



Health Claim and FOSHU System in Japan

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What is “Food”?

Food Products (Food Sanitation Law)

- Foods with health claims
(So-called health foods)
- Other foods

Approximately
¥2 trillion

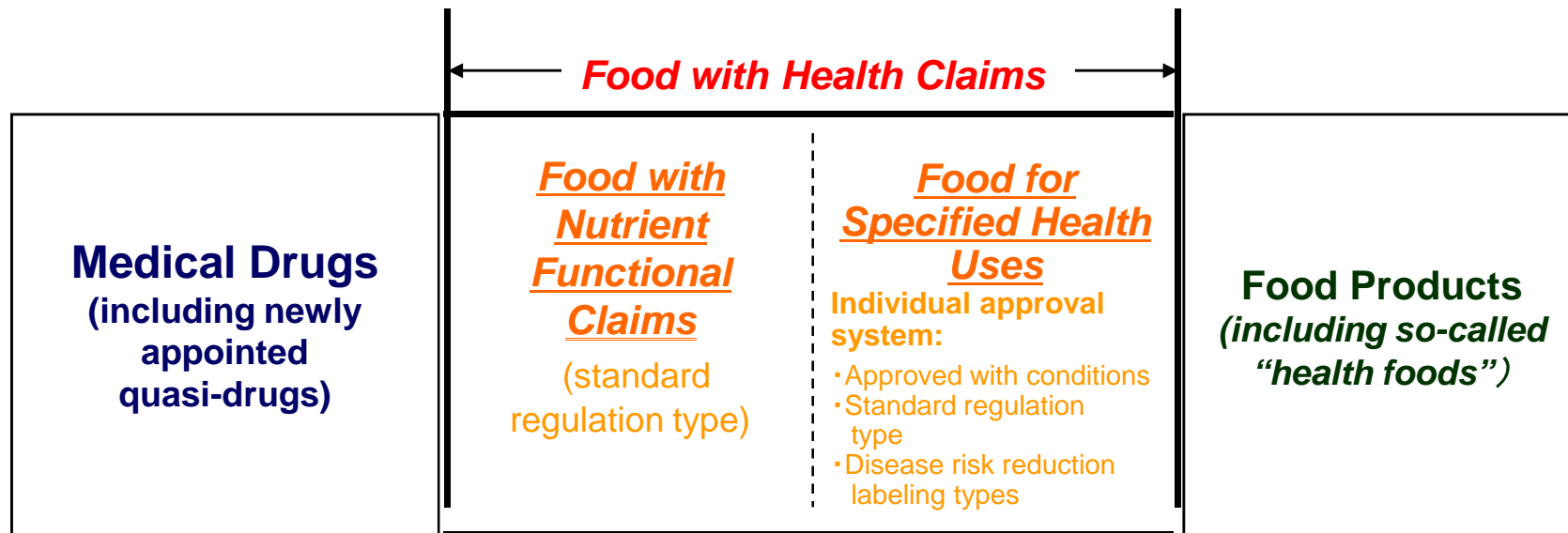
Pharmaceutical Products (Pharmaceutical Affairs Law)

- Listed in the Japanese Pharmacopeia
- Used for diagnosis, treatment, and prevention of diseases
- Used for purposes that have an effect on the structure and function of the body

