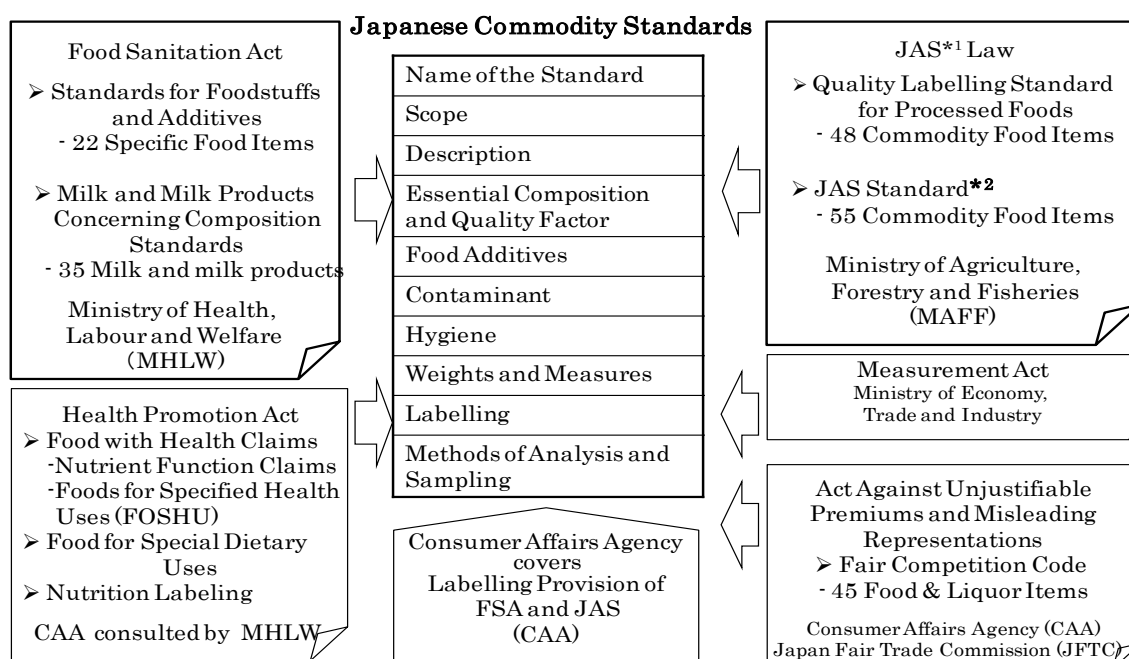


## 4.2 Japan

### 1. SUMMARY OF RELATIONSHIP BETWEEN FOOD REGULATORY SYSTEM AND COMMODITY STANDARDS

Summary chart of relationship between food regulatory system and commodity standards in Japan is shown in Figure 1.



\*1 Law Concerning Standardization and Proper Labelling of Agricultural and Forest Products  
 \*2 voluntary (other than organic foods) standard with the certification system to attach the JAS Mark  
 \*3 New governmental organization started in September 2009

**Figure 1 Summary of Relationship between Japanese Food Regulatory System and Commodity Standards**

## 2. FOOD SPECIFICATIONS AND QUALITY LABELING STANDARDS

### 2.1 Law concerning Standardization and Proper Labeling of Agricultural and Forestry Products (JAS Law)

The law consists of combination of “JAS Standards System” which is voluntary except for the JAS Standards for Organic Foods, and "the Quality Labeling Standards System" which mandate for quality labeling purposes including name of food, raw materials and place/country of origin.

#### (1) The Quality Labeling Standards System

The Quality Labeling Standards System provides cross-category standards for fresh foods, processed foods and genetically modified foods, and individual standards for 3

fresh foods and 48 processed foods (Table 1).

- Quality labeling standards for general application
  - fresh foods quality labeling standards
  - processed foods quality labeling standards
  - quality labeling standards regarding genetically modified foods

**Table 1: Individual Quality Labeling Standards for Processed Foods**

(MAFF) as of March 2010

	<b>Canned and Bottled Products</b>	25	Processed tomato
1	Canned and bottled agricultural products	26	Jams
2	Canned and bottled livestock products	27	Dried shiitake mushroom
3	Canned and bottled prepared foods		<b>Marine Products</b>
	Beverages	28	Processed <i>Uni</i> (sea urchin)
4	Fruits juice and fruit beverages	29	<i>Uni –Aemono</i> (mixture of sea urchin eggs and marine products)
5	Carbonated drinks <b>Case Study (2)</b>	30	Dried <i>Wakame</i> (undaria pinnatifida)
6	Soy milks	31	Salted <i>Wakame</i>
7	Carrot juice, Mixed carrot juice	32	<i>Kezuribushi</i> (shaved dried fish)
	<b>Livestock and Fish Paste</b>	33	Boiled and dried fishes
8	Bacon	34	Processed eel
9	Hams		<b>Seasoning</b>
10	Pressed ham	35	Dressing and dressing type seasonings
11	Mixed pressed ham	36	Edible vinegar
12	Sausage	37	Flavored seasonings
13	Mixed sausage	38	Dehydrated soup
14	Chilled hamburger stake	39	Worcester sauces
15	Chilled meat ball	40	Shoyu (Soy sauce)
16	Fish ham, Fish sausage	41	Miso (soy bean paste)
17	Specially packed steamed fish paste (abolished on Sep. 30, 2009)	42	Tuyu(Dipping soup) for noodles
18	Flavored steamed fish paste (abolished on Sep 30, 2009)		<b>Oil and Fat</b>
	<b>Cereal Products</b>	43	Edible vegetable oils and fats
19	Dried noodles	44	Margarine
20	Instant Noodles <b>Case Study (1)</b>		<b>Others</b>
21	Macaroni products	45	Retortable pouched food
22	Kori Dofu (dried frozen soy curd)	46	Frozen vegetable product
23	Breads	47	Chilled Gyoza
	<b>Agricultural and Forestry Products</b>	48	Prepared frozen food <b>Case Study (3)</b>
24	Pickled Agricultural products		

## (2) JAS Standards System

JAS Standards mainly stipulate quality, composition, grade and usefulness for food, forest and agricultural products including silk and rush tatami facing. JAS Standards System is a certification system to bear JAS marks on the label through certification by Registered Certifying Bodies. Products should meet to JAS standards, standards for maintenance

and quality control in manufacturing facility, performance of production process control etc.

As of March 2010, JAS Standards for food define 55 items in five areas (general JAS, specific JAS, organic JAS, JAS with product information, and JAS with controlled constant temperature distribution) (Table 2).

