DLA PIPER

EVERYTHING MATTERS

Health and Nutrition Claims: Growing Strong in a Regulated Industry

Prepared by DLA Piper LLP (US) for the International Sprout Growers Associations

October 19, 2011

FDA Regulatory Attorney

- FDA Compliance Advice
- Crisis Management
- Risk Assessment

Rebecca Jones McKnight
DLA Piper LLP (US)
401 Congress Avenue, Suite 2500
Austin, Texas 78701-3799
512.457.7225
rebecca.mcknight@dlapiper.com

How Can the Sprout Industry Strengthen Itself in a Regulated World?

“Knowledge is a process of piling up facts; wisdom lies in their simplification.”
-Martin H. Fischer

We Have Good News!

- Can we share it?
- How?

Image courtesy David Castillo Dominici /Free DigitalPhotos.net ; Image courtesy Arvind Balaraman / FreeDigitalPhotos.net

Who Sets the Standards for Labeling and Promotion of Sprouts?

Image courtesy hinnamsaisuy / FreeDigitalPhotos.net

U.S. Food and Drug Administration

FDA's Center for Food Safety and Applied Nutrition (CFSAN)

- CFSAN regulates conventional food and dietary supplements, which industry sometimes refers to as nutraceuticals.
- CFSAN regulates manufacturing, labeling (format, content, and permitted claims), and import and export of these products.
- Although these products typically do not require specific prior authorization for marketing (assuming ingredients and claims comply with FDA law), the Center for Drug Evaluation and Research (CDER) will step in to regulate the product as a "drug" if a company makes claims about the effectiveness of a food or dietary supplement to treat or prevent disease.

What is Labeling?

Image courtesy Stuart Miles / FreeDigitalPhotos.net

Nutrition Labeling

PART 101—FOOD LABELING

Subpart A—General Provisions

Sec.

Subpart C—Specific Nutrition Labeling Requirements and Guidelines

What Else is Labeling?

- "Label" means a display of written, printed, or graphic matter upon the immediate container of a product.
- "Labeling" means all labels and other written, printed, or graphic matter on a food or any of its containers or wrappers, or accompanying the food.
- FDA interprets "labeling" and "accompanying" broadly to cover statements in a variety of media.
  - The actual label on the product
  - Print materials accompanying or tied to the product
  - Company websites that talk about the product

21 U.S.C. § 321(k),(m)

What is Prohibited?

- Food is “misbranded” if its labeling is false or misleading.
- Takes into account not only representations made but also the extent to which the labeling fails to reveal material facts.
- The U.S. Federal Food, Drug, and Cosmetic Act (FD&C Act) prohibits, among other things, doing or causing in U.S. commerce:
  - The misbranding of food;
  - The introduction or delivery of misbranded food; and
  - The receipt of misbranded food.

21 U.S.C. § 343(a)(1), 201(n), 301, 331; 21 C.F.R. § 1.21(a)

What CAN We Say?

- There are three categories of potentially permissible claims for conventional foods:
  - Health Claims
  - Nutrient Content Claims
  - Structure/Function Claims

Refer to the FDA document, *Claims That Can Be Made for Conventional Foods and Dietary Supplements,* September 2003:

http://www.fda.gov/Food/LabelingNutrition/LabelClaims/ucm111447.htm

Image courtesy nuchylee / FreeDigitalPhotos.net

Health Claims

- "Health Claims" are claims that describe the relationship between a nutrient or dietary ingredient and a disease or health related condition.
- Health Claims fall into three categories:
  - Health Claims specifically authorized by FDA, based on extensive review of scientific literature, and these authorized claims are outlined in FDA regulations. These are referred to as "significant scientific agreement" or "SSA" Health Claims.
  - Health Claims based on an "authoritative statement" from a scientific body of the U.S. Government or National Academy of Sciences.
  - "Qualified Health Claims," in circumstances where there is not sufficient scientific agreement for an authorized health claim, but there is emerging evidence of a relationship between a food component and a reduced risk of disease or a health-related conditions. Qualifying language would be required to accurately describe the strength of evidence

Health Claims

§ 101.76 Health claims: fiber-containing grain products, fruits, and vegetables and cancer.