Approximately
¥7.4 trillion



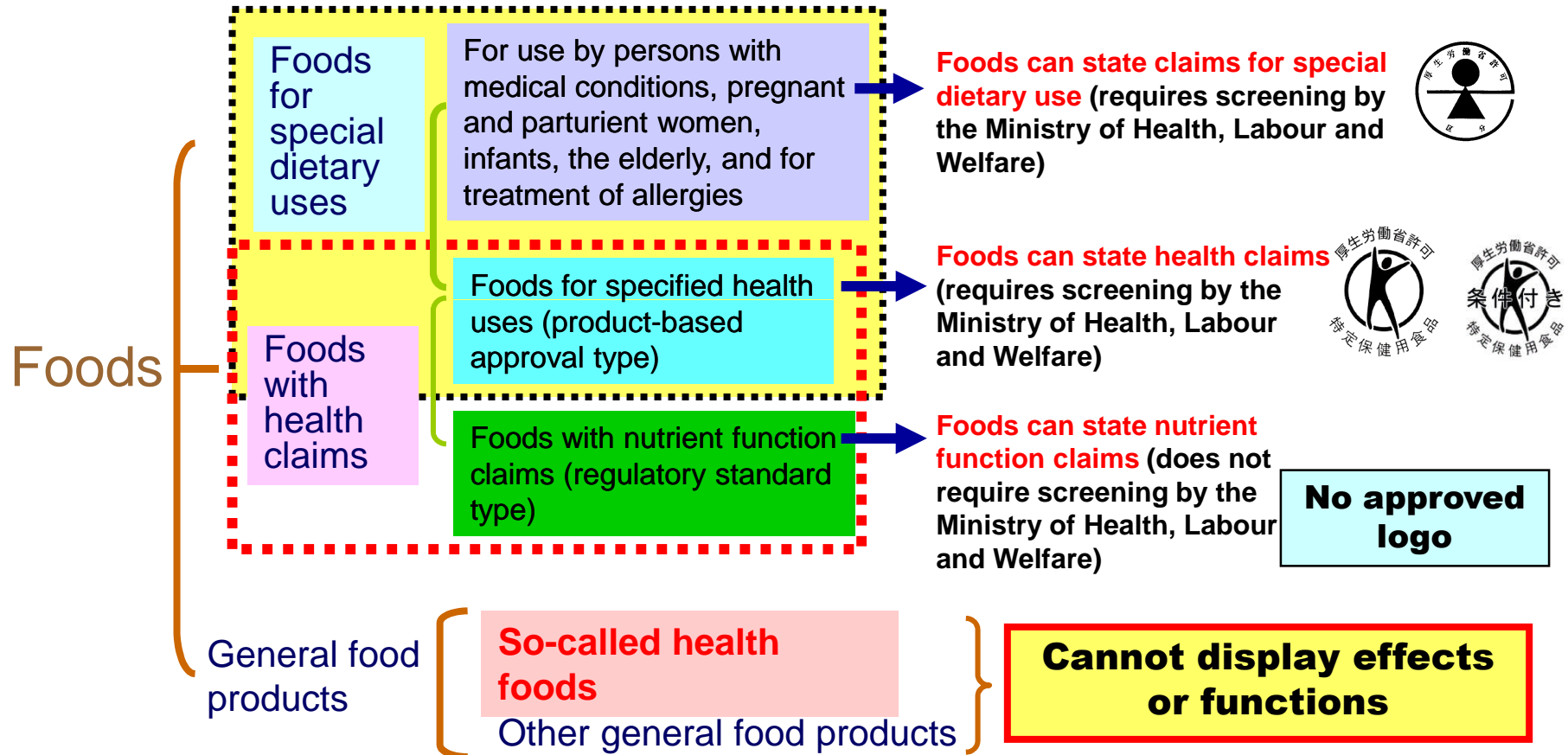
Categories of Food with Health Claims





Categories of Foods Classified by Use

Pharmaceuticals (including quasi-drugs)



“Health Foods” = Foods with Health Claims + So-Called Health Foods



Foods with Health Claims



What is the System of Foods with Health Claims?

- *Implemented in April 2001.*
- *Under this system, certain of the numerous and diverse*
“so-called health foods” that meet certain
conditions can be referred to as “foods with
health claims.”
- *There are two categories—“foods for specified*
health uses” and “foods with nutrient function
claims” with different approval conditions,
purposes, and functions, etc.



Background to the Creation of the System of Foods with Health Claims

- (1) Concern about the health of the public is increasing against a backdrop of confusion concerning eating habits, increases in lifestyle-related diseases, rising healthcare costs, etc. and demands concerning food functions are becoming more complex and diverse.*
- (2) Advances in food science and technological development are leading to the development of new foods with varied functions.*
- (3) Developments in regulatory schemes and internationalization are leading to reviews of food and pharmaceutical classifications.*
- (4) Demands from consumers for the provisions of appropriate information concerning foods are increasing.*
- (5) There have been some incidents of improper labeling and ingestion methods leading to risks to health and complaints concerning foods.*
- (6) In overseas, there has been increased consideration of regulatory standards for foods that have certain functions such as labeling that emphasizes health.*



***Foods
with Nutrient Function
Claims***



What are Foods with Nutrient Function Claims?

- *Foods with nutrient function claims are foods that supply or supplement the nutritional components (vitamins, minerals, etc.) that are necessary for sound growth, development of the body and the maintenance of health.*
- *With advancing age, confusion concerning proper eating habits, and others, it has become increasingly difficult to maintain normal eating habits; and foods with nutrient function claims are foods that supply or supplement nutritional components when it is not possible to obtain the necessary nutritional components each day.*



Handling of Foods with Nutrient Function Claims

- (1) The system for foods with nutrient function claims is a self-certifying one that does not require the filing of individual applications for approval or notice, etc. to the Minister of Health, Labour and Welfare (MHLW).*
- (2) The standards adopted by MHLW include bellows;
 - Regulatory standards that set upper and lower limits on nutrient functional components included that are ingested daily*
 - Labeling standards that specify the content of functions that can be indicated and warnings concerning the nutritional components that are ingested*Products with nutrient function claims must comply with these standards.*
- (3) Foods whose nutritional component functions may be labeled as foods with nutrient function claims are currently 12 vitamins and five minerals.*



Regulatory Standards for Foods with Nutrient Function Claims



Minerals

	Zinc	Calcium	Iron	Copper	Magnesium
Upper limit	15mg	600mg	10mg	6mg	300mg
Lower limit	2.10mg	210mg	2.25mg	0.18mg	75mg

Vitamins

	Niacin	Pantothenic Acid	Biotin	Vitamin A*
Upper limit	60mg	30mg	500µg	600µg(2,000IU)
Lower limit	3.3mg	1.65mg	14µg	135µg(450IU)

	Vitamin B1	Vitamin B2	Vitamin B6	Vitamin B12
Upper limit	25mg	12mg	10mg	60µg
Lower limit	0.30mg	0.33mg	0.30mg	0.60µg

	Vitamin C	Vitamin D	Vitamin E	Folic Acid
Upper limit	1,000mg	5.0µg(200IU)	150mg	200µg
Lower limit	24mg	1.50µg(60IU)	2.4mg	60µg

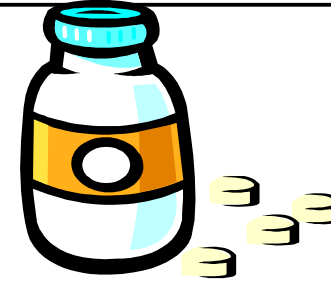
*Beta carotene, a precursor of vitamin A, is designated as a source of vitamin A for foods with nutrient function claims, but in that case the upper limit is 7,200 µg and the lower limit is 1,620 µg.