**Table 2: List of JAS Standards for Food**

(MAFF) as of Sep. 2009

■ GENERAL JAS		Seasoning	
<b>Canned and Bottled Products</b>		29	Dressings
1	Canned and bottled agricultural products	30	Fermented vinegar
2	Canned and bottled livestock products	31	Flavored seasonings
3	Canned and bottled marine products	32	Dehydrated soup
<b>Beverage</b>		33	Worcester sauces
4	Fruits juice and fruit beverages	34	<i>Shoyu</i> (soy sauce)
5	Apple straight pure juice	<b>Oil and Fat and their Processed Product</b>	
6	Carbonated drinks <b>Case Study (2)</b>	35	Edible vegetable oils and fats
7	Soy milks	36	Refined lard
8	Carrot juice, Mixed carrot juice	37	Margarines
<b>Livestock Products</b>		38	Shortening
9	Bacon	39	Edible refined and processed oils and fats
10	Hams	<b>Others</b>	
11	Pressed ham	40	Prepared frozen food <b>Case Study (3)</b>
12	Sausage	<b>■ SPECIFIC JAS WITH PRODUCTION METHODS</b>	
13	Mixed sausage	41	Matured Bacon
14	Hamburger patty	42	Matured Hams
15	Chilled ham burg stake	43	Matured sausage
16	Chilled meat ball	44	Handmade dried noodles
<b>Cereal Products</b>		45	Naturally Grown Chicken
17	Dried noodles	<b>■ ORGANIC JAS</b>	
18	Instant noodles <b>Case Study (1)</b>	46	Organic agricultural products
19	Macaroni products	47	Organic Processed foods
20	Vegetable protein	48	Organic feeds
21	Bread crumbs	49	Organic livestock products
<b>Processed Agricultural Products</b>		<b>■ JAS WITH PRODUCTION INFORMATION</b>	
22	Pickled agricultural products	50	Beef with the disclosed production information
23	Processed tomato products	51	Pork with the disclosed production information
24	Jams	52	Agricultural products with the disclosed production information
<b>Processed Marine Products</b>		53	Processed foods with the disclosed production information
25	<i>Kezuribushi</i> (shaved dried fish)	54	Farmed fishes with the disclosed production information
26	Boiled and dried fishes	<b>■ JAS WITH CONTROLLED CONSTANT TEMPERATURE DISTRIBUTION</b>	

	<b>Sugars</b>	55	Processed foods with controlled constant temperature distribution
27	Glucose		
28	High fructose corn syrup and sugar added high fructose corn syrup		

## 2.2 Food Sanitation Act and Related Laws and Regulations

Food Sanitation Act stipulates matters related food safety including food additives, pesticide residues, contaminants and hygiene.

### (1) Standards for Foodstuffs and Food Additives (Notification of Ministry of Health and Welfare No. 370)

Standards for Foodstuffs and Additives define standards for component, production and storage for 22 specific food items, in addition to general standards for component, production, processing and preparation, and storage for food (Table 3).

**Table 3: Specific Food Items in the Standards for Foodstuffs and Food Additives**

(MHLW) as of March 2010

1	Soft Drink Beverages <b>Case Study (2)</b>	12	Boiled Octopus
2	Powdered Soft Drink Beverages	13	Boiled Crab
3	Crushed Ice	14	Fresh Fish and Shellfish to be Eaten Raw
4	Frozen Confections	15	Oysters to be Eaten Raw
5	Meats and Whale Meat (with the exemption of frozen whale meat eaten raw)	16	Agar
6	Edible Birds' Eggs	17	Grains, Beans and Vegetables
7	Blood, Blood Corpuscles and Blood Plasma	18	Bean Jam or Further Processing
8	Meat Products	19	Soybean Curd ("tofu")
9	Whale Meat Products	20	Instant Noodles <b>Case Study (1)</b>
10	Fish-paste Products	21	Frozen Foods <b>Case Study (3)</b>
11	Salmon Roe and Cod Roe (defined as the ovaries of walleye or pollack preserved in salt; hereinafter the same in this section)	22	Food Packed in Containers and Sterilized by Pressurization and Heating

Note: 1. These standards are composed of 'Standard for Component', 'Standard for Production', 'Standard for Storage'

2. Details of Food Additives are available in English

<http://www.mhlw.go.jp/english/topics/foodsafety/foodadditives/index.html>

3.Details of Agricultural Chemical Residues are available in English  
<http://www.mhlw.go.jp/english/topics/foodsafety/positivelist060228/index.html>

## (2) Ministerial Ordinance on Compositional Standards for Milk and Milk Products (Ordinance of Ministry of Health and Welfare No. 52)

For milk and milk products, the ordinance specifically stipulates standards for component, production, storage and hygiene (Table 4).

**Table 4: Specific Items in Ministerial Ordinance on Compositional Standards for Milk and Milk Products** (MHLW) as of March 2010

<b>Raw Milk</b>		9	Concentrated milk
A	Raw Milk	10	Concentrated skimmed milk
B	Raw goat's milk	11	Evaporated milk
<b>Drinking Liquid Milks and Milk Drinks</b>		12	Evaporated skimmed milk
1	Cow's milk <b>Case Study (4)</b>	13	Sweetened condensed milk
2	Special cow's milk	14	Sweetened condensed skimmed milk
3	Pasteurized goat's milk	15	Whole milk powder
4	Composition-controlled cow's milk	16	Skimmed milk powder
5	Low fat cow's milk	17	Cream powder
6	Nonfat cow's milk	18	Whey powder
7	Processed milk	19	Whey powder protein concentrated
<b>Milk Products</b>		20	Butter milk powder
1	Cream	21	Sweetened milk powder
2	Butter	22	Formulated milk powder
3	Butter oil	23	Fermented milk
4	Processed cheese	24	Lactic acid bacteria drinks (nonfat milk solid not less than 3.0%)
5	Concentrated whey	25	Milk drinks
6	Ice cream	<b>Foods Mainly Made from Milk</b>	
7	Ice milk	1	Lactic acid bacteria drinks (nonfat milk solid less than 3.0%)
8	Lacto ice		

### 2.3 Fair Competition Code for Labeling of Food Items

Fair Competition Code based on Act against Unjustifiable Premiums and Misleading Representations stipulates voluntary standards for labeling of food items for individual firms and industry associations (Table 5), and is governed by Consumers Affairs Agency and the Fair Trade Commission. When their activities violate the code, penalty shall be imposed to their business activity. The Fair Trade Commission could take an action against even an outsider in accordance with social recognition of the code.

