sold under different flavors/names.						
82) Eco Balance CR. **83)** Natural Care CR. **84)** Eltos CR. **85)** Cholescare. **86)** Cholescare Neo **87)** Coresmanaged **88)** Cores Support **Note: Products (82) to (88) are from Taisho Pharmaceutical Co., Ltd. and have the same bioactive ingredient, low-molecular-weight sodium alginate, but are sold under different names.**	Taisho Pharmaceutical Co., Ltd.	soft drink	Low-molecular-weight sodium alginate	This product contains low-molecular-weight sodium alginate, a water-soluble dietary fiber derived from seaweed, which suppresses the absorption of cholesterol. It is recommended for those who tend to eat a lot of meat and fried foods, and for those who have high serum cholesterol levels.	If you drink too much, or depending on your constitution and physical condition, your stomach may become loose.	Please drink 1 can (150g) per day.
89) Saraba	Suntory Beverage & Food Limited	soft drink	Low-molecular-weight sodium alginate	This product contains low-molecular-weight sodium alginate, a water-soluble dietary fiber derived from seaweed, which suppresses the absorption of cholesterol. It is recommended for people with high serum cholesterol levels.	You may drink too much, or your stomach may become loose depending on your constitution and physical condition.	Drink 1 bottle (200 ml) per day.
90) Jelly juice isagol **91)** Isagor and green apple flavor **92)** Isagor grapefruit flavor **93)** Isagor Ginger Flavor **94)** Isagor Lemon Flavor **95)** Pure Flora **Note: Products (90) to (95) are from Fibro Pharmaceutical Co., Ltd. and have the same bioactive ingredient, dietary fiber derived from psyllium seed coat, but are sold under different flavors/names.**	Fibro Pharmaceutical Co., Ltd.	Powdered jelly drink	Dietary fiber derived from psyllium seed coat	"Jelly Juice Isagol" is made from psyllium seed coat rich in dietary fiber that suppresses the absorption of excessive cholesterol and regulates the condition of the stomach, and is devised to lower serum cholesterol, so it is useful for improving the eating habits of those who are concerned about high cholesterol and those who are concerned about the condition of the stomach.	Mix 1 stick in a glass (100 ml) of water and serve in a jelly juice form. In rare cases, people who are involved in work that comes into direct contact with psyllium (blending and manufacturing) may experience itchy skin and hypersensitivity reactions such as rashes when ingesting this product. If you are menstruating or anemic, please try to replenish iron.	Take 2 sticks per day as a guide.
96) ColoBalance	Nissin Pharma Corporation	Powdered jelly drink	Dietary fiber derived from psyllium seed coat	This food is made from psyllium seed coat, which is rich in dietary fiber, which suppresses the absorption of excessive cholesterol and regulates the condition of the stomach, and is designed to lower serum cholesterol, so it is useful for those who are concerned about high cholesterol and those who are concerned about the condition of the stomach.	- Mix 1 stick in a glass (100 ml) of water and enjoy. If you leave it for a while, it will turn into a jelly. - After consumption, it is recommended to drink an additional glass of water. - Do not put the powder directly in your mouth as it is, as the powder may absorb water and harden into jelly and get stuck in the throat. - In rare cases, if a person involved in work that directly comes into contact with psyllium (bending, manufacturing, etc.) ingests this product, it may cause itchy skin and hypersensitivity reactions such as rashes. - If you are menstruating or anemic, please try to replenish iron. - Please refer to the ingredients and do not consume if you have food allergies.	Take 2 sticks per day as a guide.
97) Cholerestol Fiber	Morishita Jintan Co., Ltd.	Powdered jelly drink	Dietary fiber derived from psyllium seed coat	"Cholesterol Fiber" is made from psyllium seed coat rich in dietary fiber that suppresses the absorption of excessive cholesterol and regulates the condition of the stomach, and is devised to lower serum cholesterol, so it is useful for those who are concerned about high cholesterol and those who are concerned about the condition of the stomach.	- Mix 1 packet with a glass (100 ml) of water and enjoy in the form of jelly juice. - Do not drink directly as granules, be sure to dissolve in water and drink in small amounts. There is a risk that the granules will absorb water and swell, causing them to get stuck in the throat. - In rare cases, if a person who is involved in work that comes into direct contact with psyllium (preparation, manufacturing,	Take 2 packets per day as a guide.

					etc.) ingests this product, it may cause itchy skin and hypersensitivity reactions such as rashes. - During menstruation and if you are anemic, please try to replenish iron. - Please refrain from using this service if you are a child or have a reduced swallowing function.	
98) Cholestemin Acerola Flavor	Yakult Health Foods Inc.	Powdered jelly drink	Dietary fiber derived from psyllium seed coat	This product is made from psyllium seed coat rich in dietary fiber, which suppresses the absorption of cholesterol and regulates the condition of the stomach, and is devised to lower serum cholesterol, so it is useful for those who are concerned about high cholesterol and those who are concerned about the condition of the stomach.	The color tone may differ, but there is no problem with the quality. Do not put directly in your mouth, be sure to mix with water before consumption. During menstruation or if you have anemia, please try to replenish iron. If you are pregnant, breastfeeding, or have been prescribed medication, please consult your doctor just in case. Depending on your constitution, it may not suit your body in rare cases. In that case, discontinue use. In rare cases, this product may cause itching of the skin and hypersensitivity reactions of rashes if ingested by a person who is involved in work that directly comes into contact with psyllium (bending, manufacturing, etc.).	Take 2 bags per day.