Representative Labels of Leading Product Formats for Foods with Nutrient Function Claims

Tablets, etc.: Chewable Multivitamins

(Vitamin B1 is a nutritional element that assists in the production of energy from carbohydrates and in maintaining the health of the skin and mucous membranes.)



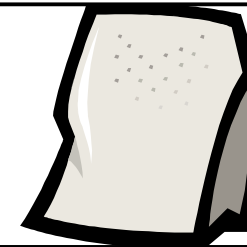
Capsules: Germ Oil Capsules

(Vitamin E is a nutritional element that has antioxidant effects that prevent oxidation of lipids in the body and helps maintain cellular health.)



Powder, etc.: Powdered Calcium

(Calcium is a nutritional element necessary for bone and tooth formation.)



Fruit Juice: Fruit Drinks with Iron

(Iron is a nutritional element necessary for red blood cell formation.)





Nutrient Function Claims and Warning Indication

Nutritional Ingredient	Function Claims	Warning Indication
Vitamin A	helps to maintain vision in the dark, and helps to maintain skin and mucosa healthy.	Increased intake of this product will not result in curing diseases nor promoting health. Please comply with the advisable daily intake. Women within the third months of pregnancy or women considering to be pregnant should be careful of over consumption.
Vitamin C	helps to maintain skin and mucosa healthy and has anti-oxidizing effect.	Increased intake of this product will not result in curing diseases nor promoting health. Please comply with the advisable daily intake.
Calcium	necessary in the development of bone and teeth.	Increased intake of this product will not result in curing diseases nor promoting health. Please comply with the advisable daily intake.



Example of Labeling on Package

商品名○○○

栄養機能食品(カルシウム)

カルシウムは、骨や歯の形成に必要な栄養素です。

「食生活は、主食、主菜、副菜を基本に、食事のバランスを。」

名称:カルシウム含有食品

原材料名:……、……、……

賞味期限:欄外に記載

内容量:○○g

製造者:△△株式会社

栄養成分表示:1粒当たり

エネルギー○kcal、たんぱく質○g、脂質○g、炭水化物○g、ナトリウム○g、カルシウム○mg

1日当たり摂取目安量:1日当たり2粒を目安にお召し上がり下さい。

摂取の方法及び摂取をする上での注意事項:水に溶かしてお召し上がり下さい。本品は多量摂取により疾病が治癒したり、より健康が増進するものではありません。1日の摂取目安量を守ってください。

1日当たりの摂取目安量に含まれる当該栄養成分の量が栄養素等表示基準値に占める割合:カルシウム○%

調理又は保存の方法:保存は高温多湿を避け、開封後キャップをしっかりと閉めて早めにお召し上がり下さい。

本品は、特定保健用食品と異なり、厚生労働大臣により個別審査を受けたものではありません。

※赤字は栄養機能食品としての義務表示事項

Name of product :○○○

Food with nutrient function claims (Calcium)

Calcium is a nutrient necessary for formation of bones and teeth.

“Eat well-balanced with staple food, as well as main and side dishes”

List of ingredients: …… , …… , ……

Best before : YY / MM / DD

Net content : ○○g

Manufacturer : ○○○

Nutrition Labeling : Per serving size (○○ g)

Energy : ○○ kcal, Protein: ○○ g, Fat: ○○ g, Carbohydrates: ○○ g, Sodium: ○○mg, Calcium: ○○mg

Recommended daily intake : “2 packages per day ”

Cautions in consuming the product : Consuming this product in a large quantity does not heal a disease or improve one’s health. Please keep the recommend daily in take.

The % of function claimable ingredient contained in the daily recommended intake level to the Nutrients Labeling Standard Value. : $\text{Calcium} \times \times \%$

Storage condition : Keep the product in a cool and dry place. Once opened fasten the cap tightly and consume it immediately.

This product has not undergone an individual evaluation by the Minister of Health, Labour and Welfare.



Ingredients Added to Foods with Nutrient Function Claims (Review)

Adoption of regulatory standards is currently being reviewed for the remaining vitamins and minerals for which nutrient function claims have not been approved (eight nutritional elements) from the perspective of normalization of function claims and providing appropriate information to consumers.

* The remaining vitamins and minerals are vitamin K, phosphorus, potassium, iodine, manganese, selenium, chromium, molybdenum

<Vitamin K, Phosphorus, and Potassium>

According to the nutritional element intake volumes from a national nutrition survey, the required amounts of these three nutritional elements are obtained across all ages groups.

<Iodine, Manganese, Selenium, Chromium, and Molybdenum>

No surveys of intake volumes, etc. have been conducted.

<Conclusions>

Accordingly, from the perspective of providing appropriate information to consumers concerning these eight nutritional elements, the database on safety and effectiveness for health foods of the National Institute of Health and Nutrition will be used for the time being to provide scientific information concerning nutritional ingredients.



Foods for Specified Health Uses





What are Foods for Specified Health Uses?