**Table 5: Fair Competition Code for Labeling of Food Items**

(CAA/FTC) as of Feb. 2010.03

<b>Milk and Milk Products</b>		19	Instant noodles	<b>Case Study (1)</b>
1	Drinking milk	20	<i>Miso</i> (soy bean paste)	
2	Fermented milk, Lactic acid bacteria beverage	<b>Confectionary</b>		
3	Pasteurized lactic acid bacteria beverage	21	Biscuits	
4	Natural cheese, Processed cheese, Cheese food	22	Chocolates	
5	Ice creams	23	Food using chocolate	
<b>Honeys</b>		24	Chewing gum	
6	Honeys	25	Souvenir for tourist	
7	Royal jelly	<b>Seasoning</b>		
<b>Processed marine Products</b>		26	Edible vinegar	
8	<i>Uni</i> (sea urchin) foods	27	Synthetic lemon juice	
9	<i>Karashi Mentaiko</i> (spicy marinated roe of pollack)	28	Margarines	
10	<i>Kezuribushi</i> (shaved dried fish)	29	Dressings	
11	<i>Nori</i> (laver)	30	<i>Shoyu</i> (soy sauce)	
<b>Processed Agricultural Products</b>		31	Table salt	
12	Canned foods	<b>Beverages</b>		
13	Processed tomato	32	Fruit drinks	
14	Powdered <i>Wasabi</i> (Japanese horseradish)	33	Coffee drinks	
15	Raw noodles	34	Regular coffee, instant coffee	
16	<i>Kori-dofu</i> (dried frozen soy curd)	35	<i>Moromi-su</i> (vinegar drink from residue of rice brandy)	
17	Soy milks	<b>Processed Livestock</b>		
18	Packed bread	36	Ham, sausage	

### 3. ACTS AND REGULATIONS RELATED TO FOOD ADDITIVES

#### 3.1 Overview

In Japan, food additives are regulated by the Ministry of Health, Labour and Welfare (MHLW). The main legal basis for regulation of food additives is found in the Food Sanitation Act (Act No. 233 of December 24, 1947) and its subsidiary legislations including:

- Ordinance of the Ministry of Health and Welfare No. 23 of July 13, 1948 “The Food Sanitation Act Enforcement Regulations”
- MHLW Notification No.370, December 28, 1959 “Specifications and Standards for Foods, Food Additives, etc.”
- Cabinet Office Ordinance No.45, August 31, 2011 on the criteria of labeling pursuant

to item (1) of Article 19 of Food Sanitation Act

The Act provides that:

- 1) Substances that are not permitted as food additives are not allowed to be used as food additives;
- 2) Permitted food additives that do not comply with specifications prescribed under the Food Sanitation Act, where such specifications are so described, are also not allowed to be used as food additives.
- 3) Manufacturing and/or use of permitted food additives should comply with standards of manufacture/use, including maximum level of use, prescribed under the Food Sanitation Act, where such standards are so described.
- 4) The government is responsible to compile “The Japanese Standards for Food Additives” to contain the standards and specifications.

Additionally, among 55 JAS Mark standards under the Law concerning Standardization and Proper Labeling of Agricultural and Forest Products (JAS Law), use of some food additives are restricted in the food so described. JAS Mark is voluntary certification system.

JAS Law also has the “Quality Labeling Standard” system. Among several standards of the system, all processed foods except for alcohol beverage are regulated by the “Quality Labeling Standard for Processed Foods” (Notification No.513 of the Ministry of Agriculture, Forestry and Fisheries of March 31, 2000). Food additives used in processed foods should be labeled in accordance with the standard.

### **3.2 Food Additive Definitions & Functional Classes**

Food additive in Japan is defined in Article 4-2 of the Food Sanitation Act as follows.

“Food additives” means substances to be used in or on food, in the process of the manufacturing of food or for the purpose of the processing or preserving of food, by adding, mixing, infiltrating, or other means.

Consequently, “food additive” includes both substances remaining in the finished food products, such as food colours and preservatives, and substances not remaining in the finished products, such as infiltration-supporting agents. Any substances added to food in order to maintain or increase the nutritional value of food is also included in “food additive”.

Article 4 of the Act also defines the term “natural flavouring agent” as follows.

“Natural flavouring agent” means food additives, intended for use for flavouring food, which are substances obtained from animals or plants, or mixtures thereof.

Neither “processing aid” nor “carry over” is defined in Article 4 (definition), but these are

defined in one of the regulations for food labeling, i.e., the provisions of article 19, paragraph 1, item 1-e of the Cabinet Office Ordinance No.45, 2011, on the Criteria of Labeling Pursuant to Item 1 of Article 19 of Food Sanitation Act. The provision defines that;

“Processing aids” means substances added to a food in processing the food, which are: 1) removed from the food before the completion of the food, 2) derived from raw materials of the food and converted into components normally included in the food but do not significantly increase the amounts of the components, or 3) present in the finished food at insignificant levels but do not have any technical or functional effect of these components on the food.

“Carry-over” means substances which are used in manufacturing or processing raw materials of a food and not used in manufacturing or processing the food and which are present in the finished food at levels less than those normally required to achieve any technical or functional effect in the food.

The provision of item 2 of article 1 of the Cabinet Office Ordinance No.45, 2011, on the Criteria of Labeling Pursuant to Item 1 of Article 19 of Food Sanitation Act, defines 8 functional classes of food additive. In case such food additive is used in food, not only the name of food additive but also the functional class of such food additive is requested to be labeled on the food. These 8 functional classes are 1) sweeteners, 2) colours, 3) preservatives, 4) thickeners/stabilizers/gelling agents, 5) antioxidants, 6) colour enhancers, 7) bleaching agents, and 8) antimold agents.

### **3.3 Permitted Food Additives and Maximum Limits**

Several lists of permitted food additives are described below. Newly designated food additive is listed as “Designated food additives” on the Attached Table 1 of the Food Sanitation Act Enforcement Regulations, July 13, 1948. There is no classification of function in these lists. Functional class of food additive is an important matter in labeling regulation.

#### **1) Designated food additives**

As of March 2012, 423 additives are designated as approved by the Minister of Health, Labour, and Welfare under Attached Table 1 of the Food Sanitation Act Enforcement Regulations, July 13, 1948.