(a) *Relationship between diets low in fat and high in fiber-containing grain products, fruits, and vegetables and cancer risk.* (1) Cancer is a constellation of more than 100 different diseases, each characterized by the uncontrolled growth and spread of abnormal cells. Cancer has many causes and stages in its development. Both genetic and environmental risk factors may affect the risk of cancer. Risk factors include: A family history of a specific type of cancer, cigarette smoking, overweight and obesity, alcohol consumption, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(2) The scientific evidence establishes that diets low in fat and high in fiber-containing grain products, fruits, and vegetables are associated with a reduced risk of some types of cancer. Although the specific role of total dietary fiber, fiber components, and the multiple nutrients and other substances contained in these foods are not yet fully understood, many studies have shown that diets low in fat and high in fiber-containing foods are associated with reduced risk of some types of cancer.

(b) *Significance of the relationship between consumption of diets low in fat and high in fiber-containing grain products, fruits, and vegetables and risk of cancer.* (1) Cancer is ranked as a leading cause of death in the United States. The overall economic costs of cancer, including direct health care costs and losses due to morbidity and mortality, are very high.

To see the full regulations go to
www.gpoaccess.gov

21 C.F.R. § 101.76 and 101.77

Image courtesy Michelle Meiklejohn / FreeDigitalPhotos.net.

Food and Drug Administration, HHS

§ 101.77 Health claims: fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.

(a) *Relationship between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.* (1) Cardiovascular disease means diseases of the heart and circulatory system. Coronary heart disease is the most common and serious form of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total- and low density lipoprotein (LDL)- cholesterol levels are major modifiable risk factors in the development of coronary heart disease. High coronary heart disease rates occur among people with high blood cholesterol levels of 240 milligrams per deciliter (mg/dL) (6.21 (mmol/L)) or above and LDL-cholesterol levels of 160 mg/dL (4.13 mmol/L) or above. Borderline high risk blood cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/L) and 130 to 159 mg/dL (3.36 to 4.11 mmol/L) of LDL-cholesterol. Dietary lipids (fats) include fatty acids and cholesterol. Total fat, commonly referred to as fat, is composed of saturated fat (fatty acids containing no double bonds), and monounsaturated and polyunsaturated fat (fatty acids containing one or more double bonds).

Nutrient Content Claims

- “Nutrient Content Claims” (such as low or high) can be made about conventional foods, in accordance with established FDA regulations.

Nutrient Content Claims

Subpart D—Specific Requirements for Nutrient Content Claims

SOURCE: 58 FR 2413, Jan. 6, 1993, unless otherwise noted.

§ 101.54 Nutrient content claims for "good source," "high," "more," and "high potency."

(a) *General requirements.* Except as provided in paragraph (e) of this section, a claim about the level of a nutrient in a food in relation to the Reference Daily Intake (RDI) established for that nutrient in § 101.9(c)(8)(iv) or Daily Reference Value (DRV) established for that nutrient in § 101.9(c)(9), (excluding total carbohydrates) may only be made on the label or in labeling of the food if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13; and

(3) The food for which the claim is made is labeled in accordance with § 101.9, § 101.10, or § 101.36, as applicable.

(b) *"High" claims.* (1) The terms "high," "rich in," or "excellent source of" may be used on the label and in the labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that the food contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (b)(1) of this section may be used on the label and in the labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The product contains a food that meets the definition of "high" in paragraph (b)(1) of this section; and

To see the full regulation go to www.gpoaccess.gov, 21 C.F.R. 101.54

Image courtesy zirconicusso / FreeDigitalPhotos.net

Structure/Function Claims

- Nutritional Support Claims, also referred to as “Structure/Function” Claims, describe
  - how an ingredient affects or acts to support the body’s structure and function, or
  - how it can alleviate a common nutritional deficiency.
- Such claims may also describe general well-being from consumption of the ingredients. An example is: "calcium builds strong bones."
- The person marketing the food must have adequate substantiation for the claims, and cannot include statements or images in the label that – when taken as a whole – create a false or misleading impression about the product.
- If FDA considers the claim or any other aspect of the product inappropriate, it may take enforcement action.
- Although FDA provides guidance indicating claims that it is likely to consider acceptable, its interpretation of what constitutes an acceptable Nutritional Support Claim may change in the future thereby requiring that revision of labeling.