- *Foods for specified health uses are foods that include functional health ingredients with physiological functions and biological activity of the body and that state claims to the effect that the expected health functions can be expected from intake of the food with the intention of achieving a specific health function in eating habits.*
- *When foods are sold as foods for specified health uses, a screening by the national government must be conducted concerning the efficacy of the individual physiological functions and specified health functions as well as safety, etc. and approval must be obtained.*

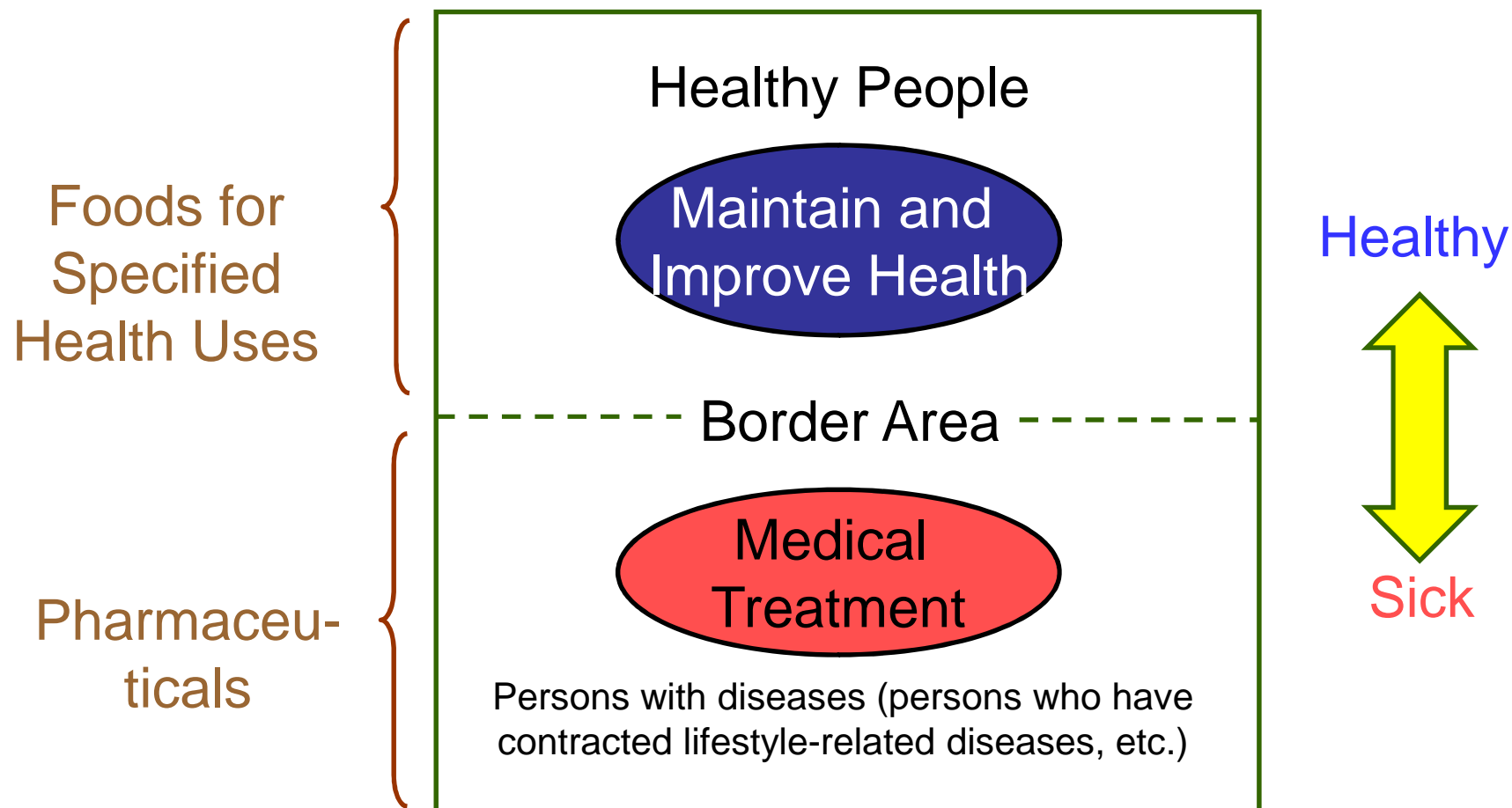


Applicable Scope of Foods for Specified Health Uses (Part 1)

Foods for specified health uses are foods that contribute to improving diets and thereby maintaining or improving the health of persons who have not yet contracted lifestyle-related diseases, etc. that arise from eating habits or who are on the verge of contracting such diseases.



Applicable Scope of Foods for Specified Health Uses (Part 2)





Example of Labeling on Package

特定保健用食品

商品名○○○

名称:清涼飲料水

原材料名:・・・

賞味期限:○○/△△/□□

内容量:○○g



許可表示:○○は△△を含んでいるため、食生活で不足しがちな食物繊維が手軽に取れ、お通じを良好に保つことに役立ちます。

栄養成分表示:1粒当たり

エネルギー○kcal、たんぱく質○g、脂質○g、炭水化物○g、ナトリウム○g、カルシウム○mg、関与成分○g

1日当たりの接種目安量:1日当たり2袋を目安にお召し上がり下さい。

摂取方法:水に溶かしてお召し上がり下さい。

摂取をする上での注意事項:一度に多量に摂りすぎると、おなかゆるくなることがあります。1日の摂取量を守ってください。

調理又は保存の方法:直射日光を避け、涼しいところに保存してください。

製造者:○○○株式会社 東京都△△区・・・

(1日あたりの摂取目安量に含まれる該当栄養成分の量が栄養素等表示基準値に占める割合:関与成分が栄養所要量の定められた成分である場合)

Food for Specified Heal

Name of product :○○○

List of ingredients:,

Best before :YY / MM / DD

Net content :○○g



Permitted Labeling : As this product is ○○-rich, you can easily take dietary fiber and keep the bowel movements in a good state.