Separately from the designation process described below (3.6 Application, Assessment, and Approval of Designation for New Food Additives), the MHLW has started a project to designate certain food additives which are not permitted their use in Japan but seemed to be important in international harmonization. The MHLW itself even carries out additional safety test when necessary. This action underlies such background that there is a growing possibility that imported foods may contain food additives that are authorized in other countries but unauthorized in Japan.



The numbers and examples of food additives which are newly designated to the list by this process in last 9 years are;

2004	7 items	magnesium stearate, magnesium triphosphate, isobutanol, 2,3,5,6-tetramethylpyrazine, etc.
2005	8	propanol, isopropanol, amyl alcohol, hydroxypropylcellulose, natamycin, etc.
2006	7	acetaldehyde, 2-ethyl-3-methylpyridine, butanol, potassium alginate, etc.
2007	6	tocopherol acetate ester, isobutyraldehyde, 2-methylbutanol, butylaldehyde, etc.
2008	18	calcium L-ascorbate, polysorbate 20, magnesium hydroxide, etc.
2009	6	nisin, isovaleraldehyde, 2,3-dimethylpyrazine, valeraldehyde, etc.
2010	18	2-ethylpyrazine, sodium stearyl lactylate, calcium sorbate, propionaldehyde, etc.
2011	12	5-ethyl-2-methylpyridine, pyrazine, 1-penten-3-ol, 3-methyl-2-butenal, isoquinoline, etc.
2012	5	trans-2-methyl-2-butanol, trimethylamine, saccharin calcium, 2-ethyl-6-methylpyrazine, 3-amino-3-carboxypropyl, dimethyl sulfonium chloride, etc.

## **2) Existing Food Additives**

Until 1995, the designation system had been applied only to chemically synthesized food additives. In 1995, Food Sanitation Act was amended and all types of additives are equally subject to the designation system, ignoring they are synthetic or non-synthetic, with minor exceptions, that is;

Substances that were already marketed or used on the date of the amendment of the Food Sanitation Act in 1995 were listed on the Existing Food Additives. The list was noticed in 1996 for the first time. The MHLW is conducting continuous survey of marketing and use of Existing Food Additives, and such additives that are no more marketed nor used are delisted from the list. The last delisting was in May, 2011, 53 food additives are delisted from the list.

Beside the marketing and use survey, akane-shikiso or Madder colour, colour from root of *Rubia tinctorum*, had been delisted from the list of Existing Food Additives based of the report from Food Safety Council in 2004.

As of March 2012, there are 365 Existing Food Additives in the list.

## **3) Natural Flavouring Agents**

See “3.2 Food Additive Definitions & Functional Classes” for the definition of natural flavouring agents. “Natural flavouring agent” is a food additive which is exempted from the designation system of food additives. Chemicals which can be used for extraction of natural flavouring agents and maximum residual level of such chemicals are regulated by

the manufacturing standards for several natural flavouring agents.

“List of plant or animal sources of natural flavourings” is given in Appendix 2, the CAA Notice, No. 377, October 20, 2010. This list is for labeling of “Natural flavouring agents” and is NOT a positive list of source of flavouring agents. If someone manufacture natural flavouring agent from a source which is not listed on the list, some scientifically proper name which can specify the source should be labeled on the flavour agents.

#### **4) Substances that are both generally provided for eating or drinking as foods and used as food additives**

Substances that are both generally provided for eating or drinking as foods and used as food additives have been excluded from the designation system.

“List of substances which are generally provided for eating or drinking as foods and which are used as food additives” is given in Appendix 3, the CAA Notice, No. 377, October 20, 2010. This list is also NOT a positive list of food additives that are both generally provided for eating or drinking as foods and used as food additives. If someone manufactures a food additive from a source which is not listed on the list, some scientifically proper name which can specify the source should be labeled on the flavour agents.

Standard of Use for food additives, including the maximum level of use, are described in the MHLW Notification No.370, 1959 “Specifications and Standards for Foods, Food Additives, etc.” Generally, if a food additive preparation contains food additives for which standards for use have been established, the established standards are regarded as standards for use for the preparation, but some exemption are specified.

### **3.4 Prohibited Substances for Use as Food Additives**

The food additive is controlled by the designation system (positive list) and there is no list of prohibited substances as food additives (negative list). However, among 55 JAS Mark Standards under the Law concerning Standardization and Proper Labeling of Agricultural and Forest Products (JAS Law), use of some food additives are restricted in the food so described. JAS Mark is voluntary certification system.

### **3.5 Specifications and Standards for Food Additives**

Food additives that are produced, imported and distributed must follow the specifications laid out in the MHLW Notification No.370, 1959 “Specifications and Standards for Foods, Food Additives, etc.”

### **3.6 Application, Assessment, and Designation for New Food Additives**

Designation of a new food additive is normally based on application from a person who wishes to use it. The MHLW will ask the Food Safety Commission for opinions concerning health effects of the food additive and the Pharmaceutical Affairs and Food Sanitation Council to discuss the adequacy of draft standards. If the discussion of the Pharmaceutical Affairs and Food Sanitation Council proves that the additive is safe and

effective, it will be designated as an additive approved for use.

Documents accompanying an application should contain;

- 1) Summary of documentation
- 2) Documentation on origin or details of development and overseas conditions on use
- 3) Documentation on physicochemical characteristics and specifications
- 4) Documentation on effectiveness
- 5) Documentation on safety
- 6) Documentation on draft standard of use

### **3.7 Labeling of Food Additives Used in Foods**

Labeling of food additives used in foods is regulated by both Food Sanitation Act and JAS law. The “Quality Labeling Standard for Processed Foods” (Notification No.513 of the Ministry of Agriculture, Forestry and Fisheries of March 31, 2000) requests food manufacturers that “Names of food additives shall be labeled in the descending order by weight in the total ingredients, pursuant to the provisions of article 1, item 2-e, item 4, article 11 and article 12 of the Cabinet Office Ordinance No.45, 2011, on the criteria of labeling pursuant to item 1 of Article 19 of Food Sanitation Act.

### **3.8 Official Compilation of “Japanese Standards of Food Additives”**

According to the article 21 of Food Sanitation Act, regarding additives for which the specifications and standards have been established pursuant to the provisions of Article 11, paragraph 1 and additives for which the labeling standards have been established pursuant to the provisions of Article 19, paragraph 1, the Minister of Health, Labour and Welfare shall compile the Japanese Standards of Food Additives to contain such specifications and standards.

The 1<sup>st</sup> edition of Japanese Standards of Food Additives were issued in 1960, the latest one is the 8<sup>th</sup> edition issued in 2007. English translation of the 7<sup>th</sup> edition, issued in 1999, is available on website (<http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/spec.stand.fa>).