What Else Does FDA Say About Food Claims?

- Some claims, if made about a food product, are not permitted:
  - Drug Claims
  - Unauthorized Health Claims
- Drug claims are representations that a product is intended to diagnose, mitigate, treat, cure or prevent a disease.
- Drug claims are prohibited from use in the labeling of conventional foods and dietary supplements and can result in enforcement action.

Who Else Regulates Food Claims?

- The U.S. Federal Trade Commission (FTC) regulates claims in food advertising.
- FTC often works in coordination with FDA.

Federal Trade Commission

ORIGINAL

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of

POM WONDERFUL LLC and,
ROLL GLOBAL LLC,
as successor in interest to
Roll International Corporation,
companies, and

STEWART A. RESNICK,
LYNDA RAE RESNICK, and
MATTHEW TUPPER, individually and
as officers of the companies.

Docket No. 9344

PUBLIC

COMPLAINT COUNSEL'S PRE-TRIAL BRIEF

Respondents did not possess or rely upon competent and reliable scientific evidence to substantiate their claim the Challenged Products treat prostate cancer.

Respondents' evidence is inadequate to substantiate their claims that the Challenged Products prevent, reduce the risk of, or treat heart disease.

IV. CORPORATE RESPONDENTS POM AND ROLL ARE LIABLE FOR THE DECEPTIVE AND FALSE ADVERTISING

POM and Roll are each liable for their involvement in making the false and unsubstantiated health claims discussed in section I. POM is liable for claims made in its advertisements for its products; Roll is liable because of its role in creating POM's advertisements through Fire Station, promoting POM products through its public relations employees, and sponsoring and funding research on POM products. Additionally, Roll and POM are also jointly liable under the common enterprise theory.

What is the FTC Standard for Advertising Claims?

GENERAL ADVERTISING POLICIES

WHAT TRUTH-IN-ADVERTISING RULES APPLY TO ADVERTISERS?

Under the Federal Trade Commission Act:

- advertising must be truthful and non-deceptive;
- advertisers must have evidence to back up their claims; and
- advertisements cannot be unfair.

Additional laws apply to ads for specialized products like consumer leases, credit, 900 telephone numbers, and products sold through mail order or telephone sales. And every state has consumer protection laws that govern ads running in that state.

FTC, *Advertising FAQs: A Guide for Small Businesses*, April 2001, http://business.ftc.gov/documents/bus35-advertising-faqs-guide-small-business

What is the FTC Standard for Advertising Claims?

What makes an advertisement deceptive?

According to the FTC's *Deception Policy Statement*, an ad is deceptive if it contains a statement — or omits information — that:

- is likely to mislead consumers acting reasonably under the circumstances; and
- is "material" — that is, important to a consumer's decision to buy or use the product.

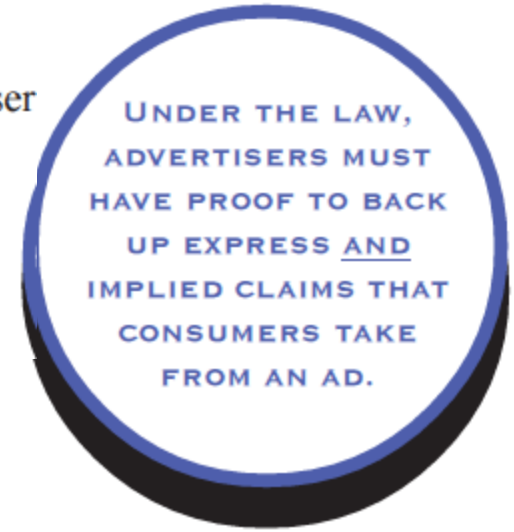
What makes an advertisement unfair?

According to the Federal Trade Commission Act and the FTC's *Unfairness Policy Statement*, an ad or business practice is unfair if:

- it causes or is likely to cause substantial consumer injury which a consumer could not reasonably avoid, and
- it is not outweighed by the benefit to consumers.

What is the FTC Standard for Advertising Claims?

- The FTC looks at whether the advertiser has sufficient evidence to support the claims in the ad. The law requires that advertisers have proof *before* the ad runs.



What is the FTC Standard for Advertising Claims?