“Eat well-balanced with staple food, as well as main and side dishes”

Nutrition Labeling : Per serving size (○○g)

Energy : ○○ kcal, **Protein:** ○○ g, **Fat:** ○○ g, **Carbohydrates:** ○○ g, **Sodium:** ○○ mg, **associated ingredient:** ○○ g

Recommended daily intake : “2 packages per day”

Warning : You may have loose bowels if you take the product in large quantities at one time.

Please keep the recommended daily intake.

Storage condition : Keep the product in a cool and dry place, away from direct sunlight.

Manufacturer : ○○○

※赤字は特定保健用食品としての義務表示事項



Categories of Foods for Specified Health Uses

• Foods for Specified Health Uses



• Foods for Specified Health Uses (regulatory standard type)

Those foods for specified health uses are foods that are capable of undergoing administrative review as there is established scientific basis concerning those foods such as an adequate approval record and that are approved under the regulatory standards **without individual screening** by the review committee.



• Foods for Specified Health Uses (disease risk reduction claims)

Those foods for specified health uses are foods that can indicate a **reduction of diseases risks** when the components have been medically and nutritionally established to reduce the risk of diseases.



• Conditional Foods for Specified Health Uses

Those foods concerning which certain effects have been scientifically confirmed but do not reach the level of ordinary foods for specified health uses and approval is **conditioned on indication of the limited scientific basis**.





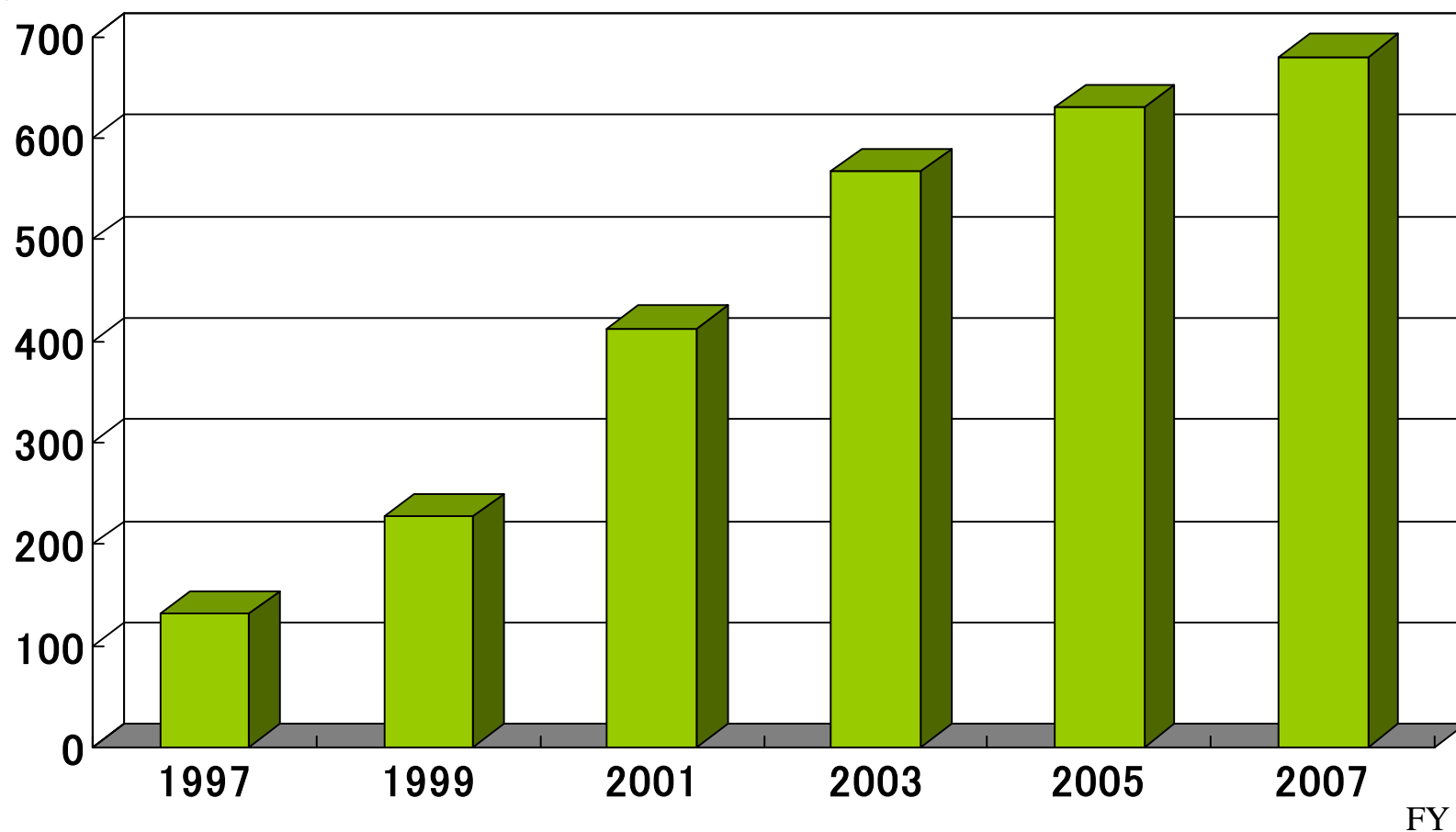
Breakdown of Designated Foods for Specified Health Uses (as of November 19, 2008)

