

## **Food Additive Regulations: Investigation of Commodity Food Standards and Regulatory Framework on Food Additives in Asia**

*Mr. Hiroaki Hamano*  
*ILSI Japan*  
*Japan*

### **Purpose of the Project**

To support business activities of food industry in Asia (China, Korea, ASEAN countries and Japan) to strengthen their international competitiveness.

### **Description of the Project**

To contribute to the promotion of smooth business within Asian region by conducting an investigation on possible harmonization or integration of food standards and organizing an opportunity for dialogue with experts from countries concerned.

### **Summary of the Investigation**

In order to enhance regional food security and to expand distribution of food ingredients and food products in Asian region, commodity food standards on major food categories, methods of analysis and regulatory framework for food additives were investigated. Based on the results of the investigation, their differences and points to be considered for their possible future harmonization or integration were extracted and reviewed.

### **Countries Investigated**

In the light of marketability, such as population, business potential in Asian countries, the investigation covered the countries of China, Korea, Malaysia, Singapore, Philippines, Indonesia, Thailand, and Vietnam (8 countries) and Japan.

### **Food Categories Investigated**

Designing the investigation program, the first pilot formats covered Instant noodles, Carbonated soft drinks, Prepared frozen foods, Cow's milk and Food additives.

### **Method of Investigation**

The investigation program was designed by ILSI Japan and was conducted in cooperation with ILSI's international network, namely ILSI branches in China, Korea and Southeast Asia Region (ASEAN countries).

### **Information Sharing**

The first Workshop was held on March 29, 2010 in Tokyo, the second International Conference on March 4, 2011 in Bangkok, Thailand and the third International Conference for Sharing Information on Food Standards is to be held on February 21, 2012 In Jakarta, Indonesia.



**Overseas Business Support Project for Food Industry in Asia**

**Investigation of Commodity Food  
Standards and Methods of Analysis  
in Asia**

2012.02.21, Jakarta, Indonesia  
Hiroaki Hamano, ILSI Japan

**Overseas Business Support Project  
for Food Industry in Asia**

**[ Purpose of the Project ]**

**To support business activities of food industry in  
Asia (ASEAN + 3 countries) to ensure food  
security in the region and to strengthen their  
international competitiveness**

**[ Description of the Project ]**

**To contribute to the promotion of smooth  
business within Asian region by conducting an  
investigation on possible harmonization or  
integration of food standards and/or methods  
of analysis, and organizing an opportunity for  
dialogue with experts from countries concerned**

**“Investigation of Commodity Food Standards and Analytical Methods in Asia”**

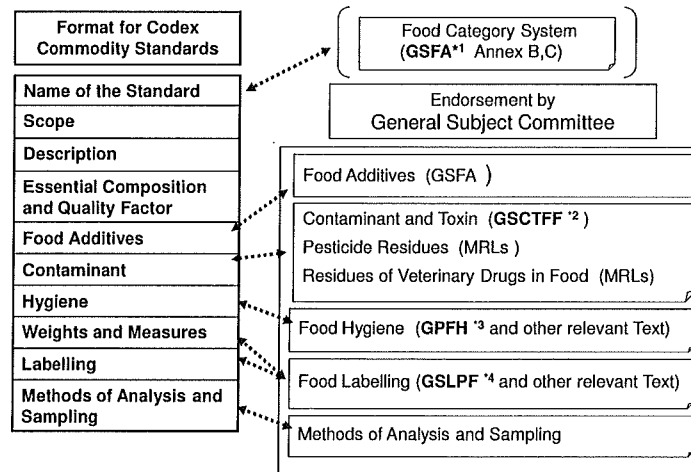
**1<sup>st</sup> Term: June 2009 - March 2010**

**Objectives:**

- **To investigate regulatory framework on food and commodity food standards, taking examples of Instant noodles, Carbonated soft drinks and Prepared frozen foods**
- **To facilitate harmonization of food standards/regulations and fare trade in Asia , and further to help secure food safety within Asian region**
- **To build ILSI Asian branches close communication/collaboration**

**Elaboration of Codex Commodity Standards**

Procedural Manual : Section III Elaboration of Codex Standards and Related Text

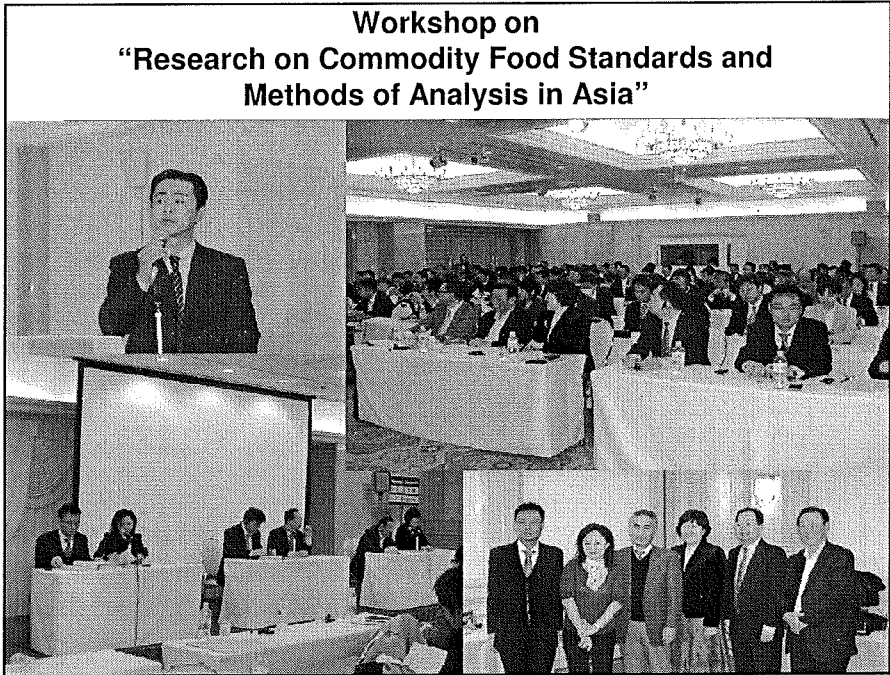
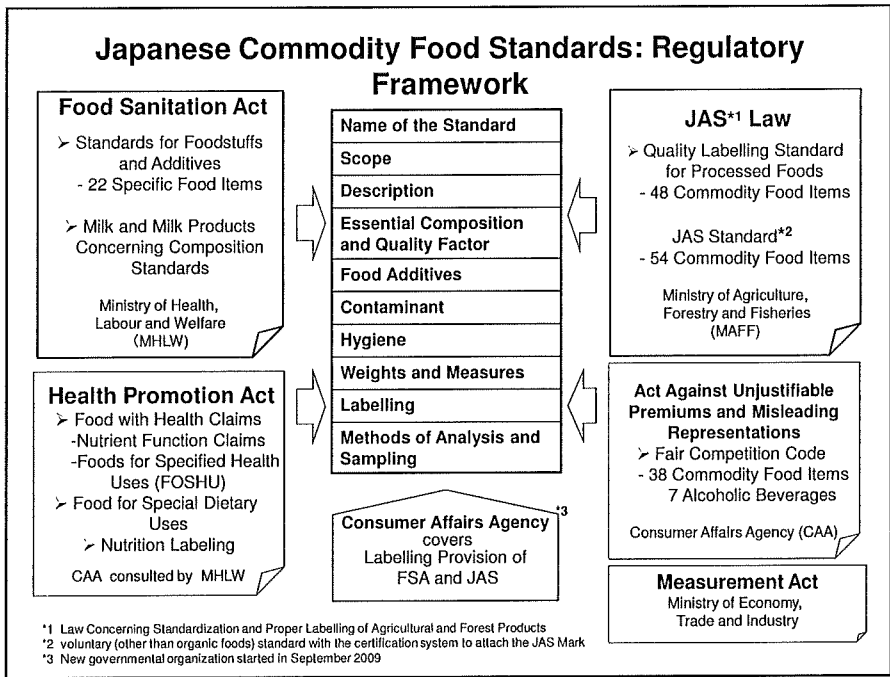