WHAT KIND OF EVIDENCE MUST A COMPANY HAVE TO SUPPORT THE CLAIMS IN ITS ADS?

Before a company runs an ad, it has to have a "reasonable basis" for the claims. A "reasonable basis" means objective evidence that supports the claim. The kind of evidence depends on the claim. At a minimum, an advertiser must have the level of evidence that it *says* it has. For example, the statement "Two out of three doctors recommend ABC Pain Reliever" must be supported by a reliable survey to that effect. If the ad isn't specific, the FTC looks at several factors to determine what level of proof is necessary, including what experts in the field think is needed to support the claim. In most cases, ads that make health or safety claims must be supported by "competent and reliable *scientific* evidence" — tests, studies, or other scientific evidence that has been evaluated by people qualified to review it. In addition, any tests or studies must be conducted using methods that experts in the field accept as accurate.

Where is FTC's Focus?

The FTC pays closest attention to:

- ads that make claims about health or safety, such as:

ABC Sunscreen will reduce the risk of skin cancer.	ABC Water Filters remove harmful chemicals from tap water.	ABC Chainsaw's safety latch reduces the risk of injury.

Image courtesy Simon Howden / FreeDigitalPhotos.net

082 3145

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

COMMISSIONERS: Jon Leibowitz, Chairman
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch

In the Matter of	)	
	)	**DOCKET NO. C-4262**
KELLOGG COMPANY,	)	
a corporation.	)	

COMPLAINT

The Federal Trade Commission, having reason to believe that Kellogg Company, a corporation ("respondent"), has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Kellogg Company is a Delaware corporation with its principal office or plac of business at One Kellogg Square, P.O. Box 3599, Battle Creek, Michigan, 49016.

2. Respondent has labeled, advertised, promoted, offered for sale, sold, and distributed Kellogg's® Frosted Mini-Wheats® cereal to consumers.

3. Kellogg's® Frosted Mini-Wheats® cereal is a "food" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

4. The acts and practices of respondent, as alleged herein, have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

5. Respondent has disseminated or caused to be disseminated advertisements for Kellogg's® Frosted Mini-Wheats® cereal, including but not limited to the attached Exhibits A through H. These advertisements contain the following statements:

C. **Product Packaging** (Exhibit C)

Appearing at the top of the front and back panels of Frosted Mini-Wheats cereal boxes:

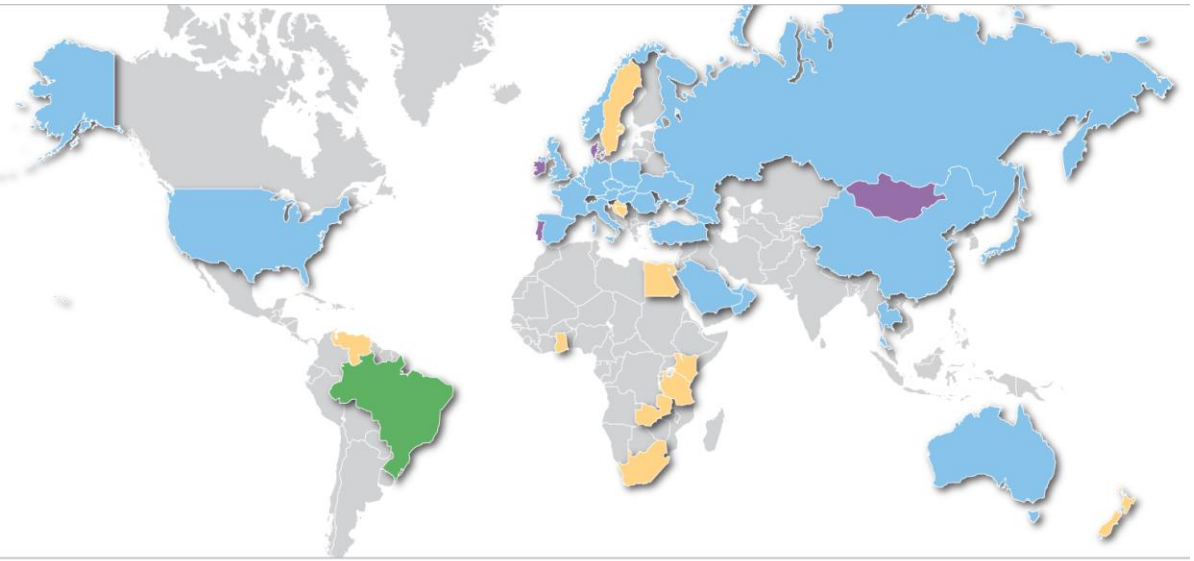
Appearing at the bottom of the back panel of Frosted Mini-Wheats boxes, in small type:

"Based upon independent clinical research, kids who ate Kellogg's® Frosted Mini-Wheats® cereal for breakfast had up to 18% better attentiveness three hours after breakfast than kids who ate no breakfast. For more information, visit www.frostedminiwheats.com"

Outside the U.S.

Image courtesy digitalart / FreeDigitalPhotos.net

Food Has Global Implications



DLA PIPER OFFICES

AUSTRALIA
Brisbane
Canberra
Melbourne
Perth
Sydney

AUSTRIA
Vienna

BAHRAIN
Manama

BELGIUM
Antwerp
Brussels

CHINA
Beijing
Hong Kong
Shanghai

CZECH REPUBLIC
Prague

FRANCE
Paris

GEORGIA
Tbilisi

GERMANY
Berlin
Cologne
Frankfurt
Hamburg
Munich

HUNGARY
Budapest

ITALY
Milan
Rome

JAPAN
Tokyo

KUWAIT
Kuwait City

NETHERLANDS
Amsterdam

NORWAY
Oslo

OMAN
Muscat

POLAND
Warsaw

QATAR
Doha

ROMANIA
Bucharest

RUSSIA
Moscow
St. Petersburg

SAUDI ARABIA
Riyadh

SINGAPORE
Singapore

SLOVAK REPUBLIC
Bratislava

SPAIN
Madrid

THAILAND
Bangkok

TURKEY
Istanbul

UKRAINE
Kyiv

UNITED ARAB EMIRATES
Abu Dhabi
Dubai

UNITED KINGDOM
Birmingham
Edinburgh
Glasgow
Leeds
Liverpool
London
Manchester
Sheffield

UNITED STATES
Atlanta
Austin
Baltimore
Boston
Chicago
Dallas
Delaware
Houston
Los Angeles
Miami
New Jersey
New York
Northern Virginia
Philadelphia
Phoenix
Raleigh
Sacramento
San Diego
San Francisco
Seattle
Silicon Valley
Tampa
Washington, DC

DLA PIPER GROUP FIRMS

BOSNIA-HERZEGOVINA
Sarajevo

CROATIA
Zagreb

EGYPT
Cairo

GHANA
Accra

KENYA
Nairobi

NEW ZEALAND
Auckland
Wellington

SOUTH AFRICA
Cape Town
Johannesburg

SWEDEN
Stockholm

TANZANIA
Dar es Salaam
Mwanza

VENEZUELA
Caracas

ZAMBIA
Lusaka

DLA PIPER FOCUS FIRMS

DENMARK
Copenhagen

IRELAND
Dublin

MONGOLIA
Ulan Bator

PORTUGAL
Lisbon

PREFERRED FIRMS

BRAZIL
Rio de Janeiro
São Paulo

TURKEY
Ankara
Istanbul

DLA Piper is a Global Organization

- 4,200+ lawyers overall, in 30 countries and 76 offices
  - 1,500+ lawyers in the US
- 200+ lawyers in Asia, including in Beijing, Shanghai, Hong Kong, Tokyo, Singapore and Bangkok
- 100+ lawyers in Central and Eastern Europe and Russia, including in Moscow, Budapest, Prague and Warsaw
- 150+ lawyers in the Middle East, including in Abu Dhabi, Dubai, Egypt, Kuwait, Qatar, Saudi Arabia and Oman

E.U. Regulation

- In December 2006 EU decision makers adopted a Regulation on the use of nutrition and health claims for foods.
- It lays down harmonised EU-wide rules for the use of health or nutritional claims on foodstuffs based on nutrient profiles.
- The Regulation applies to all nutrition and health claims for food intended for final consumer including:
  - commercial communications (labeling, presentation and promotional campaigns); and
  - trademarks and other brand names which may be construed as nutrition or health claims.
- The Regulation supplements Directive 2000/13/EC relating to food labeling and Directive 2006/114/EC on misleading and comparative advertising which could mislead the consumer.