### **3.9 Summary of Food Additives**

The definitions regarding food additives such as flavourings, processing aids, and carry over are summarized in Table 6, and other definitions such as designated/existing food additives and prohibited substances are summarized in Table7.

## **4. SPECIFICATIONS & STANDARDS AND METHODS OF ANALYSIS FOR GENERAL FOODS**

Specifications & Standards and Methods of Analysis for "General Foods" are shown in Table 8. Specifications & Standards and Methods of analysis for the food categories taken up in the Case Studies are described in these food categories, respectively.

## **5. CASE STUDIES**

### **(1) Instant Noodles**

#### **Commodity Food Standards and Methods of Analysis:**

Codex Commodity Standard for Instant Noodles was proposed by Japan and other Asian countries and adopted in 2006. Instant noodles are classified in 06.4.3 Pre-cooked pastas and noodles and like products in FCS (Food Category System) and this standard is a sole commodity standard in 06.4 category: Pastas, Noodles and like products.

In Table 9, summaries of "Instant Noodles" were compared with Codex Commodity Standards, Standards for Foodstuffs in Food Sanitation Act, Quality Labeling Standards in JAS Law and JAS Standards. In Table 10, the Methods of Analysis for "Instant Noodles" by Codex Standard are compared with those by Standards for Foodstuffs in Food Sanitation Act, Quality Labeling Standards in JAS Law, and JAS Standards.

#### **Food Additives:**

Standards for "Instant Noodles" is defined by Food Sanitation Act, but it only includes specification and standards of storage for oil-processed type Noodles. Limitation of use of some food additives to Instant Noodles (including their attached soups) are defined at JSFA. Standards including maximum limits for use of food additives are also defined by JAS Law (Table 11).

### **(2) Carbonated Soft Drinks**

#### **Commodity Food Standards and Methods of Analysis:**

In Codex Food Commodity Standards, beverages are classified in 14.0: Beverages excluding dairy products, 14.1: Non-alcoholic beverages and 14.2: Alcoholic beverages. Codex Commodity Food Standards defined in 14.1 are only for 3 items; Natural Mineral Waters (Stan 108-1981), Bottled/Packaged Waters other than natural mineral waters (Stan 227-2005) and Fruit juice and Nectars (Stan 247-2005).

Carbonated Drinks are fallen into 14.1.4.1: Carbonated water-based flavored drinks, in 14.1.4: Water-based flavored drinks including sport drinks, energy drinks and electrolyte beverages.

In Food Sanitation Act, Carbonated Drinks are included in wide-ranging "Soft Drinks"

defined in specified food items. Quality Labeling Standard and JAS Standard for "Carbonated Drinks" are set in JAS System. Summaries are compared in Tables 12 and 13.

#### **Food Additives:**

In Food Sanitation Act, there is a standard of use for food additives in "non-alcoholic beverage". Carbonated Soft Drinks is a subcategory of non-alcoholic beverage in FSA and there is no independent standard for Carbonated Soft Drinks in FSA.

"Carbonated Soft Drinks" is one of 55 JAS Mark standards under JAS Law. Limitation in use of some food additives to non-alcoholic beverage are defined at JSFA. Food additives which can be used in JAS Mark Carbonated Soft Drinks are restricted (Table 14).

### **(3) Prepared Frozen Foods**

#### **Commodity Food Standards and Methods of Analysis:**

JAS Quality Labeling Standard defines that Prepared Frozen Foods are Frozen Fried Foods, Frozen Shaomai, Frozen Gyoza, Frozen Harumaki (spring rolls), Frozen Hamburger Steaks, Frozen Meatballs, Frozen Fish Hamburgers, Frozen Fishballs, Frozen Steamed Rice and Frozen Noodles. Prepared Frozen Foods are defined as food filled into containers or food packaged. Quality labeling standard are defined in details including name of materials, their contents, and percentage of coating and wrapping material. Prepared Frozen Foods was selected for a case study because large amounts of their materials and processed products are being imported to Japan and they are foods in high demand. In Food Sanitation Act, Prepared Frozen Foods are included in wide-ranging Frozen Foods defined in specified food items and should follow microbiological criteria and storage standards.

Twenty-three commodity standards for quick frozen foods (for example, vegetables, fruits, meat, fish and shellfish) are defined in Codex, while only one commodity standard for corresponding prepared frozen food in Japan (Quick frozen Fish Sticks (Fish fingers)), Fish portions and fish Fillets-Breaded in Batter (Stan 166-1989). Table 15 provides table for their comparison.

#### **Food Additives:**

"Frozen Foods" is defined and standard for use of food additive in "Frozen Foods" is set in Food Sanitation Act. Under the Food Sanitation Act, the limitations in use of food additives are applied to the foods to be frozen, not to the frozen foods themselves. "Prepared Frozen Foods" is one of JAS Mark standards under JAS Law (Table 16).

### **(4) Cow's Milk**

#### **Commodity Food Standards and Methods of Analysis:**

Commodity Food Standards and Methods of Analysis for Cow's Milk are defined by the

Ministerial Ordinance on Compositional Standards for Milk and Milk Products (Table 5), and are described in Table 17.

**Food Additives:**

Use of Food Additives in Cow's Milk is prohibited by Food Sanitation Act. There is no JAS Standards for Cow's Milk (Table 18).

**Table 6: Summary/Definition of Food Additives (General)**

	<b>Summary/Definition</b>	<b>Reference</b>
<b>Related Legislation</b>	Food Sanitation Act, 1947	<a href="http://www.japaneselawtranslation.go.jp/law/detail/?id=12&amp;vm=04&amp;re=02">http://www.japaneselawtranslation.go.jp/law/detail/?id=12&amp;vm=04&amp;re=02</a>
<b>Summary (General)/Definition</b>		
<b>Definition of food additives</b>	“Food additives” means substances to be used in or on food, in the process of the manufacturing of food or for the purpose of the processing or preserving of food, by adding, mixing, infiltrating, or other means.	FSA Article 4, 2 <a href="http://www.mhlw.go.jp/english/topics/foodsafety/foodadditives/index.html">http://www.mhlw.go.jp/english/topics/foodsafety/foodadditives/index.html</a>
<b>Flavour</b>	Flavour is classified in the food additive category. “Natural flavouring agent” means food additives, intended for use for flavouring food, which are substances obtained from animals or plants, or mixtures thereof.	FSA Article 4, 3
<b>Processing aids</b>	Processing aid is classified in the food additive category.  “Processing aids” means substances added to a food in processing the food, which are: 1) removed from the food before the completion of the food, 2) derived from raw materials of the food and converted into components normally included in the food but do not significantly increase the amounts of the components, or 3) present in the finished food at insignificant levels but do not have any technical or functional effect of these components on the food.  “Processing aids” are not found in the functional classification of food additives. “Manufacturing agents” exist in the functional classifications, and are assumed to be the closest to “Processing aids” in Codex.	Article 21, 1-e, of the Food Sanitation Act Enforcement Regulations, 1948
<b>Carry-over</b>	“Carry-over” is defined, but only for labeling purposes. “Carry-over” means substances which are used in manufacturing or processing raw materials of a food and not used in manufacturing or processing the food and which are present in the finished product at levels less than those normally required to achieve any technical or functional effect in the food.	Article 21, 1-e, of the Food Sanitation Act Enforcement Regulations, 1948