\*1 Codex Stan 192-1955 General Standard for Food Additives

\*2 Codex Stan 193-1995 General Standard for Contaminants and Toxins in Foods and Feeds

\*3 CAC/RCP1-1969 General Principles of Food Hygiene

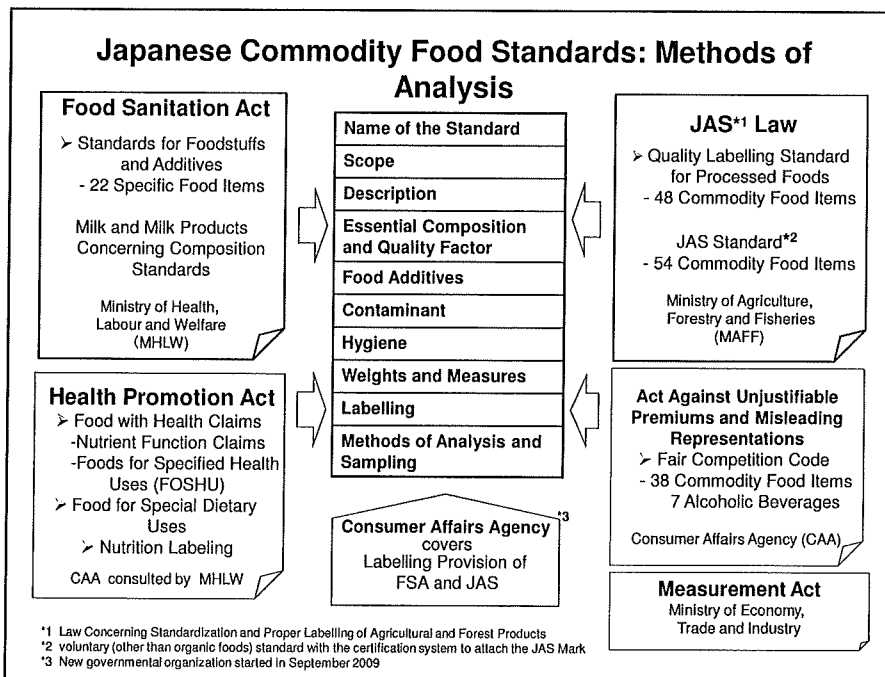
\*4 Codex Stan 1-1985 General Standards for the Labelling of Prepackaged Foods



## “Investigation of Commodity Food Standards and Analytical Methods in Asia”

**2<sup>nd</sup> Term (June 2010 – March 2011):**

- **To expand the countries, i.e. Indonesia, Thailand and Vietnam** (in addition to Malaysia, Philippines and Singapore), **and to further add Cow’s milk** (in addition to Instant noodles, Carbonated soft drinks and Prepared frozen foods) **to investigate**
- **To investigate Methods of Analysis for the foods concerned**
- **To have the 2<sup>nd</sup> International Conference in Bangkok, Thailand (March 4, 2011)**



<sup>\*1</sup> Law Concerning Standardization and Proper Labelling of Agricultural and Forest Products

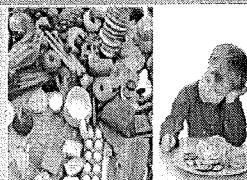
<sup>\*2</sup> voluntary (other than organic foods) standard with the certification system to attach the JAS Mark

<sup>\*3</sup> New governmental organization started in September 2009

| Research on Methods of Analysis in Asia: Food in General (Japan) |  |   |   |  |
|--|--|---|---|--|
| Legislation  | Item   | Specification                                   | Methods of Analysis   | Reference  |
| Food Sanitation Act  | Antibiotics or chemically synthesized antibacterial substances   | Shall not be contained in foods                 |   | Food sanitation test guidance on "Veterinary Medicine & Food Additives 2003"   |
|  | Foods shall not contain substances used as ingredients of agricultural chemicals and other chemical substances   | Not detectable in foods                         | Each test method of 2,4,5-T, Azocyclotin and cyhexatin, Amitrol, Captafol, Carbadox, Coumaphos, Chloramphenicol, Chlorpromazine, Diethylstilbestrol, Dimetriadazole, Daminozide, Nitrofurazone, Nitrofurantoin, Furazolidone, Furfaltadone, Propham, Malachite Green, Metroidazole and Ronidazole                         | Specifications and Standards for Foods, Food Additives, etc.<br><br>Test methods of the substances being the elements of agricultural chemicals, feed additives or veterinary products remaining in foods (Notice from the MHLW) |
|  | Pesticide residues in foods  | The residual standards is individually provided |   |  |
|  | Compositional standards which are not specified in the above shall not contain substances used as agricultural chemicals nor other chemical substances in excess of amount | Not exceed 0.01mg/kg                            | Systematic or individual analytical methods are generally as follows:<br>(1) Sample preparation<br>(2) Extraction with solvent<br>(3) Purification by chromatography<br>(4) Preparation of test solution<br>(5) Instrumental analysis: GC or GC-MS for volatile substances, LC or LC-MS for non-volatile substances, etc. |  |

**International Conference for Sharing Information on Food Standards, Resource and Environmental Conservation for Food Industries in Asia-Pacific**

**Challenges and Opportunities for Food Safety & Human Health**




**March 4, 2011**  
Fahruwan Princess Hotel  
Bangkok, Thailand

**Sponsor:**  
Ministry of Agriculture, Forestry and Fisheries (MAFF), Japan

**Supporters:**  
Food and Drug Administration (FDA), Thailand  
National Bureau of Agricultural Products Inspection and Quarantine (NAPIS), Thailand

**Organizer:**  
International Life Sciences Institute (ILSI) Japan  
In collaboration with  
HLS Food Food in Asia  
HLS Asia  
HLS Southeast Asia Pacific

## International Conference for Sharing Information on Food Standards, Resource and Environmental Conservation for Food Industries in Asia-Pacific

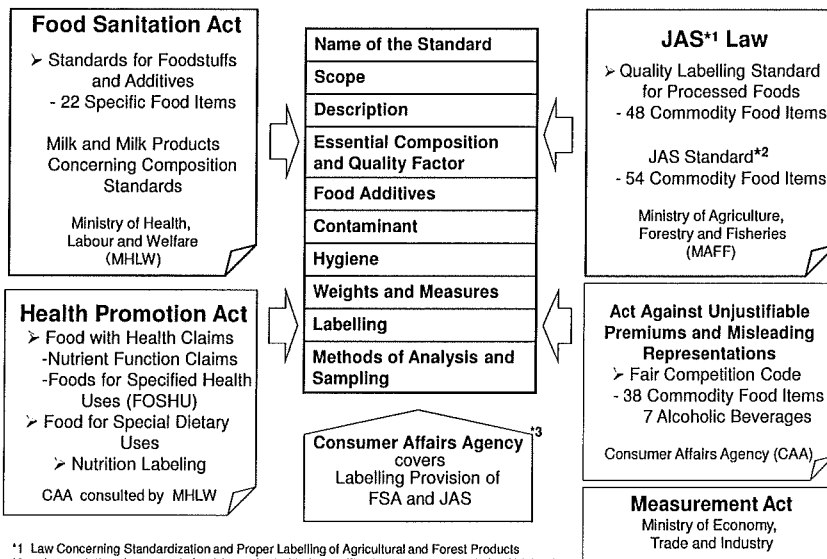


## “Investigation of Commodity Food Standards and Analytical Methods in Asia”

### 3rd Term (July 2011 – March 2012):

- To investigate Regulatory Framework on Food Additives in countries concerned
- To preliminarily start investigating Regulatory Framework on Foods in India, and the Data-base System for the data/ information collected
- To have the 3rd International Conference in Jakarta, Indonesia (Feb. 21, 2012)