Category	Number
Foods for specified health uses	531
Conditional foods for specified health uses	1
Foods for specified health uses (regulatory standard type)	18
Foods for specified health uses (disease risk reduction claims)	6
Foods for specified health uses (re-approved, etc.)	264
Total	820



Market Size of Foods for Specified Health Uses

billion yen



Source; Estimates made by Japan Health Food & Nutrition Food Association



Approval Requirements for Foods for Specified Health Uses

- ❑ *Efficacy in humans has been clearly established.*
- ❑ *There are no recognized safety problems (toxicity testing using animals, confirmation of effects in case of overdose, etc.)*
- ❑ *There are no nutritional problems (excessive salt, etc.)*
- ❑ *Compliance with products standards until the food is consumed has been confirmed.*
- ❑ *Quality control methods are established (product and ingredient standards, manufacturing methods, testing and inspections, etc.)*



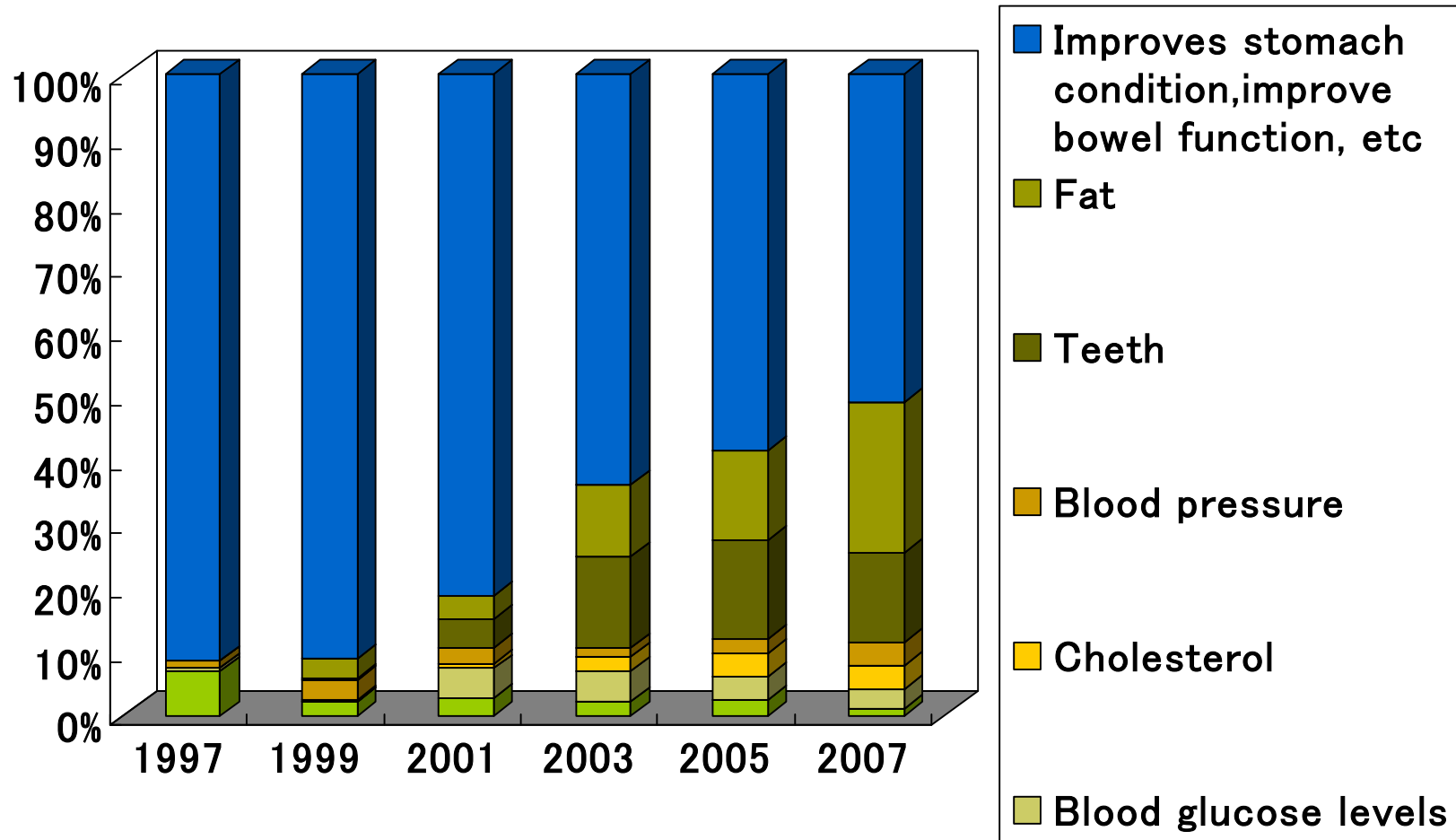
Classification of Approved Foods for Specified Health Uses by Health Effects