**Table 7: Summary/Definition of Food Additives (Specific)**

	<b>Summary/Definition</b>	<b>Reference</b>
<b>Related legislation</b>	Food Sanitation Act, 1947	<a href="http://www.japaneselawtranslation.go.jp/law/detail/?id=12&amp;vm=04&amp;re=02">http://www.japaneselawtranslation.go.jp/law/detail/?id=12&amp;vm=04&amp;re=02</a>
<b>Summary (Specific)/Additional Laws</b>		
<b>1</b>	<b>List of Designated Food Additives</b>	Food additive is listed as “Designated food additives” on the attached table 1 of the Food Sanitation Act Enforcement Regulations, 1948. There is no classification of function in these lists. As of March 2012, 423 additives are designated as approved by the MHLW.
		<a href="http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/list-desin.add-x">http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/list-desin.add-x</a>
<b>2</b>	<b>List of Existing Food Additives</b>	Substances that were already marketed or used on the date of the amendment of the FSA in 1995 were listed on the Existing Food Additives. The MHLW is conducting continuous survey of marketing and use of food additives on the list. As of March 2012, there are 365 Existing Food Additives in the list.
		<a href="http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/list-exst.add">http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/list-exst.add</a>
<b>3</b>	<b>List of Plant or Animal sources for Flavouring agents</b>	“List of plant or animal sources of natural flavourings” is given in Appendix 2, the CAA Notice, No. 377, 2010. This list is for labeling of “Natural flavouring agents” and is NOT a positive list of source of flavouring agents.
		<a href="http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/list-nat.flavors">http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/list-nat.flavors</a>
<b>4</b>	<b>List of substances which are generally provided for eating or drinking as foods and are used as food additives as well</b>	Substances that are both generally provided for eating or drinking as foods and used as food additives have been excluded from the designation system. “List of substances which are generally provided for eating or drinking as foods and which are used as food additives” is given in Appendix 3, the CAA Notice, No. 377, 2010.
		<a href="http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/list-general.provd.add">http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/list-general.provd.add</a>
<b>Negative list</b>	There is no negative list of food additives under FSA.	
<b>Specifications of Food Additives, Weights and Measures, Contaminants, Methods of Analysis and Sampling, Standards of manufacturing of food additives</b>	The last 8 <sup>th</sup> edition is issued in 2007. English translation of 7 <sup>th</sup> edition, issued in 1999, is available on website.	<a href="http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/spec.stand.fa">http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/spec.stand.fa</a>
<b>Official publication and/or gazette for food additives</b>	Regarding additives for which the specifications and standards have been established pursuant to the provisions of Article 11, paragraph 1 and additives for which the labeling standards have been established pursuant to the provisions of Article 19, paragraph 1, the MHLW shall compile the Japanese Standards of Food Additives to contain such specifications and standards.	<a href="http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/spec.stand.fa">http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/spec.stand.fa</a>



**Table 8: Specifications and Methods of Analysis for General Foods**

Related Legislation	Item	Specification	Method of Analysis	Reference
Food Sanitation Act	Antibiotics or Chemically synthesized antibacterial substances	Shall not be contained in foods		Food Sanitation Test Guideline "Animal Medicine·Feed Additive 2003"
	Foods shall not contain substances used as ingredients of agricultural chemicals and other chemical substances	Not detectable in foods	Each Test Methodology of 2,4,5-T, Azocyclotin and cyhexatin, Amitrol, Captafol, Carbadox, Coumaphos, Chloramphenicol, Chlorpromazine, Diethylstilbestrol, Dimetridazole, Daminozide, Nitrofurazone, Nitrofurantoin, Furazolidone, Furaltadone, Propham, Malachite Green, Metronidazole and Ronidazole.	Specifications and Standards for Foods, Food Additives, etc.
	Pesticide residues in foods	The residual standard is individually provided.	Systematic or individual analytical methods are generally as follows:	Test methodology of the substances being the elements of agricultural chemicals, feed additives or verterinary products remaining in foods. (Notice from the Ministry of Health, Labour and Welfare)
	Compositional standards which are not specified in 0-1 through 0-3 shall not contain substances used as agiricultural chemicals nor other chemical substances in excess of the amount.	Not exceed 0.01mg/L	(1)Sample preparation→(2)Extraction with solvent→(3)Purification by chromatography→(4)Preparation of test solution→(5)Instrumental analysis: GC or GC-MS for volatile substances, LC or LC-MS for non-volatile substances etc.	

**Table 9: Case Study (1) Instant Noodles: Specifications & Standards (comparisons with Codex)**

	Codex Commodity Standard	Food Sanitation Act	JAS Law	
		Standard for Foodstuffs	Quality Labeling Standard	JAS Standard
<b>Name of the Standard</b>	Instant Noodles CODEX STAN 249-2006	Instant Noodles	Instant Noodles	Instant Noodles
<b>Scope</b>	ready for consumption after dehydration process	● Fried noodles	● include raw type	
<b>Description</b>	Fried noodles, Non-fried noodles			
<b>Essential Composition and Quality Factor</b>	3.1 Composition 3.1.1 Essential Ingredients 3.1.2 Optional Ingredients 3.2 Quality Criteria 3.2.1 Organoleptic 3.2.2 Foreign Matter 3.2.3 Analytical Requirement for Noodle Block (a) Moisture Content maximum : fried 10% : non-fried 14% (b) Acid value maximum 2mg KOH/g oil	● Acid value not more than 3 mg KOH/g oil ● Peroxide value not more than 30 meq/kg	● Wheat flower and/or buckwheat flower as the main ingredients ● Add salt or lye water	● Moisture not more than 14.5% (non-fried) ● Acid value not more than 1.5 mg KOH/g oil ● pH 3.8-4.8 (non-fried)
<b>Food Additives</b>	MRLs of GSFA			● Positive List (limited use)
<b>Contaminant</b>	MRLs of GSCTFF			
<b>Hygiene</b>	6. Containers or Packing Condition 7.1 General Principle of Food Hygiene and other relevant Codex Text 7.2 Principle for the establishment and application of Microbiological Criteria for Foods	● Storage Standard		● Container and Packing Condition
<b>Weights and Measures</b>				