### Regulatory Framework for Food Additives in Japan



\*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



### 1-1. Regulatory Framework for Food Additives in Japan

|   | Description / Definition   | Reference  |
|---|--|--|
| Related Legislation                       | 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>General descriptions / Definitions</b> |  |  |
| Definition of Food Additives              | "Food Additive" 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.    | <b>FSA Article 4, 2</b><br><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> |
| Flavors                                   | Flavor is classified in the food additive category.<br>"Natural Flavoring Agent" means food additives, intended for use for flavoring food, which are substances obtained from animals or plants, or mixtures thereof. | <b>FSA Article 4, 3</b>  |
| Processing aids                           | Processing aid is classified in the food additive category.  | <b>Article 21, 1-e, of the Food Sanitation Act Enforcement Regulations, 1948</b>   |
| Carry-over                                | "Carry-over" is defined, but only for labelling purposes.  | <b>Article 21, 1-e, of the Food Sanitation Act Enforcement Regulations, 1948</b>   |

### 1-2. Regulatory Framework for Food Additives in Japan

|   | Description / Definition   | Reference  |
|---|--|--|
| Related Legislation   | Food Sanitation Act (FSA), 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>Specific descriptions / Additional explanations</b>  |  |  |
| 1 List of Designated Food Additives   | Originally listed from so-called Synthetic Food Additives until 1996. From 1996 it includes those permitted for their use through "designation" process whether natural or synthetic | <b>Table 1 of Article 12 of the Ministerial Ordinance</b><br><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> |
| 2 List of Existing Food Additives   | Listed in 1996 from so-called Natural Food Additives   | <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>  |
| 3 List of Plant or Animal sources for Flavoring agents  | Natural Flavoring 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>  |
| 4 List of substances which are generally provided for eating or drinking as foods and are used as food additives as well                            |  | <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>  |
| Negative List (if any)  | There is no negative list of food additives under FSA.   |  |
| Specifications of Food Additives, Weighs and Measures, Contaminants, Methods of Analysis and Sampling, Standards of manufacturing of food additives | "Japan's Specifications and Standards for Food Additives" published by the Ministry of Health, Labor and Welfare, 2000   | <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>  |
| Official publication and/or Gazette for food additives  | Food Sanitation Act, Article 21<br><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>         |  |

## 2-1. Case Studies on Food Additives in Japan

| 1. Instant Noodles                     |   | Food Sanitation Act  |   | JAS Law (voluntary standards) |  |  |
|--|---|--|---|-------------------------------|--|--|
| Scope and/or Descriptions              | No description in FSA   | Positive List (limitation in use)  | Ref. to the attached Table 2  |                               |  |  |
| Positive and/or Negative List          |   |  |   |                               |  |  |
| Use Limitation / Maximum Level, if any |   |  |   |                               |  |  |
| 2. Carbonated Soft Drinks              |   | Food Sanitation Act  |   | JAS Law (voluntary standards) |  |  |
| Scope and/or Descriptions              | Specifications of soft drinks are described in FSA.   | Section 1, Article D in Specifications and Standards for Food, Food Additives, etc. under FSA<br><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> | -Preservatives: only sodium benzoate and p-hydroxybenzoic acid allowed<br><br>-Antioxidants: only L-ascorbic acid and sodium L-ascorbate allowed<br><br>-Emulsifiers: only sucrose fatty acid esters and glycerin fatty acid esters allowed | Ref. to the attached Table 2  |  |  |
| Positive and/or Negative List          | No positive/negative list on food additives   |  |   |                               |  |  |
| Use Limitation / Maximum Level, if any | Some food additives are not allowed to use in soft drinks and maximum levels in soft drinks are set for another food additives. |  |   |                               |  |  |

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

## 2-2. Case Studies on Food Additives in Japan

| 3. Prepared Frozen Foods               |   | Food Sanitation Act  |   | JAS Law (voluntary standards) |  |  |
|--|---|--|---|-------------------------------|--|--|
| Scope and/or Descriptions              | Specifications of prepared frozen foods are described in FSA. No positive/negative list on food additives | Section 1, Article D in Specifications and Standards for Food, Food Additives, etc. under FSA.   | Positive List (limitation in use)                 | Ref. to the attached Table 2  |  |  |
| Positive and/or Negative List          |   |  |   |                               |  |  |
| Use Limitation / Maximum Level, if any |   |  |   |                               |  |  |
| 4. Cow's Milk                          |   | Food Sanitation Act  |   | JAS Law (voluntary standards) |  |  |
| Scope and/or Descriptions              | Use of food additives in milk is prohibited or restricted by FSA  | Article 2 of "Attached Table" of the Ministerial Ordinance on Milk and Milk Products Concerning Compositional Standards, etc., 1951<br><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 Japanese Agricultural Standards for Cow's Milk |                               |  |  |
| Positive and/or Negative List          |   |  |   |                               |  |  |
| Use Limitation / Maximum Level, if any |   |  |   |                               |  |  |

**International Conference for Sharing Information on Food Standards in Asia**

**[ Objectives ]**

In order to ensure regional food security through enhancing international competitiveness of the regional food industry, it is the key to enhance industry's understanding of food standards.

This Conference aims to:

- (1) Share information on commodity food standards and methods of analysis in the region,
- (2) Share information on regional initiatives for food standards harmonization,
- (3) Share information on food safety issues, such as on risk communication.

These should facilitate possible future harmonization or integration of food standards in Asia, which should also facilitate food trade and enhance business opportunities in the region.

International Conference for Sharing Information on  
Food Standards in Asia

***Thank you very much  
for your participation !!***

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## **Regulatory Framework for Food Additives in China**

***Dr. Li Yu***  
***Mars Foods***  
***China***

The regulatory framework for food additives in China consists of a series standards which regulate production and preparation of food additives, their use in foods, and test methods respectively.

The definition of food additives is stated in the “GB2760 Standard for use of food additives”, in which it is also states the general principle of using food additives, including food flavoring agents and food processing aids. Example and case studies are given in the presentation to introduce how the standard works in details. Standards of specification, test, or preparation of food additives are not introduced in details. One who may be interest of that can find these standards from the official food safety information website at:

<http://www.nfsiw.gov.cn/publicfiles/business/htmlfiles/foodaqxxw/s69/index.html>.