99) Egao no Kolestere	Egao Corporation	Powdered jelly drink	Dietary fiber derived from psyllium seed coat	"Egao no Cholestere" is made from psyllium seed skin, which is rich in dietary fiber that suppresses the absorption of excessive cholesterol and regulates the condition of the stomach, and is devised to lower serum cholesterol, so it is useful for those who are concerned about high cholesterol and those who are concerned about the condition of the stomach.	- Mix 1 bag with a glass (100 ml) of water and enjoy in the form of jelly juice. - In rare cases, if a person involved in work that directly comes into contact with psyllium (bending, manufacturing, etc.) ingests this product, it may cause itchy skin and hypersensitivity reactions such as rashes. - During menstruation and if you are anemic, please try to replenish iron.	Take 2 bags per day as a guide.
100) Firm taste of catechin green tea **101)** Rich aroma catechin roasted tea **102)** Catechin Jasmine Tea **103)** Catechins Green Tea **104)** Catechin Green Tea W **105)** Two functions catechins, green tea **106)** Two functions catechin hojicha **107)** Two functions catechins, oolong tea **108)** 2 Working Catechins Green Tea **109)** Catechins, 500 green tea **110)** Two Working Catechins Jasmine Tea **Note: Products (100) to (110) are from ITO EN CORPORATION and have the same bioactive ingredient, tea catechins, but are sold under different flavors/names.**	ITO EN CORPORATION	Tea-based beverages	Tea catechins	This product is characterized by lowering serum cholesterol, especially LDL (bad) cholesterol, by the action of tea catechins, which suppress the absorption of cholesterol. It helps to improve the diet of people with high cholesterol.	Consuming large amounts does not cure diseases or improve health.	(PET 350ml) 2 bottles a day, 1 bottle at meals. (PET 1.05L, 1.5L) 700 ml per day, 350 ml at meals.
111) O~i Tea Catechin Green Tea	ITO EN CORPORATION	Tea-based beverages	Tea catechins	Since this product contains tea catechins, it suppresses the absorption of dietary fat and increases excretion, making it difficult for fat to stick to the body. In addition, this product is characterized by reducing serum cholesterol, especially LDL (bad) cholesterol, due to the action of tea catechins, which slow down the absorption of cholesterol. It is suitable for those who have a lot of body fat or high cholesterol.	Consuming large amounts does not cure diseases or improve health.	500ml: Take 2 bottles a day, 1 bottle at meals. 1L, 2L: Drink 1L per day, 500ml at meals.
112) Health Salalah	Ajinomoto Corporation	Consume conditioning oils	Phytosterols	Made from soybean germ, "Health Salala" is rich in natural phytosterols that suppress the absorption of cholesterol into the body, so it is characterized by lowering total blood cholesterol and bad (LDL) cholesterol. It is recommended for daily meals for those with high cholesterol.	Consuming large amounts does not improve your health.	As a cooking oil, use 11g per day as a guide, in the same way as the cooking oil you usually use.

113) Healthy Choleste **114)** Oil for healthy choleste frying **115)** CO-OP Well Plus Healthy Choleste **116)** CO-OP rice bran oil plus **117)** Nissin rice bran oil plus **Note: Products (113) to (117) are from Nissin Oilio Group Corporation and have the same bioactive ingredient, phytosterols, but are sold under different flavors/names.**	Nissin Oilio Group Corporation	Consume conditioning oils	Phytosterols	This oil is rich in phytosterols, which reduce the absorption of cholesterol into the body, so it is characterized by lowering blood cholesterol. It helps to improve the eating habits of those who are concerned about cholesterol.	Consuming large amounts does not cure diseases or improve health.	You can use it in the same amount as the cooking oil you usually use. Please take about 14g per day.
118) Pure Select Salaria	Ajinomoto Corporation	condiment	Plant sterol esters	"Pure Select Salaria" contains phytosterol esters that suppress the absorption of cholesterol into the body, so it is characterized by lowering blood cholesterol, especially bad (LDL) cholesterol. It is recommended for meals of people with high cholesterol.	Ingestion of this product does not cure diseases or improve health by ingestion of large amounts.	Take about 15g per day, a tablespoon as a guide.
119) Rama Pro Active	J-Oil Mills Inc.	margarine	Plant sterol esters	Rama Pro Active is characterized by lowering blood cholesterol, especially LDL cholesterol (bad cholesterol), by formulating phytosterol esters that work to inhibit the absorption of cholesterol. It is recommended not only for maintaining health, but also for those with high cholesterol.	Plant sterols may inhibit the absorption of β-carotene, so take them with fruits and vegetables. Consuming large amounts does not cure diseases or improve health.	Take 15g per day, or 1 tablespoon in 2 portions.
120) Kewpie Diffe	Kewpie Corporation	condiment	Vegetable sterols	This product is characterized by lowering total blood cholesterol and LDL cholesterol by blending vegetable sterols that have the function of suppressing the absorption of cholesterol. It is useful for improving the eating habits of those who are concerned about cholesterol.	Ingestion of this product does not cure diseases or improve health by ingestion of large amounts.	Take 15g per day, or 1 tablespoon as a guide.
121) Salana in Green	Sunstar Corporation	soft drink	SMCS (natural amino acids) derived from broccoli and cabbage	This product is rich in SMCS (natural amino acids) derived from broccoli and cabbage, which have the function of lowering blood cholesterol (especially LDL cholesterol). It is suitable for those who are concerned about cholesterol or have high cholesterol.	・ Ingestion of large amounts does not cure diseases or improve health. ・If your doctor has told you to be careful about taking vitamin K, please consult your doctor.	Consume 2 cans per day (1 can at a time) as a guide.