<b>Labeling</b>	8.1 Name of the Food 8.2 Labeling for "HALAL"		● Specific Labeling Methods	● JAS Mark
<b>Methods of Analysis and Sampling</b>	9.1 Sampling 9.2 Determination of Moisture 9.3 Extraction of oil from Instant Noodle 9.4 Determination of Acid Value	● Acid value ● Peroxide value		● Moisture ● Acid value ● pH

\* This Table does not contain details of standards regulated for all foodstuffs such as;

- Quality Labeling Standard for Processed Foods ( JAS Law)
- General Compositional Standard for Food; General Food Production Processing and Preparation Standards; General Food Storage Standards (Food Sanitation Act)

**Table 10: Case Study (1) Instand Noodles: Specifications and Methods of Analysis**

Related Legislation	Item	Specification	Method of analysis	Reference
Food Sanitation Act	<b>Acid value</b>	Not more than 3 mg KOH/g oil	Acid value measurement method by titration	Specifications and Standards for Foods, Food Additives, etc.
	<b>Peroxide value</b>	Not more than 30 meq/kg	Peroxide value measurement method by titration	
JAS Standard	<b>Moisture</b>	Not more than 14.5% (non-fried)		
	<b>Acid value</b>	Not more than 1.5 mg KOH/g oil		
	<b>pH</b>	3.8-4.8 (non-fried)		

**Table 11: Case Study (1) Instant Noodles: Food Additives**

	Codex Commodity Standards or GFSA Food Categories	Food Sanitation Act	JAS Law (voluntary standards)
<b>Scope and/or Description</b>	Codex stan 249-2006 (Standard for Instant Noodles), (06.4.3) Pre-cooked pastas and noodles and like products	Standards for "Instant Noodles" is defined in Food Sanitation Act, but it only includes specification and standards of storage for oil-processed type Noodles. Limitation of use of some food additives to Instant Noodles (including their attached soup powder) are defined at JSFA.	Positive List (limitation in use)
<b>Positive and/or Negative List</b>			
<b>Use Limitation and/or Maximum Level, if any</b>			

"JAS" Law : The Law Concerning Standardization and Proper Labeling of Agriculture and Forestry Products.

**Table 12: Case Study (2) Carbonated Soft Drinks: Specifications & Standards**

	Food Sanitation Act	JAS Law	
	Standard for Foodstuffs	Quality Labeling Standard	JAS Standard
<b>Name of the Standard</b>	Soft Drink Beverages	Carbonated Soft Drinks	Carbonated Soft Drinks
<b>Scope</b>	Non-alcoholic (less than 1% alcohol) beverages, excluding lactic acid bacterial drinks, milk and milk drinks	Water-based flavoured drinks with added carbon dioxide, sweetener, acidulant and others	Water-based flavoured drinks with added carbon dioxide, sweetener, acidulant and others
<b>Description</b>			
<b>Essential Composition and Quality Factor</b>	<ul style="list-style-type: none"> <li>● Must not be turbid (with some exception)</li> <li>● Must not contain any sediment or any solid foreign matter (with some exception)</li> <li>● Must not contain detectable levels of arsenic, lead or cadmium. The tin content must not exceed 150.0 ppm</li> <li>● Tests for coliform bacilli must be negative</li> <li>● Mineral water with a carbon dioxide pressure inside of the container of not more than 98 kPa at 20 degree in Celsius , and that has not been sterilized or disinfected, must test negative for enterococci or green pus bacilli</li> <li>● For beverages made for solely apple juices and/or juiced fruit, the patulin content must not exceed 0.050 ppm</li> </ul>		<ul style="list-style-type: none"> <li>● Must have satisfactory tone of colour</li> <li>● Must have refreshing flavour without off-taste and off-odour</li> <li>● Must not be turbid (with some exception)</li> <li>● Must carbon dioxide be dissolved well and have fine bubbles sustainably</li> <li>● No foreign matters</li> </ul>
<b>Contaminant Hygiene</b>			
<b>Food Additives</b>			<ul style="list-style-type: none"> <li>● Preservative: only sodium benzoate and p-hydroxybenzoic acid allowed to use</li> <li>● Antioxidant: only L-ascorbic acid and sodium L-ascorbate allowed to use</li> <li>● Emulsifier: only sucrose fatty acid ester and glycerin fatty acid ester allowed to use</li> </ul>
<b>Weights and Measures</b>			Must meet designated volume appeared on the label
<b>Labeling</b>	<ul style="list-style-type: none"> <li>➢ Production Standards</li> <li>➢ Packaging Standards</li> <li>➢ Storage Standards</li> </ul>	Specific labeling methods	JAS mark
<b>Methods of Analysis and Sampling</b>	<ul style="list-style-type: none"> <li>● Tests for arsenic, lead, cadmium, tin, patulin, coliform bacilli, enterococci or green pus bacilli</li> <li>● Tests for water used as raw material</li> <li>● Standards and testing methods for implements, containers and packaging</li> </ul>		<ul style="list-style-type: none"> <li>● Gas volume</li> </ul>

**Table 13: Case Study (2) Carbonated Soft Drinks: Specifications and Methods of Analysis**

Sub-category	Related Legislation	Item	Specification	Method of analysis	Reference
<b>Soft drink beverages</b>	Food Sanitation Act	Turbidity	Negative		Specifications and Standards for Foods, Food Additives, etc.
		Foreign matter	Negative		
		Arsenic	Not detectable	Wet degradation method or Dry incineration method →Gutzeit method or Silver diethyldithiocarbamate method	
		Lead	Not detectable	Wet degradation method or Dry incineration method →Atomic absorption spectrophotometry or Polarographic analysis	
		Cadmium	Not detectable		
		Tin	Not exceed 150.00 ppm	Wet degradation method or Dry incineration method →Salicylidenamino-2-thiophenol method or Polarographic analysis	
		Coliform bacilli	Negative	Presumptive test (BTB lactose broth) →Confirmation test (Endo or EMB culture medium, or BGLB fermentation tube) →Conclusive test (Lactose broth fermentation tube and agar slant)	
<b>Mineral water</b>	Food Sanitation Act	Enterococci	Negative	Presumptive test (AC culture medium) →Confirmation test (new AC culture medium) →Conclusive test (Glucose agar medium)	
		Green pus bacilli	Negative	Presumptive test (Asparagine broth)→Confirmation test (Cetrimide agar medium)	