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## **Regulatory Framework for Food Additives in China**

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ILSI Japan/MAFF Project :  
Investigation of Commodity Food Standard  
and Analytical Methods in Asia

Yu Li PhD,  
ILSI FP China;  
Mars Foods (China)

Feb 2012, Jakarta

## **Regulatory Framework for Food Additives in China**

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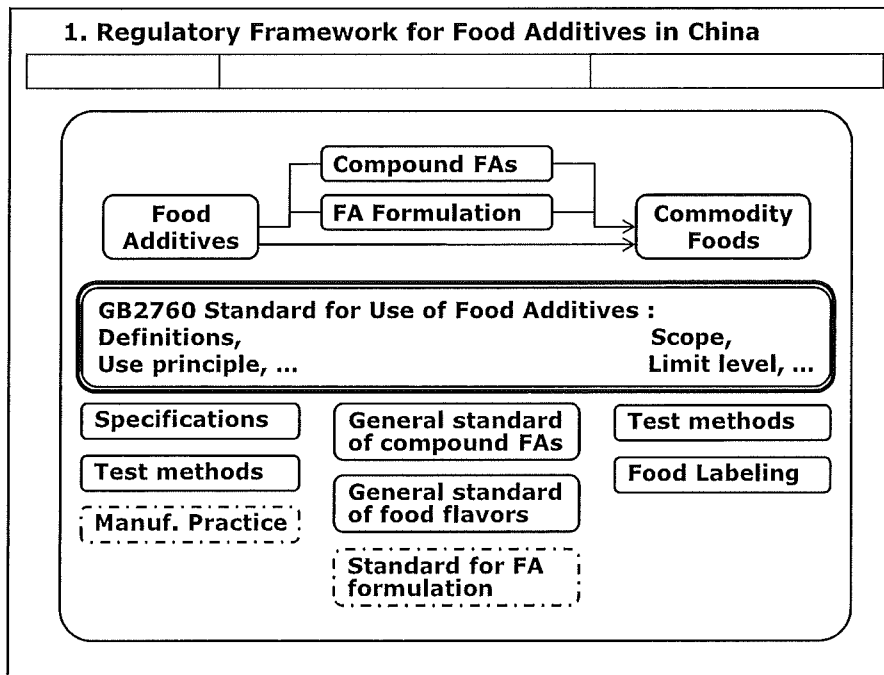
### **Abstract**

The regulatory framework for food additives in China consists of a series standards which regulate production and preparation of food additives, their use in foods, and test methods respectively.

The definition of food additives is stated in the "GB2760 Standard for use of food additives", in which it is also states the general principle of using food additives, including food flavoring agents and food processing aids. Example and case studies are given in the presentation to introduce how the standard works in details.

Standards of specification, test, or preparation of food additives are not introduced in details. One who may be interest of that can find these standards from the official food safety information website at:

<http://www.nfsiw.gov.cn/publicfiles/business/htmlfiles/foodaqxxw/s69/index.html>



| 1-1. Regulatory Framework for Food Additives in China |  |   |
|---|--|---|
|   | Regulation/Standard Name   | Reference   |
| <b>Related Legislation</b>                            | <b>GB2760-2011 Standard for Use of Food Additives</b>  | <a href="http://www.nfsiw.gov.cn/publicfiles/business/htmlfiles/foodaqxw/cmsmedia/document/doc321.pdf">http://www.nfsiw.gov.cn/publicfiles/business/htmlfiles/foodaqxw/cmsmedia/document/doc321.pdf</a> |
| <b>General descriptions / Definitions</b>             |  |   |
| <b>Food Additives</b>                                 | Food additive refers to an artificially chemosynthetic or natural substance to be added to foods in order to improve food quality, color, fragrance and taste, and for the purpose of preservation, fresh keeping and processing technology. Nutrition enhancers, flavoring agents, gum-based substances in chewing gum and processing aids in food industry are also included in food additives.  | <b>GB2760-2011 Article 2. Terms and definitions: 2.1 Food additive</b>  |
| <b>"Carry-over" Principles</b>                        | In the following cases, food additives can be introduced into foods through ingredients (including food additives):<br>1. The food additive can be used in ingredients according to this standard;<br>2. The level of the additive in food ingredients should not exceed the allowable maximum level;<br>3. These ingredients shall be applied in the normal production process. The content of this additive in the food should not exceed the level that is carried over by the ingredients;<br>4. The content of this additive introduced into the food by ingredients shall be notably lower than the required level of such additive through direct adding into the food. | <b>GB2760-2011 Article 3. Principles for use of food additives: 3.4 Carry-over principles</b>   |



### 1-1. Regulatory Framework for Food Additives in China

#### General descriptions / Definitions (continued 1)

|  |  |   |
|--|--|---|
| <p><b>Provisions for Application of Food Additives</b></p> | <p>1. Table A.1 stipulates the allowable varieties, scope of application, and maximum level or residue level of food Additives;<br/>                 2. For food additives with the same function (colorings of same color, preservatives, and antioxidant) as specified in Tables A.1, when used together, the sum of their respective ratios to the maximum level should not exceed 1;<br/>                 3. Table A.2 lists all additives that can be used in all types of foods with appropriate dose as required in production;<br/>                 4. Table A.3 specifies food categories in exception to Table A.2. When using food additives, these food categories should comply with provisions in Tables A.1, and they shall not use food additives allowed in higher food categories as stipulated in Tables A.1;<br/>                 5. Tables A.1 and A.2 do not cover stipulations about food flavorings, gum-based substances in chewing gums, and processing aids;<br/>                 6. The column "function" in above tables refers to the main functions of the additive for reference during application.</p> | <p><b>GB2760-2011 Annex A. Provisions for Application of Food Additives</b></p> |
|--|--|---|

### 1-1. Regulatory Framework for Food Additives in China

#### General descriptions / Definitions (continued 2)

|                                    |   |   |
|------------------------------------|---|---|
| <p><b>Flavoring Agents</b></p>     | <p>Processing aid refers to various kinds of substances to enable food processing to go smoothly, irrelative to food itself, for example, filtration aids, clarifiers, absorbents, lubricants, mold release agents, de-coloring agents, peeling agents, extraction solvents, and nutritional substances for fermentation, etc.</p>  | <p><b>GB2760-2011 Article 2. Terms and definitions: 2.4 Food processing aid; Annex C. Provisions on Use of Processing Aid for Food Industry ("processing aid"): C.1 Principles for use of processing aids</b></p> |
| <p><b>Food Processing Aids</b></p> | <p>The flavoring agents and flavoring essences are used in foods in order to create, change or improve the flavor of foods. The flavoring agents are usually made into flavoring essences for flavoring the food, but some of them may be directly added into the food. The flavoring agents and flavoring essences exclude the substances which only make the food sweet, sour or salty and the flavor enhancer.</p> | <p><b>GB2760-2011 Annex B. Provision on Use of Flavoring Agents: B.1 Principles for application of flavoring agents and flavoring essences</b></p>  |

### 1-2. Regulatory Framework for Food Additives in China

|  | Description / Definition                              | Reference   |                                |
|--|---|---|--------------------------------|
| <b>Related Legislation</b>                             | <b>GB2760-2011 Standard for Use of Food Additives</b> | <a href="http://www.nfsiw.gov.cn/publicfiles/business/htmlfiles/foodagxxw/cmsm/edia/document/doc321.pdf">http://www.nfsiw.gov.cn/publicfiles/business/htmlfiles/foodagxxw/cmsm/edia/document/doc321.pdf</a> |                                |
| <b>Specific descriptions / Additional explanations</b> |   |   |                                |
| 1  | Table A.1   | Allowable varieties, scope of application, and maximum level or residue level of food additives. (the scope of application is represented by number of food category and food name)                         | GB2760-2011 Annex A. Table A.1 |
| 2  | Table A.2   | Allowable additives to be used in foods in According to GMP   | GB2760-2011 Annex A. Table A.2 |
| 3  | Table A.3   | List of exceptional food category for additives to be used in According to GMP  | GB2760-2011 Annex A. Table A.3 |
| 4  | Table B.1   | List of foods requiring no flavoring agent and flavoring essence  | GB2760-2011 Annex B. Table B.1 |
| 5  | Table B.2   | List of allowable natural flavoring agents  | GB2760-2011 Annex B. Table B.2 |
| 6  | Table B.3   | List of allowable artificial flavoring agents   | GB2760-2011 Annex B. Table B.3 |
| 7  | Table C.1   | List of processing aids permitted for food processing without restriction on their residual level (excluding enzyme preparation)  | GB2760-2011 Annex C. Table C.1 |