Content of Labeled Health Effects	Representative Ingredients	Number Approved	Percentage to total approved products (820 products)
Improves stomach condition, improve bowel function, etc.	Various oligosaccharides, lactulose, bifidobacteria, various lactic acid bacteria, dietary fiber (indigestible dextrin, polydextrose, guar gum, psyllium seed coat, etc.)	301	36.7
Blood glucose levels	Indigestible dextrin, wheat albumin, guava leaf polyphenol, L-arabinose, etc.	119	14.5
Blood pressure	Lactotripeptide, caseindodecapeptide, eucommia leaf glycoside (geniposidic acid), sardine peptide, etc.	102	12.4
Cholesterol	Chitosan, soy bean protein, low-molecular sodium alginate	95	11.6
Teeth	Paratinose, multitose, erythritol, etc.	65	7.9
Fat	Diacylglycerol, globin protein resolvent, etc.	60	7.3
Cholesterol and stomach condition, cholesterol and fat, etc.	Low-molecular sodium alginate, psyllium seed coat dietary fiber, etc.	33	4.0
Bones	Soy isoflavon, myelin basic protein (MBP), etc.	30	3.7
Mineral absorption	Calcium citrate malate, caseinphosphopeptides, heme iron, fructooligosaccharide, etc.	6	0.7

As of November 19, 2008



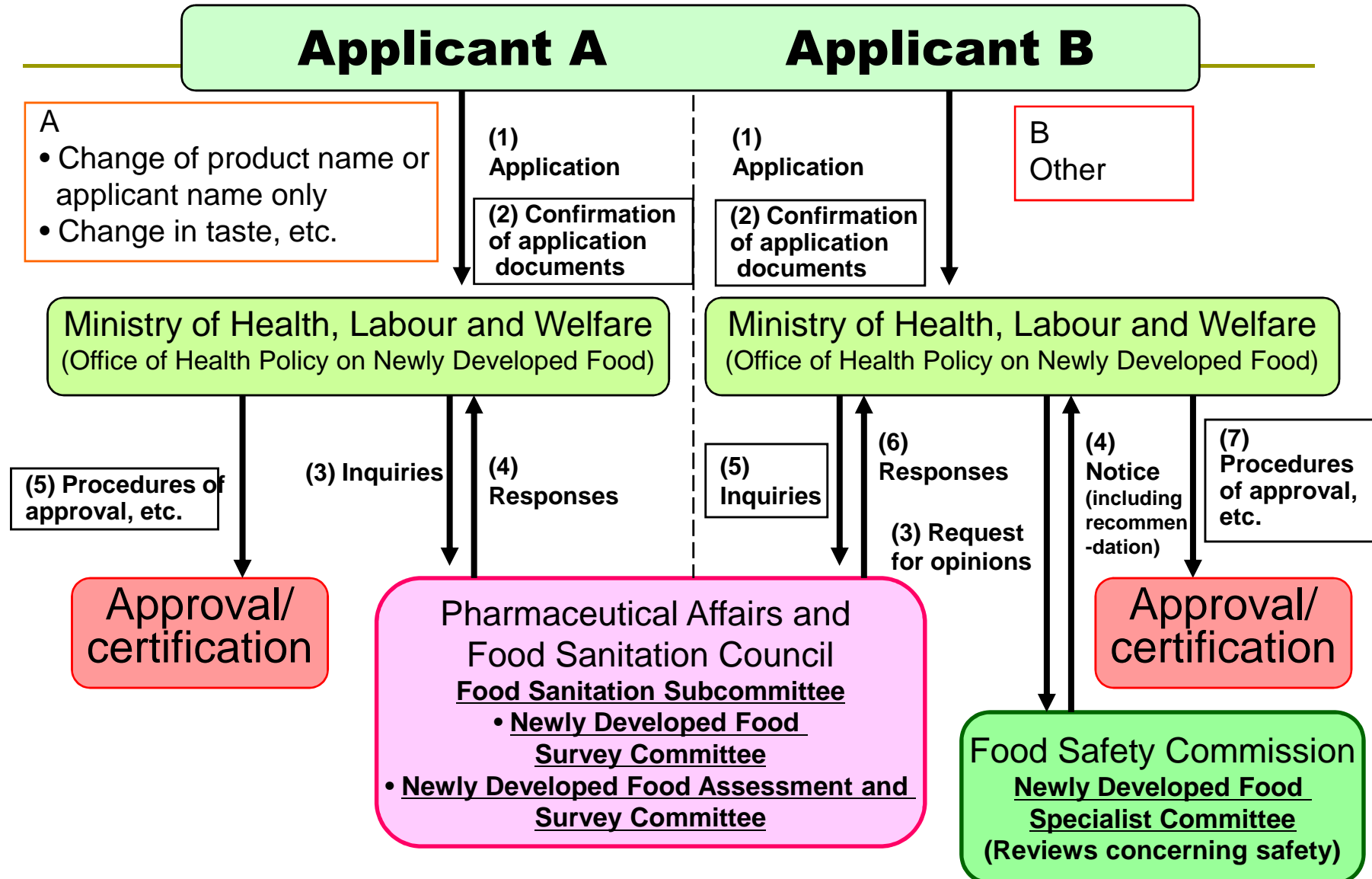
Proportional Transition of Foods for Specified Health Uses



Source; Estimates made by Japan Health Food & Nutrition Food Association

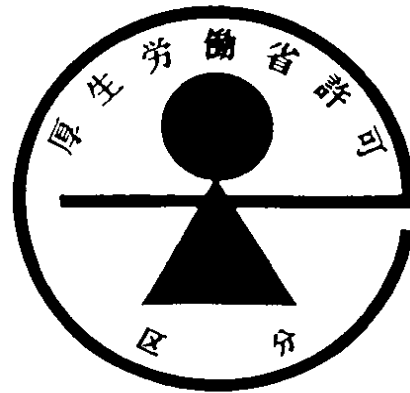


Review Procedure Flow for Foods for Specified Health Uses





Foods for Special Dietary Uses





What are Foods for Special Dietary Uses?