Regulation (EC) N° 1924/2006* of the European Parliament and of the Council on nutrition and health claims made on foods adopted on 20 December 2006.

E.U. Nutrition Claims

- A nutrition claim states or suggests that a food has beneficial nutritional properties, such as “low fat”, “no added sugar” and “high in fibre.”

E.U. Health Claims

- A health claim is any statement on labels, advertising or other marketing products that health benefits can result from consuming a given food, for instance that a food can help reinforce the body's natural defences or enhance learning ability.
- The Commission authorises different health claims provided they are based on scientific evidence and can be easily understood by consumers.
- The European Food Safety Authority (EFSA) is responsible for evaluating the scientific evidence supporting health claims. The Commission draws up lists of health claims including the different types of authorised and rejected health claims in the EU.

E.U. Health Claims

- Health claims are subject to specific requirements. The labeling, presentation and publicity related to them must provide certain obligatory information:
  - a statement indicating the importance of a varied and balanced diet and a healthy lifestyle;
  - the quantity of the food and pattern of consumption which will ensure the claimed beneficial effect;
  - a statement addressed to persons who should avoid the substance concerned; and
  - a warning of the health risks caused by excessive consumption.

E.U. Health Claims

- The Regulation prohibits health claims which refer to the rate or amount of weight loss or suggest it is detrimental to health not to consume a certain type of food.
- However, by way of derogation from Directive 2000/13/EC on labeling (which prohibits any reference to properties for the prevention, treatment or cure of a human disease), the Regulation authorises claims concerning the reduction of the risk of a disease, provided that an application for authorisation has been approved.

E.U. Health Claims

- **Application for Authorisation**
  - To obtain authorisation for a new claim or amend the existing list, the manufacturer must submit an application to the Member State concerned, which will forward it to the European Food Safety Authority (EFSA). The Commission then makes a decision on the use of the claim on the basis of the EFSA's opinion.
  - So far, EFSA has published 125 opinions providing scientific advice for more than 900 health claims, out of the draft a list of 4,637 health claims submitted to EFSA by the Commission between July 2008 and March 2010.

E.U. General Function Health Claims

- The European Commission is required to draw up a “positive list” of the many well-established “general function” health claims in the EU, such as “calcium is good for your bones”, on the basis of claims submitted by the EU Member States.
- This type of health claims, dealt with under Article 13.1 of the Regulation, include those referring for instance to growth, development and the functions of the body and to psychological and behavioural functions, but not to the reduction of disease risk nor to child development or health which are separately addressed under Article 14 and Article 13.5 of the Regulation.

E.U. Conditions for Nutrition and Health Claims

- Nutritional and health claims must meet the following conditions:
  - the presence, absence or reduced content of a nutrient or other substance in respect of which the claim is made must have a beneficial nutritional or physiological effect, and be scientifically proven;
  - the nutrient or substance in respect of which the claim is made is present in significant quantities in order to produce the nutritional or physiological effect claimed. Its absence or presence in a reduced quantity should also produce the expected nutritional or physiological effect;
  - the nutrient or substance in respect of which the claim is made is in an immediately consumable form;
  - the specific conditions of use must be complied with, for example, the active substance (e.g. vitamins, fibres, etc.) must be present in sufficient quantity in the food to have beneficial effects.
  - Nutritional and health claims relating to beverages containing more than 1.2% of alcohol by volume are prohibited, with the exception of those which refer to a reduction in the alcohol or energy content of an alcoholic beverage.

E.U. Nutrient Profiles

- Nutrient profiles are nutritional requirements that foods must meet in order to bear nutrition and health claims.
- One of the key objectives of this Regulation is to ensure that any claim made on a food label in the EU is clear and substantiated by scientific evidence.
- The profiles will help ensure that consumers who utilise claims to guide healthy diet choices, and who may perceive foods bearing claims as having a nutritional or health advantage, are not misled as to their overall nutritional value.
- The European Commission and Member States are required to establish a nutrient profiling system and set nutrient profiles for foods bearing nutrition and health claims taking into account EFSA's scientific advice.