### 1-2. Regulatory Framework for Food Additives in China

| <b>Specific descriptions / Additional explanations (Continued)</b> |           |  |                                |
|--|-----------|--|--------------------------------|
| 8  | Table C.2 | List of Processing Aids with Designated Function and Scope of Application (excluding enzyme preparation) | GB2760-2011 Annex C. Table C.2 |
| 9  | Table C.3 | List of Food Enzyme Preparations and Their Sources   | GB2760-2011 Annex C. Table C.3 |
| 10   | Table D.1 | List of Substances Allowed for Use of Gum Base and its Ingredients                                       | GB2760-2011 Annex D. Table D.1 |
| 11   | Annex E   | Function Categories of Food Additives  | GB2760-2011 Annex E.           |
| 12   | Table D.1 | List of Substances Allowed for Use of Gum Base and its Ingredients                                       | GB2760-2011 Annex D. Table D.1 |
| 13   | Table F.1 | Food Classification System   | GB2760-2011 Annex F. Table F.1 |


## 1-2. Regulatory Framework for Food Additives in China

### An example in GB2760

| Name and code of Food Additive |                                   | Recommended Function |               |
|--------------------------------|-----------------------------------|----------------------|---------------|
| 氯化钙<br>CNS 号 18.002            | calcium chloride<br>INS 号 509     | 功能 稳定剂和凝固剂、增稠剂       |               |
| 食品分类号                          | 食品名称                              | 最大使用量(g/kg)          | 备注            |
| 01.05.01                       | 稀奶油                               | 按生产需要适量使用            |               |
| 04.01.02.04                    | 水果罐头                              | 1.0                  |               |
| 04.01.02.05                    | 果酱                                | 1.0                  |               |
| 04.02.02.04                    | 蔬菜罐头                              | 1.0                  |               |
| 04.04                          | 豆类制品                              | 按生产需要适量使用            |               |
| 05.04                          | 装饰糖果(如工艺造型, 或用于蛋糕装饰)、顶饰(非水果材料)和甜汁 | 0.4                  | remark        |
| 11.05                          | 调味糖浆                              | 0.4                  |               |
| 14.01.03                       | 其他饮用水(自然来源饮用水除外)                  | 0.1g/L               | 以 Ca 计 36mg/L |

Food category to be allowed      Limit level or use as GMP

## 1-2. Regulatory Framework for Food Additives in China

| Description / Definition  | Reference  |
|---|--|
| <b>Specific descriptions / Additional explanations</b>  |  |
| <b>Negative List (if any)</b>   | There is no negative list of food additives under GB2760.                            |
| <b>Specifications of Food Additives, Contaminants, and Analytical Methodology :</b><br><br>The specifications of food additive, including analytical method, are part of National Food Safety Standards, which should be issued by Ministry of Health. Nevertheless, there are still some food additives that lack of specification, and MOH is working on that to cover the gap as soon as possible. All published food safety standards including the food additives specification can be found at the website lined below. |  |
| <a href="http://www.nfsiw.gov.cn/publicfiles/business/htmlfiles/foodaqxw/s69/index.html">http://www.nfsiw.gov.cn/publicfiles/business/htmlfiles/foodaqxw/s69/index.html</a>   |  |

## 2. Case Studies on Food Additives in China

| Food Products  | Food Category in GB2760 Referring to Use Food Additives   | Remark  |
|--|---|---|
| 1. Instant Noodles   | 06.0 Cereals and cereal products<br>06.03 Wheat flour and its product<br>06.03.01 Wheat flour<br>06.03.01.01 All-purpose wheat flour<br>06.03.02 Wheat flour product<br>06.07 Pre-cooked (instant) noodles and rice   | Accessories should be compliant with requirement of "12.0 Condiment" and/or "4.2.2.2 Dried Vegetable", etc.                 |
| 2. Carbonated Soft Drinks  | 14.0 Beverage<br>14.04 Water-based flavored beverage<br>14.04.01 Carbonated drink<br>14.04.01.01 Cola type carbonated drink<br>14.04.01.02 Other carbonated drink   |   |
| 3. Prepared Frozen Foods   | 06.0 Cereals and cereal products<br>06.03 Wheat flour and its product<br>06.03.01 Wheat flour<br>06.03.01.01 All-purpose wheat flour<br>06.03.01.02 Special wheat flour<br>06.03.02 Wheat flour product<br>06.03.02.01 Fresh pasta<br>06.08 Frozen rice and flour product<br>06.1 Filling for grain product | Product with filling, e.g., meat or veg, should meet corresponding requirement of Food Additives for meat or veg in GB2760. |
| 4. Caw's Milk  | 01.0 Milk and dairy product<br>01.01 Pasteurized milk, sterilized milk and recombined milk<br>01.01.01 Pasteurized milk<br>01.01.02 Sterilized milk   | Caw's Milk is not allowed to add flavoring agent and flavoring essence.   |
| <input type="checkbox"/> In GB2760-2011, the Table of allowed Food Additives (A.1) is organized by the name of food additives in stead of Food Categories.<br><input type="checkbox"/> There is not any 'Voluntary Standard' for use of Food Additives in China. |   |   |

Thank You

## **Regulatory Frameworks of Food Additives in Korea**

*Prof. Jong Kyung Lee*  
*Hanyang Women's University*  
*Korea*

Food additives are substances that are added to food to improve its shelf-life, appearance and flavour and by law are considered as safe with the designated uses in food. The possible health effects of food additives, however, are often the issue of causing social concern among the public, pressing for up-to-dated scientific evaluation. Authorized by the Korea Food Sanitation act, Korea Food and Drug Administration (KFDA) is responsible for setting and enforcing standards and specifications for food additives in Korea. The office in KFDA responsible for approving food additives is Food Additives Standardization Division. Policy of the Korean government states that regulation of food additives including standards setting of food additives are to be based on the scientific evidences and may refer to the international standards and/or harmonization when necessary. Accordingly, over the years, safety reevaluation of food additives and risk communication have been reinforced while continuing survey and establishing database on food additive intake have been priority area for consumer protection of Korea.

The legal basis for the management of food additives are under the Food Sanitation Act, especially the article 2.2 (definition of food additives), article 6 (Prohibition against Sale, etc. of Chemical Synthetics, etc., Criteria and Standards for which are not Publicly Announced), and article 7 (Criteria and Standards concerning Foods or Food Additives). In addition, the article 14 (Code of Foods, etc.) should be considered when applying a food additive(s) to specific food, because the Food Code contains general standards and specifications governing food products and individual standards and specifications.

Korea Food Additive Code contains standard specifications for individual food additives and usage standards. In principle, Korea has a positive list of approved food additives and mixture of approved additives. However, for some individual food items (e.g. Instant noodles, carbonated beverages, etc.), negative lists of food additives are described in Food Additive Code. Most food additives are approved and tolerance levels are established on a product-by-product basis in Korea. Usually it takes about a year to get a new additive added to the approved list upon petition by a producer and/or user.

When the Korea Food Sanitation act was legislated and promulgated in 1962, a total of 217 food additives items were designated. The enactment and amendment of the standards of food additives has been conducted over the years. Currently, 602 food additives in total are approved with the permission of use. Standard and specification of the synthetic additives (400 items), natural additives (195 items) and mixed additives (7 items) are listed in current Korea Food Additive Code. English version of the Korea Food Additive Code is available electronically at the website (<http://fa.kfda.go.kr/foodadditivescode.html>) where its contents are expected to be updated periodically.

As participants to the 3rd ILSI Japan/MAFF project, the regulation framework of food additives in Korea (2012, Jan) as well as the case studies on instant noodles, carbonated drinks, frozen food, and cow's milk have been investigated, based on the information of KFDA and Animal, Plant and Fisheries Quarantine and Inspection Agency and Korean Industrial Standards (KS) sites.