**Table 14: Case Study (2) Carbonated Soft Drinks: Food Additives**

	Codex Commodity Standards or GFSA Food Categories	Food Sanitation Act		JAS Law (voluntary standards)
<b>Scope and/or Description</b>	(14.1.2.1) Fruit juice	Maximum level of several food additives in “non-alcoholic beverage” is set in “the Standards for use of Food Additives ” Standards of soft drinks are described in FSA. But no positive/negative list on food additives in it.	<a href="http://www.ffcr.or.jp/zaidan/FFC_RHOME.nsf/pages/spec_stand_fa">http://www.ffcr.or.jp/zaidan/FFC_RHOME.nsf/pages/spec_stand_fa</a>	-Preservatives: only sodium benzoate and p-hydroxybenzoic acid allowed -Antioxidants: only L-ascorbic acid and sodium L-ascorbate allowed -Emulsifiers: only sucrose fatty acid esters and glycerin fatty acid esters allowed
<b>Positive and/or Negative List</b>	(14.1.3.1) Fruit nector			
<b>Use Limitation and/or Maximum Level, if any</b>	(14.1.4.1) Carbonated water-based flavoured drinks (14.2.2) Cider and Perry	In “the Standards for use of Food Additives”, maximum level of several food additives in “non-alcoholic beverage” is set and some food additives are prohibited to be used in “non-alcoholic beverages”.		

**Table 15: Case Study (3) Prepared Frozen Foods: Specifications and Methods of Analysis**

Related Legislation	Sub-category	Item	Specification	Method of analysis	Reference
Food Sanitation Act	Without heating	<b>Bacteria</b>	<100,000/g	Standard agar medium 35±1.0°C, 24±2h	Specifications and Standards for Foods, Food Additives, etc.
		<b>Coliform bacilli</b>	Negative	Presumptive test (desoxycholate agar medium) →EMB medium →Lactose broth fermentation tube and agar slant. The lactose broth fermentation tube : gas generation →agar slant : microscopic test →Gram-negative nonspore-forming bacilli : coliform bacilli positive	
	After heating (heated before freezing)	<b>Bacteria</b>	<100,000/g	Standard agar medium 35±1.0°C 24±2h	
		<b>Coliform bacilli</b>	Negative	Presumptive test (desoxycholate agar medium) →EMB medium →Lactose broth fermentation tube and agar slant. The lactose broth fermentation tube : gas generation →agar slant : microscopic test →Gram-negative nonspore-forming bacilli : coliform bacilli positive	
	After heating (other than 2 above)	<b>Bacteria</b>	<3,000,000/g	Standard agar medium 35±1.0°C, 24±2h	
		<b>Coliform bacilli</b>	Negative	EC fermentation tube (EMB medium) →Gas generation : Presumptive test positive →EMB medium →Lactose broth fermentation tube and agar slant. The lactose broth fermentation tube : gas generation →The agar slant : microscopic test →Gram-negative nonspore-forming bacilli : <i>E.coli</i> positive	

**Table 16: Case Study (3) Prepared Frozen Foods: Food Additives**

	<b>Codex Commodity Standards or GFSA Food Categories</b>	<b>Food Sanitation Act</b>	<b>JAS Law (voluntary standard)</b>
<b>Scope and/or Description</b>	Not applicable	Specifications of prepared frozen foods are described in FSA. No positive/negative list on food additives in it. The restrictions in use of food additives are applied to the foods to be frozen, not to the frozen foods.	Positive List (limitation in use)
<b>Positive and/or Negative List</b>			
<b>Use Limitation and/or Maximum Level, if any</b>			

**Table 17: Case Study (4) Cow's Milk: Specifications and Methods of Analysis**

<b>Related Legislation</b>	<b>Item</b>	<b>Specification</b>	<b>Method of analysis</b>	<b>Reference</b>
Ministerial Ordinance on Milk and Milk Products Concerning Compositional Standards	<b>Nonfat milk solids (%)</b>	8.0%<	Calculated by subtraction of the amount of milk fat % from the amount of the material % dried until a constant weight % at 98-100°C	Ministerial Ordinance on Milk and Milk Products Concerning Compositional Standards
	<b>Milk fat (%)</b>	3.0%<	The frequency of fat layer is expressed as the amount of fat % by operating of the Gerber lactobutyrometer etc.	
	<b>Specific gravity (at 15°C)</b>	1.028-1.034 (Those using milk of cows other than Jersey cows only as raw materials)	The measurement of specific gravity by the floatage type lactometers in the range of 1.015 to 1.040.	
		1.028-1.036 (Those using milk of Jersey cows only as raw materials)		
<b>Acidity (as lactic acid %)</b>	< 0.18% (Those using milk of cows other than Jersey cows only as raw materials)	Titration with sodium hydroxide solution		

		< 0.20% (Those using milk of Jersey cows only as raw materials)		
	<b>Bacteria (count /mL)</b>	< 50,000/mL	Standard agar medium (32-35°C 48±3h)	
	<b>Coliform bacilli</b>	Negative	BGLB fermentation tube : gas formation →E.MB medium →Lactose broth fermentation tube and agar slant. The lactose broth fermentation tube : gas generation →The agar slant : microscopic test →Gram-negative nonspore-forming bacilli : Coliform bacilli positive	

**Table 18: Case Study (4) Cow's Milk: Food Additives**

	<b>Codex Commodity Standards or GFSA Food Categories</b>	<b>Food Sanitation Act</b>		<b>JAS Law (voluntary standard)</b>
<b>Scope and/or Description</b>	01.1.1.1 Milk (plain)	Use of food additives in milk is prohibited or restricted by FSA	<a href="http://www.mhlw.go.jp/english/topics/foodsafety/dl/t-1.pdf">http://www.mhlw.go.jp/english/topics/foodsafety/dl/t-1.pdf</a>	No JAS Mark standard for Cow's Milk
<b>Positive and/or Negative List</b>				
<b>Use Limitation and/or Maximum Level, if any</b>				