E.U. Prohibitions

- The Regulation protects consumers by prohibiting any information which:
  - is false, difficult to understand or misleading (e.g. which attributes medicinal properties to food wrongly or without scientific evidence);
  - casts doubt on the safety or nutritional adequacy of other foods;
  - encourages or condones excessive consumption of a food;
  - encourages consumption of a food by stating or suggesting directly or indirectly that a balanced diet does not provide all the nutrients that are needed;
  - attempts to scare consumers by mentioning changes in bodily functions.

Japan

農林水産省

- The Japanese Agricultural Standard (JAS) System consists of the combination of “the JAS Standard System” and “the Quality Labeling Standard System.
  - Quality Labeling Standard System: Requires all producers, distributors and other parties to label in accordance with the Quality Labeling Standards established by the Minister of Agriculture, Forestry and Fisheries. All the Quality Labeling Standards are mandatory.
  - JAS Standard System: Refers to the certification system to attach the JAS marks to the products inspected in accordance with the JAS Standards established by the Minister of Agriculture, Forestry and Fisheries. The JAS Standards are voluntary other than JAS Standards for Organic Foods. The only Certified Business Entities such as producers and manufacturers can attach JAS marks to the products.

MAFF

Ministry of Agriculture, Forestry and Fisheries

消費者庁 Consumer Affairs Agency, Government of Japan

Source: http://www.caa.go.jp/en/index.html

A society where consumers and ordinary citizens play a leading role

There have been a number of incidents in recent years which have affected the everyday life of the people. Examples include poisoning by frozen gyoza imported from China, illegal distribution of tainted rice, carbon monoxide poisoning by gas water heaters, elevator accidents, and choking deaths from konjac jellies. A series of false food labeling cases were uncovered. Dishonest businesses targeting elderly people are rampant.

Behind these incidents is strong influence of past administrative policies which mainly focused on the perspectives of producers rather than consumers as well as the so-called "vertical bureaucracy".

The problem with the vertical bureaucracy was that a consumer who has encountered troubles would not know where to bring his complaint, or would be passed around from section to section even if one did. Furthermore, there was no central system to gather complaints and inquiries from consumers. As a result, the lack of sharing of information often delayed government response.

The Consumer Affairs Agency (CAA) was established on September 1, 2009 under such circumstances with the objectives of building a society where consumers and ordinary citizens play a leading role.

The CAA is the administrative agency that puts the best interest of consumers and ordinary citizens first.

For security at your table

Food labelling system

Food labels

Presentation of important information to consumers for their decision-making at stores.

In recent years, there have been a series of incidents, such as misrepresentation on food labels, which have undermined the confidence of consumers in the food they eat.

The food labelling system involves many laws, including the Food Sanitation Act which aims to prevent health hazards relating to food and beverages, the JAS Act which aims to assist consumer decision-making with the appropriate labelling of quality information, such as ingredients and product origin, and the Health Promotion Act which aims to improve nutrition for the people so as to promote their health.

In past, the Food Sanitation Act and the Health Promotion Act were under the jurisdiction of the Ministry of Health, Labor and Welfare, and the JAS Act under the Ministry of Agriculture, Forestry and Fisheries. Consumer Affairs Agency was given the mandate to govern these laws as a single agency to administer the food labelling system.

At present, we are working on issues relating to food labelling, including an expansion of the scope of requirements for identification of ingredients and product origins in processed foods, and a review of the ways to provide information on health foods on their labels.

We are also reviewing various ways to operate a single legal system relating to food labelling. We will be implementing necessary measures.