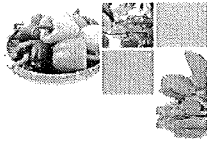



**International Conference  
for Sharing Information  
on Food Standards in Asia**

**Regulatory Frameworks  
of Food Additives  
in Korea**

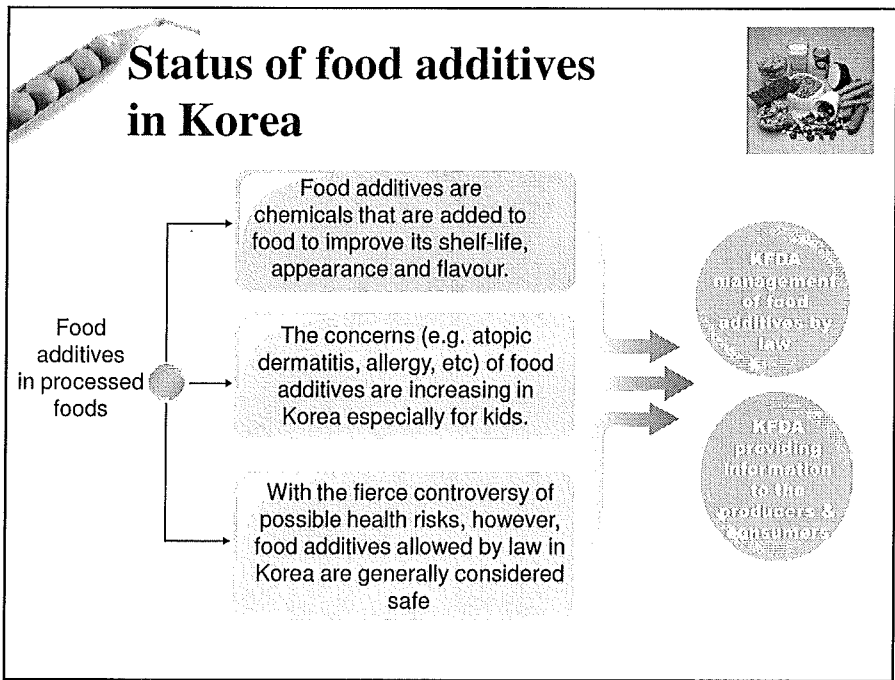
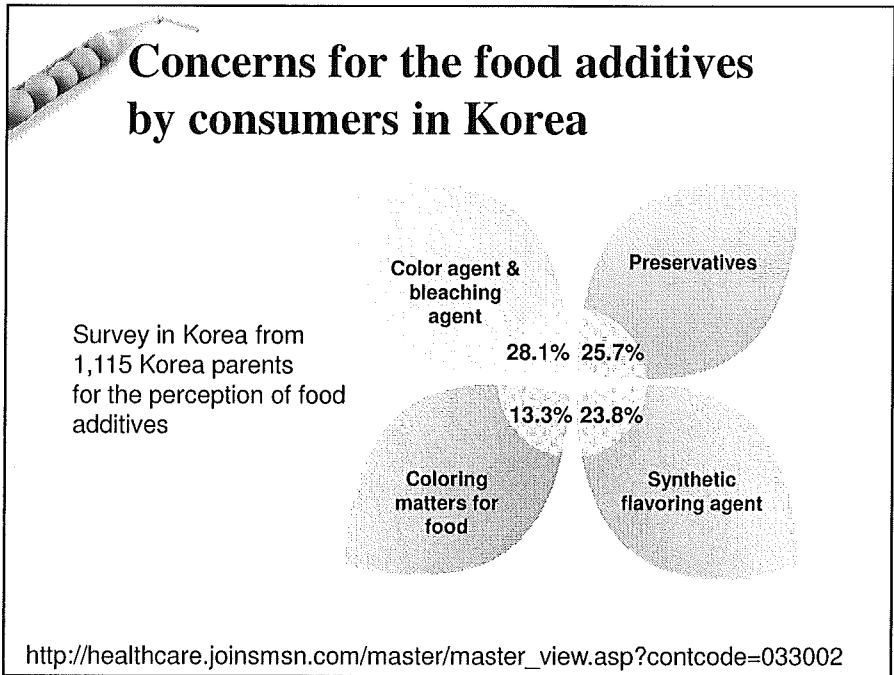
Jong-Kyung Lee (PhD)  
Hanyang Women's University

February 21, 2012  
Jakarta, Indonesia



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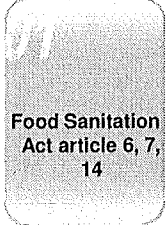
- 1 Regulation of Food Additives in Korea
- 2 Case studies of food additives for instant noodles, carbonated drinks, frozen food, and cow's milk in Korea
- 3 Procedure of safety evaluation and notification of food additives






## Legal basis of food additives in Korea

**Korea Food Sanitation act**



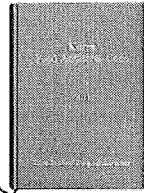
Food Sanitation Act article 6, 7, 14

**Korea Food & Drug Administration (KFDA)**



KFDA Commissioner notice

**Korea Food Additives Code**



Korea Food Additives Code 2011

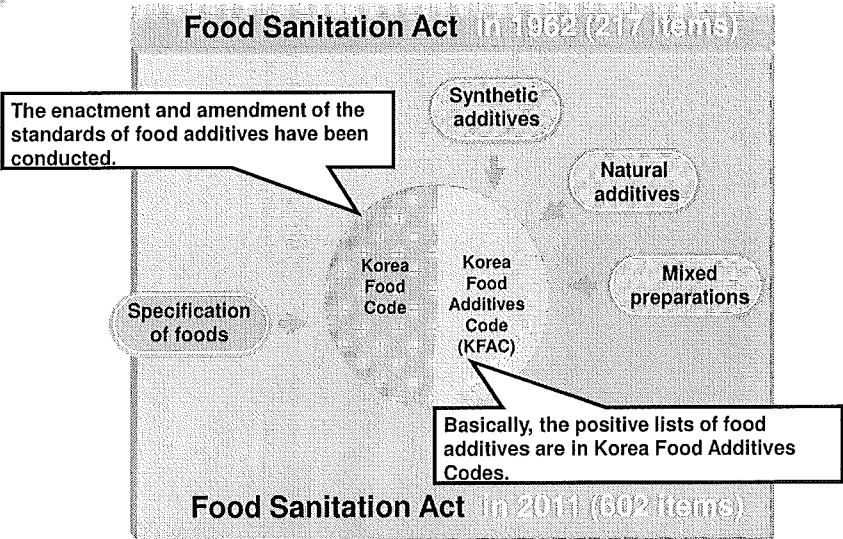
**Contents**

- 1. General Provisions
- 2. Synthetic Additives, Natural Additives and Mixed Preparations
  - Article 1. Standards for the Manufacture of Food Preparations
  - Article 2. General Descriptions for Food Additives to Foods
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    - A. Synthetic Additives
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    - C. Mixed preparations
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- 3. General Test Methods
- Annexes
- Index

[http://www.kfda.go.kr/fa/ebook/egongjeon\\_intro.jsp](http://www.kfda.go.kr/fa/ebook/egongjeon_intro.jsp)

## Legal basis of food additives in Korea (cont'd)

**Food Sanitation Act In 1962 (217 items)**




**Food Sanitation Act In 2011 (602 items)**



## Food additives management by the Food Sanitation Act (FSA)

| FSA article 2.2 Definition of food additives   |   |                    |
|--|---|--------------------|
| FSA 6  | FSA 7   | FSA 14             |
| Prohibition against Sale, etc. of Chemical Synthetics, etc., Criteria and Standards for which are not Publicly Announced | Criteria and Standards concerning Foods or Food Additives | Code of Foods, etc |