○ *Foods for special dietary uses are foods for persons with medical conditions, dried milk for pregnant and nursing women, formula milk for infants, foods for the elderly and that are labeled for special purposes such as the development of persons with medical conditions, etc. and maintenance and restoration of health.*

○ *When approving labeling, the suitability of those items for which there are established approval standards is reviewed and individual assessments are conducted for those items without approval standards.*

○ *Food formats include individual foods (soy sauce, jams, etc.) and compound foods (combinations of multiple foods).*

○ *Under the Health Promotion Law, approval for special-purpose labeling includes foods for specified health uses.*



Classification of Foods for Special Dietary Uses

Foods for Special Dietary Uses

Foods for persons with medical conditions (approval standard type)

Individual foods for persons with medical conditions

Low-sodium foods

Low-calorie foods

Low-protein foods

Low (no) protein, high-calorie foods

High-protein foods

Allergen-free foods

Lactose-free foods

Compound foods for persons with medical conditions

Low-sodium adjustment compound foods

Diabetes adjustment compound foods

Liver disease adjustment compound foods

Adult obesity adjustment compound foods

Foods for persons with medical conditions (product-based approval type)

Dried milk for pregnant and nursing women

Formula milk for infants

Foods for the elderly

Foods for persons who have trouble chewing

Foods for persons who have trouble chewing or swallowing

Foods for specified health uses (product-based approval type)



***Regulations Prohibiting
False and Misleading
Advertising, etc.***



Prohibition of False and Misleading Labeling, etc. under the Food Sanitation Law

False or misleading labeling or advertising that poses a risk of harm to public health is prohibited (Food Sanitation Law, Article 20)



- Revocation of business license, etc.
- Disposal of foods, etc.
- Penalties (imprisonment, fines)



Prohibition of False and Misleading Labeling, etc. concerning Health Maintenance and Promotion Effects, etc.

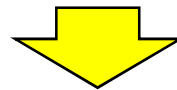
(Related to the Health Promotion Law, Articles 32-2 and 32-3)

Effective August 29, 2003

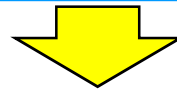
No person may engage in advertising or other labeling concerning a food that is offered for sale that is:

- (1) Differs substantially from the facts, or
- (2) Substantially confuses people

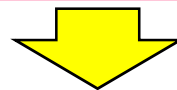
With respect to health maintenance or promotion effects.



If there is a risk of a significant impact on the maintenance or promotion of the health of the public, a recommendation shall be issued concerning the necessary measures that should be taken (Minister of Health, Labour and Welfare and heads of local health offices)



If the measures specified in the recommendation are not taken without due grounds, the person in question shall be ordered to take the specified measures (Minister of Health, Labour and Welfare and heads of local health offices)



If the person does not comply with the order, penalties shall be imposed (imprisonment of six months or less or a fine of 1 million yen or less)



Decision-Making Flow under the Provisions of Article 32-2

Labeling concerning Foods That Are Offered for Sale

Can the item objectively be determined to be advertising?

- (1) The intent of attracting customers (encouraging purchasing intent on the part of customers) is clear;
- (2) The name of a specific food, etc. is clear; and
- (3) The general public can understand the content.

Does the item claim health maintenance or promotion effects?

- (1) Health maintenance or promotion effects
- (2) Matters specified by Ministry of Health, Labour and Welfare ordinances
- (3) Indirect health maintenance or promotion effects, etc.

Does the advertising differ substantially from the facts or substantially confuse people?

When determining if the advertising differs substantially from the facts or substantially confuses people, the decision is based on the overall content and the impression and understanding of the general public.

A decision is made taking into consideration the detrimental impact on the health of the public based on the “subject food (does the food lend itself to incorrect expectations?)” and the “degree of strength of the appeal.”



Relationship with Regulation of Advertising, etc. under Other Laws

- ❑ **Pharmaceutical Affairs Law**
(Prohibition of advertising of medical products prior to approval, etc.)
- ❑ **Act against Unjustifiable Premiums and Misleading Representations**
(Regulations concerning transactions involving products and services)
- ❑ **Specific Commercial Transaction Law**
(Fairness in transactions involving designated products and preventing harm to purchasers)
- ❑ **JAS (Japanese Agricultural Standard) Law**
(Regulations concerning standardization and proper labeling of agricultural and forestry products)



***Information System
on Safety and
Effectiveness for Health
Foods, etc.***



Information System on Safety and Effectiveness for Health Foods, etc.

The National Institute of Health and Nutrition Web site has a list of representative health food ingredients and a system for obtaining objective information on the safety, effectiveness, etc. of each health food. <http://www.nih.go.jp/eiken>

Information on the Web Site

Basic knowledge concerning the use of health foods

(Health and eating habits, systems concerning health foods such as foods with health claims, analysis of scientific papers, etc.)

Information on the safety and harm of health foods

(Examples of harm to health, etc.)

Scientific information on food ingredients that are currently in the public light

(Information on individual foods for specified health uses, basic information on vitamins and minerals, etc.)

Health food ingredient database

- (1) Basic information (for the general public): names, summary, ingredient properties and quality, general information on safety and effectiveness
- (2) Detailed information (for specialists): In addition to the information in (1), analysis methods of main ingredients, assessment of safety and effectiveness based on animal and in vitro testing, and reference materials.