For shopping with peace of mind

Act against Unjustifiable Premiums and Misleading Representations

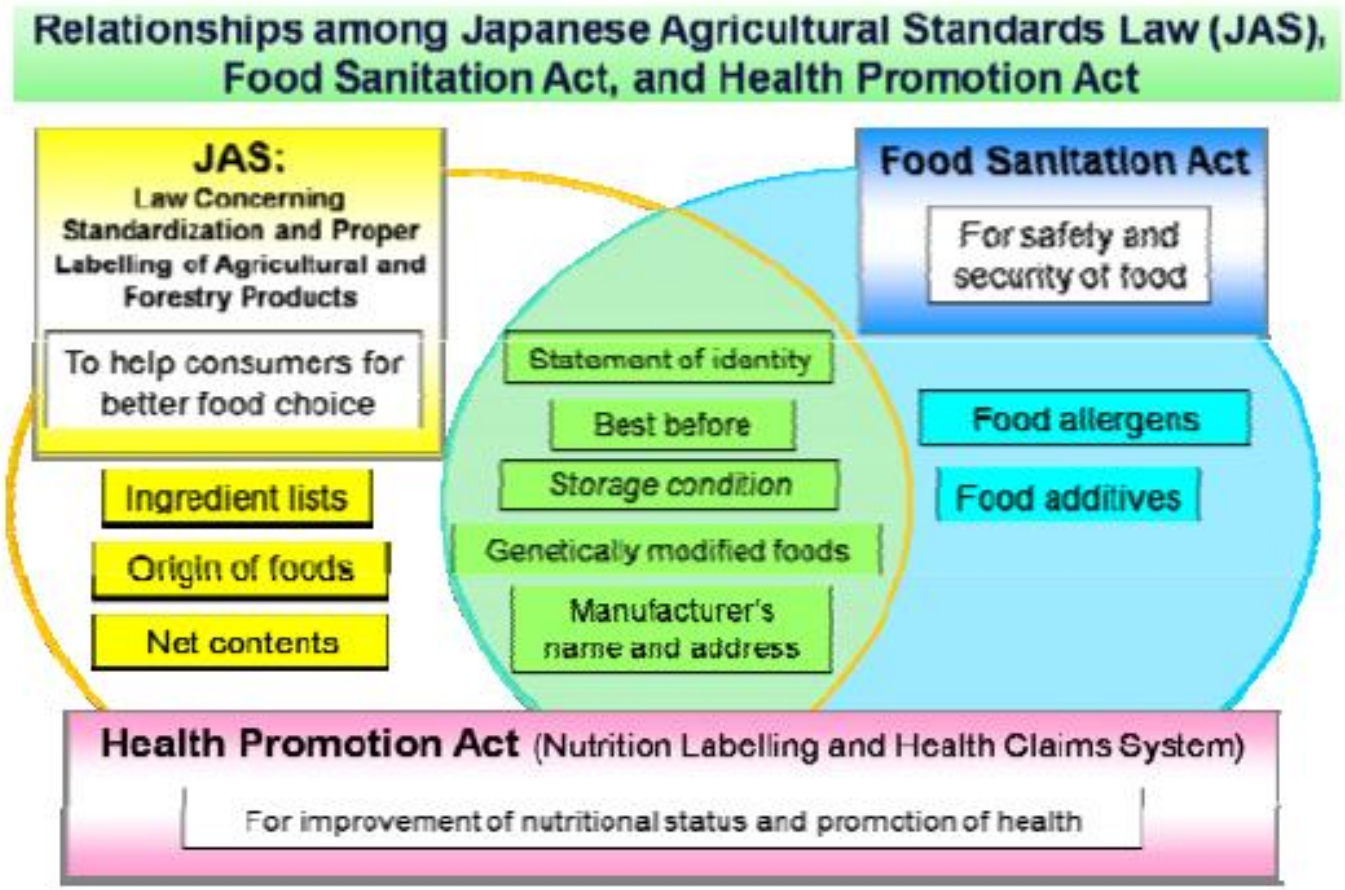
Rules for fair representation

Representations of quality and price are important clues for consumers to choose their products and services.

Consumers may be purchasing a poor quality or overpriced product or service without knowing it because of false or misleading representations. The Act against Unjustifiable Premiums and Misleading Representations (the "Premiums and Representation Act") exists to control such misleading representations. Consumer Affairs Agency is working hard to make your shopping environment worry-free based on this law.

Some examples of misrepresentation ...

Japan


Relationships among Japanese Agricultural Standards Law (JAS), Food Sanitation Act, and Health Promotion Act
JAS:
Law Concerning Standardization and Proper Labelling of Agricultural and Forestry Products
To help consumers for better food choice
Ingredient lists
Origin of foods
Net contents
Food Sanitation Act
For safety and security of food
Statement of identity
Best before
Storage condition
Genetically modified foods
Manufacturer's name and address
Food allergens
Food additives
Health Promotion Act (Nutrition Labelling and Health Claims System)
For improvement of nutritional status and promotion of health

Thank You