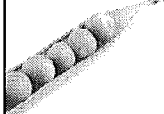


## Definition of Food Additives

**FSA 2.2**


**“Food additives” means materials added to or mixed with foods or materials used for wetting foods in the processes of manufacturing, processing or preserving of foods.**

**In such cases, food additives shall include materials used in sterilizing or disinfecting apparatus, containers or packages, which may be transferred to foods in an indirect manner.**

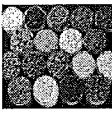


## Food additives management by the Food Sanitation Act (FSA)

| FSA 6  | FSA 7  | FSA 14   |
|--|--|--|
| <p>Regulation of drug additives which are cleared of synthetics. The criteria and standards of which are to be publicly announced.</p> <p><b>(Positive list of Food additives)</b></p> | <p>The Commissioner of the Korea Food and Drug Administration shall determine and publicly announce the matters concerning foods or food additives.</p> <p><b>(Notice of Food Additives)</b></p> | <p>The Commissioner of the Korea Food and Drug Administration shall formulate and distribute the code of foods including the criteria and standards of foods or food additives.</p> <p><b>(Distribution of Food Additive Code)</b></p> |



## Current category of food additives approved in Food Additive Code



|                                      | Synthetic additives | Natural additives | Mixed additives | Total |
|--------------------------------------|---------------------|-------------------|-----------------|-------|
| 2010, Nov<br>(Notification #2010-82) | 400                 | 195               | 7               | 602   |

## Case studies of food additives for instant noodles, carbonated drinks, frozen food, and cow's milk in Korea

### 1-1. Regulatory Framework for Food Additives in Korea

|                 | General Description / Definition  |
|-----------------|---|
| Flavors         | <p>The category of <u>flavoring agent</u> is listed in the <u>Korea Food Additive Code (2011)</u>. Flavoring agents are defined as the substances added to improve, modify, or restrain the flavor of the products such as food, cosmetics, medicine, soap, toothpaste etc.</p> <p>Flavoring substances listed at "<u>Item No. 424. Synthetic flavoring substances</u>" are found in in "<u>Part A. Synthetic Additives, II 3. Specifications and Standards of the Favoring Agents</u>" of the <u>Korea Food Additives Code</u>.</p> <p>Natural Flavoring Substances are defined as the substances that are the refined oils, the extracts, the oleoresins (excluding the spice oleoresins having the standard) produced by extraction, distillation, etc. to give or improve the flavor from the sources. Merely water, ethanol, or plant oils can be added for the purpose of preservation.</p> |
| Processing aids | <p>Processing aids are generally defined as any substances that are not added for a specific purpose but used during production, processing or the other purpose (e. g. N-nucleic acids)</p>  |
| Carry-over      | <p>"Carry-over" is not defined in the <u>food additive category of KFAC</u>. However, the Korea Food Code describes "carry-over" as below:</p> <p>(1) Standards of food additives in food shall comply to the Food Additive Code.<br/>(2) <u>If a food additive that cannot be used in a food is derived from a raw material for which the food additive can be used, the restriction on the use of food additives may not be applied within the range of such deriving from the raw material.</u></p>  |

## 1-2. Regulatory Framework for Food Additives in Korea

| Description / Definition                               |   |
|--|---|
| <b>Specific descriptions / Additional explanations</b> |   |
| 1 List of Designated Food Additives                    | As of November 2010 (Notification #2010-82), 602 food additives in total are approved with the permission to use in respectively designated food groups. Standard and specification of the synthetic additives (400 items), natural additives (195 items) and mixed additives (7 items) are listed in the current KFAC. The e-book of English version ( <a href="http://www.kfda.go.kr/fa/ebook/egongjeon_intro.jsp">http://www.kfda.go.kr/fa/ebook/egongjeon_intro.jsp</a> ) still contains those officially deleted (33 synthetic additives and 12 natural additives deleted from KFAC).<br><br><u>According to the Notification number 2011-71 (Nov. 2011), the six new food additives (synthetic -xylanase, 5'-deaminase, alpha-glucosidase, phosphoesterase.; natural-sodium selenate, sodium molybdate) have been approved and will be effective as of July 2012.</u> |
| 2 List of Existing Food Additives                      | Not applicable in Korea   |


## 1-2. Regulatory Framework for Food Additives in Korea (cont'd)

| Description / Definition   |  |
|--|--|
| <b>Specific descriptions / Additional explanations</b>   |  |
| 3 List of Plant or Animal sources for Flavoring agents   | <u>Natural Flavoring Substances (273 items) are listed in the KFAC.</u>  |
| 4 List of substances which are generally provided for eating or drinking as foods and are used as food additives as well | <u>The raw materials for food or drinking purpose are controlled by Korea food code, while the food additives are separately managed by Korea Food Additive Codes.</u> |

## 1-2. Regulatory Framework for Food Additives in Korea (cont'd)

| Description / Definition   |  |
|--|--|
| <b>Specific descriptions / Additional explanations</b>   |  |
| Negative List (if any)   | In principle, the positive list of food additives are managed under the Korea Food Sanitation Act. However, for some individual food items (e.g. Instant noodles, carbonated beverages, etc.), negative list of food additives are described.  |
| Specifications of Food Additives, Weights and Measures, Contaminants, Methods of Analysis and Sampling, Standards of manufacturing of food additives | General provisions of KFAC provides the information of [weight, volume and temperature], [tests], [container], and [definition of terms].<br><br>KFAC main text provides standards for manufacturing and preparation, general standards for food additive used in foods, food contact surface sanitizing solutions and general test methods as well. |
| Official publication and/or Gazette for food additives   | <a href="http://www.kfda.go.kr/fa/ebook/egongjeon_intro.jsp">http://www.kfda.go.kr/fa/ebook/egongjeon_intro.jsp</a> (KFAC)   |

## 2-1. Case Studies on Food Additives in Korea

| 1. Instant Noodles   | Food Sanitation Act  | KS (voluntary standards)   |
|--|--|--|
| <p><b>Scope and/or Descriptions</b></p> <p><b>Positive and/or Negative List</b></p> <p><b>Use Limitation / Maximum Level, if any</b></p>  | <p>Specification of noodles are described in Korea Food Code.</p> <p>Positive /negative list of food additives for noodles should be complied in Korea.</p> <p>Below food additives should <b>not</b> be detected in the products :</p> <ul style="list-style-type: none"> <li>- Prepared Tar Dyes (color)</li> <li>- Preservatives</li> <li>- Titanium dioxide</li> </ul> <p>Sodium Stearoyl Lactylate is permitted for use in noodles.</p> | <p><a href="http://safefood.kfda.go.kr/RS/food_eng_menu2.jsp?menu=04&amp;level=2&amp;step_2=009">http://safefood.kfda.go.kr/RS/food_eng_menu2.jsp?menu=04&amp;level=2&amp;step_2=009</a> (English Definition)</p> <p>Noodles were specified as fried noodles and non-fried noodles</p> <p>Tar color should not be detected.</p> <p>Non-fried noodles are dried noodles, (KS H 2505), fresh noodles (KS H 2506), and Pre-cooked noodles (KS H 2507).</p> <p>Also refer to the table 3.3-8 of the report (p 36, ILSI Japan 2010)</p> |

## 2-2. Case Studies on Food Additives in Korea

| 2. Carbonated Soft Drinks              | Food Sanitation Act  |   | KS (voluntary standards)   |                                    |
|--|--|---|--|------------------------------------|
| Scope and/or Descriptions              | Specification of carbonated beverages are described in Korea Food Code- Carbonated beverages, Carbonated water.  | <a href="http://safefood.kfda.go.kr/RS/food_eng_menu2.jsp?menu=040&amp;level=2&amp;step_2=011">http://safefood.kfda.go.kr/RS/food_eng_menu2.jsp?menu=040&amp;level=2&amp;step_2=011</a> (English) | No positive/negative list included. It is recommended to follow the Korea Food Code. | Carbonated soft drinks (KS H 2016) |
| Positive and/or Negative List          | Positive/negative list on food additives (Korea Food Additives Code)   |   |  |                                    |
| Use Limitation / Maximum Level, if any | <p>Some food additives are allowed to use in carbonated beverages and maximum levels in soft drinks are set as below:</p> <ul style="list-style-type: none"> <li>- Preservatives: Benzoic acid, sodium benzoate, potassium benzoate, and calcium benzoate less than 0.6g/kg are permitted to only carbonated beverages (excluding carbonated water).</li> <li>- Ester Gum less than 0.1/kg</li> <li>- Manganese gluconate (no maximum level specified)</li> </ul> <p>Some food additives are <u>not</u> allowed to use in carbonated beverages:</p> <ul style="list-style-type: none"> <li>-Food Red No.2 and</li> <li>-Food Red No. 2 Aluminum Lake.</li> </ul> | Korea Food Additives Code<br><a href="http://www.kfda.go.kr/fa/ebook/egongjeon_intro.jsp">http://www.kfda.go.kr/fa/ebook/egongjeon_intro.jsp</a> (English)  |  |                                    |

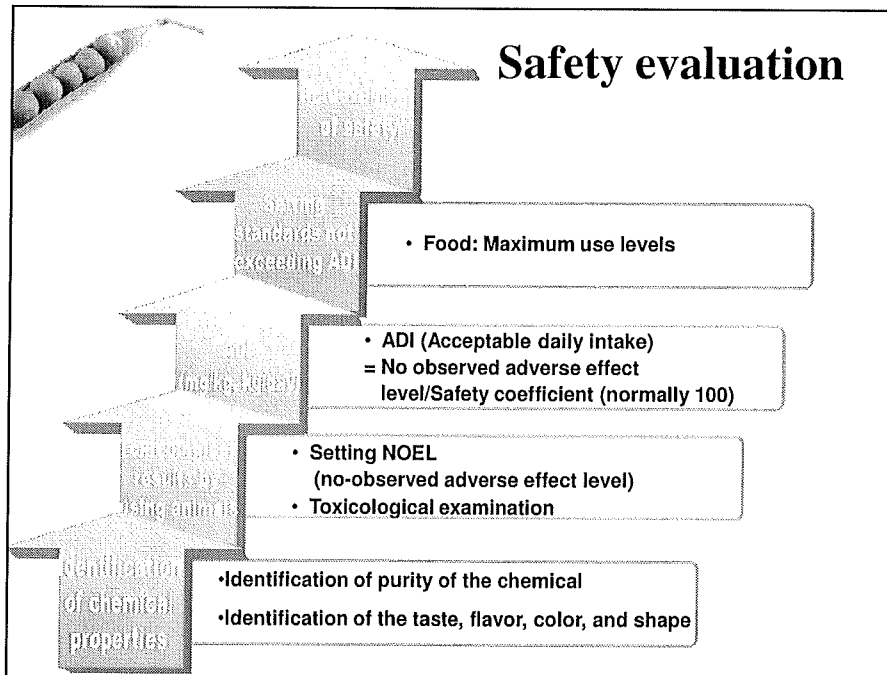
## 2-3. Case Studies on Food Additives in Korea

| 3. Prepared Frozen Foods               | Food Sanitation Act  |   | KS (voluntary standards)  |  |
|--|--|---|---|--|
| Scope and/or Descriptions              | Food additive standards for frozen food should comply to those for respective food item as designated in the Korea Food Code and/or Food Additive Code.  | Korea Food Code 3-1-2 (English; <a href="http://www.kfda.go.kr/eng/eng/index.do?menuCode=43&amp;searchKeyCode=122&amp;page=1&amp;mode=view&amp;boardSeq=66020">http://www.kfda.go.kr/eng/eng/index.do?menuCode=43&amp;searchKeyCode=122&amp;page=1&amp;mode=view&amp;boardSeq=66020</a> ) | No positive/negative List is included. Generally, it should comply the Korea Food Code and/or Food Additive Code. | Frozen MANDU (KS H 4001), Frozen CROQUETTE (KS H 4002), Frozen raw breaded shrimp (KS H 4003), frozen pork cutlet (KS H 4004), and Frozen fish cutlet (KS H 6032) are defined. |
| Positive and/or Negative List          |  |   |   |  |
| Use Limitation / Maximum Level, if any | <p>"Frozen food" means a food made by filling the manufactured, processed, cooked food into container and packaging materials after freezing treatment for the purpose of long-term storage.</p> <p>(1) Frozen food not requiring heat process before consumption:<br/>Frozen food that can be consumed without a separate heating process.</p> <p>(2) Frozen food requiring heating process before consumption:<br/>Frozen food that can be consumed only after a separate heating process.</p> |   |   |  |

## 2-4. Case Studies on Food Additives in Korea

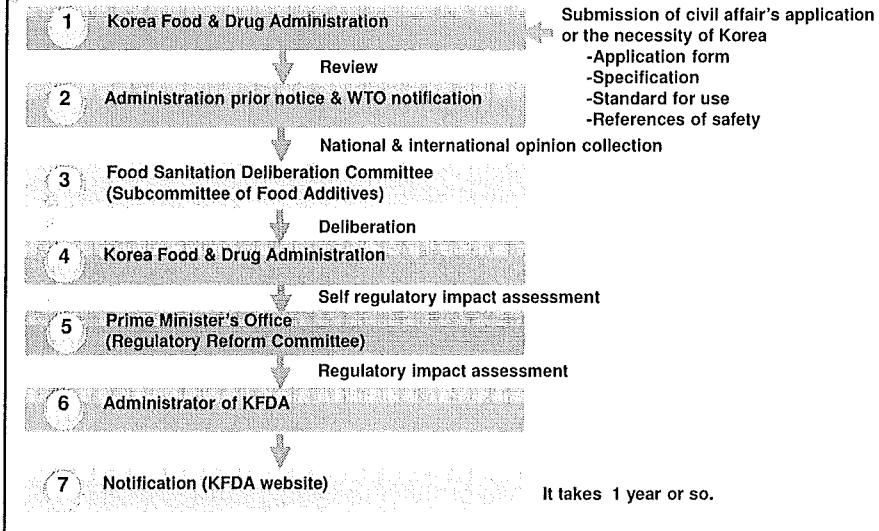
| 4. Cow's Milk   | Food Sanitation Act   |   | KS (voluntary standards)   |
|---|---|---|--|
| Scope and/or Descriptions   | Milk is defined as the milk pasteurized or sterilized.  | Processing of Livestock Products Act. Article 4.2. "SANITARY CONTROL FOR LIVESTOCK PRODUCTS"  | There is no positive/negative list in KS.<br><br>Milk was included in the milks (KS H 2195) in KS. |
| Positive and/or Negative List   |   |   |  |
| Use Limitation / Maximum Level, if any  | Use of food additives in milk is prohibited or restricted under the Korea FSA.  | Notification on Standard and Specification of Livestock Products (No. 2010-2)<br><a href="http://www.qia.go.kr/viewWebQiaCom.do?id=7660&amp;type=1_41jgbz">http://www.qia.go.kr/viewWebQiaCom.do?id=7660&amp;type=1_41jgbz</a> (Korean) |  |
|  | (Sanitary control for livestock products has designated milks for milk, fortified milk, reconstituted milk, and lactic acid bacteria added milk.) |   |  |

## Safety evaluation





## Designation procedure of food additives standards in Korea



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