Laws and Regulations on Food Safety and Food Quality in Japan

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Introduction

This document is composed of the juridical and regulatory systems on food safety and food quality in Japan and some the comparison with those in the EU and the USA, focusing on those after the fundamental reform caused by the apparition of the BSE in Japan in 2001.

Since the end of the Pacific War, the Food Sanitation Law and the JAS Law have controlled the safety and quality of food for many years. The incidence of the BSE was the decisive trigger to restructuring the existing juridical and administrative systems in Japan. This document describes the back ground of the reform of the present systems and the contents of the new structure of the related laws and the administration. The risk analysis was adopted as the basic principle in the Food safety Basic Law that was newly established, and also the traceability was introduced. However, the Japanese law has not made clear its views on the precautionary principle in the legislation. Following the principle of “the farm to the table” adopted, laws related to materials for agricultural and livestock industries, like pesticides, feed, veterinary drugs were revised.

The document also describes the new legislations and regulations concerning the nutrition labelling and the nutrition and health claims, such as “Food for Specified Health Use (FOSHU)”, “Nutrition Functional Food” under the Health Promotion Law. In Japan the health functional food has been very popular, as the consumers are highly conscious about the nutrition and health in recent years. The regulations are still under the elaboration, taking into account of the proper labelling and the evolution of the technology.

This document features the main issues related to the food safety such as GMO, BSE, pesticides, import, in addition to the traceability and the precautionary principle. The readers may understand in a clear manner the characteristics of legislations and regulations on these matters and how Japan’s systems are different from those in the USA and the EU. In this relation, the documents analyses the differences of opinions related to the principles and measures to be applied and taken to these issues among Japan, EU and USA. The most important point is the question if new measures such as traceability, measures based on the precautionary principle, measures intervening on the process of production and the distribution are necessary or appropriate, in view of securing consumers confidence on food safety.

The document explains the system of the legal import procedures in detail and how to secure food safety of imported products, which would be interesting for foreign exporters of food to Japan. In Japan consumers are very worried about the efficiency of the import quarantine system how the food safety could be secured for such large amount of imported food. It is one of the reasons why the positive list of residue of pesticides was introduced in the reform.
Regarding the food quality, regulations under the JAS law have been developed for many years. The original objective of the law was to prevent very poor quality food from circulating in the market. At the end of 1960s the objective of the Law was shifted to the protection of consumers from the smooth transaction of goods among the industry by means of proper labelling. At the middle of 1990s the Law introduced the category of specific JAS which certifies the process of the production or the distribution of products (process defined products), as the consumers have been interested in the positive qualities of food. Accordingly, the organic products are one of JAS standards under the jurisdiction of the JAS law. The GMO labelling regulation is one of JAS quality standards.

In Japan very peculiar system of labelling obligation of the origin of products to be applied to wide range of products has been elaborated under the JAS law, in responding to the consumers demand. However, Japan decided that the geographical indications should be under the jurisdiction of the Trade Mark Law, after the intensive discussions inside the government.

The document describes the characteristics of each type of JAS quality standards and labelling standards and the recent evolution of the JAS Law as well as the geographical indications under the Trade Mark Law. In relation to the labelling and the presentation, the document describes the laws and regulations related to the fair trade.

The consumers became aware of the social qualities of food such as food taking into account of environment protection, animal well- fare, diversity of natural resources, sustainable agriculture, etc. The systems for these qualities are well advanced in EU countries, such as integrated farming, Global GAP (EurepGAP), agriculture raisonee. In Japan, systems are being elaborated, however, on a premature basis. The document describes the Japan’s efforts in both government and the private sector on the social qualities of food.

In preparing the document, I studied in the doctor course of the faculty of law in the Toulouse university in France as well as in the distant course of the international food law provided by the Michigan State University.

It could be concluded that this documents are interesting to people who are engaged in export of food to Japan and useful to learn about the whole range of legal and regulatory system in Japan concerning food safety and quality for government officials and people of food industry associations as well as scientists in the world.
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A General

I. Structure of Japanese Laws on Food Safety and Quality

1 Food Sanitation Law and the JAS Law

After the Second World War ended, two principal laws have been regulating food safety and food quality for many years in Japan. The first one is the Food Sanitation Law promulgated in 1947. The second one is the Law Concerning Standardization and Proper Labeling of Agricultural and Forestry Products (JAS Law) established in 1950.

The Food Sanitation Law covers all aspects of safety of all types of foods, containers and packages, and toys in the light of human health. This law has been elaborated for many years; introducing import inspection (1952), labeling standards (1956), clear definition of food additives (1957), prohibition of sales of food which may contain harmful substance (1963), prohibition of placing novel food in the market (1963), approval of HACCP (1995), labeling of allergens (2000), pre-market approval and labeling of GMOs (2000), positive list system of pesticides (2003). Accordingly, the scope of the law is as follows.

- Specifications and standards of food and food additives
- Standard of milk and dairy products
- Designation of food additives
- Labeling of food and additives
- Residue standards for pesticides, feed additives, veterinary drugs
- Examination and inspection
- Import notification and inspection
- Approval of HACCP
- Approval and labeling of GMOs
- Labeling of food containing allergens
- Approval of operations of business related to food

In the process of the elaboration of the law, these regulations have been influenced by regulations of the US and European countries and efforts of international harmonization taken by the Codex Alimentarius Commission of FAO/WHO and WTO, in particular since 1980s. Therefore, many Japanese regulations are similar to corresponding ones in the EU and the USA, while some particularities of Japan exist.

Any regulation of alcoholic beverages has not been established under this law, although the law could establish such regulations. Actually, the Liquor Tax Law regulates product and labeling standards of alcoholic beverages.

The JAS Law was established in 1995. This law succeeded the standards of foods under the Government Inspection Law for Agricultural and Forestry Products in association with the supply and demand adjustment policy including the government procurement and ration
system. The initial objective of the JAS Law was to prevent distribution of low-quality food in the market by establishing common standards including labeling of various foods, which producers should respect.

In 1960s consumer movements intensified in Japan and resulted in the establishment of the Consumer Protection Fundamental Law (1968). Then the objective of the JAS Law was shifted to the consumer protection. And the regulation of labeling became one of the important objectives of the JAS Law.

Another important change took place in the JAS Law in 1990s. Organic products have become legally regulated by one of JAS Standards (2000) that replaced the guideline introduced in 1992. Since then, the Law covers quality-certified products. At the moment, several systems for this type of products have been established. However, the legal system such as Geographical Indications (including Appellation Controlée) and Label Agricole in some European countries has not been introduced, despite many studies taken by the government. In Japan, quality-certified products that are produced following regulations on the production or distribution process (process-defined products) have gradually been popular. These products are regarded as products to meet various requirements of consumers such as food safety, traditional high-quality food, specified regional food, and food representing environmental protection and sustainable agriculture. Accordingly, the scope of the JAS Law at the moment is as follows.

JAS Standards (standards for items as of 2008)
- JAS standards (41 items)
- Specified JAS standards (5 items)
- JAS standards of organic products (4 items)
  - JAS standards specially grown agricultural products
  - JAS Standards with public disclosure of manufacturing
  - JAS standards of specially distributed products
General Quality Labelling Standards
- Processed Food
- Perishable Food
- Genetically modified food
- Brown Rice and Milled rice
- Fisheries products
- Quality labeling standards of indication of place of origin of ingredient of processed food for 6 items
- Quality labeling standards of individual products
  (standards for 51 products, as of 2008)

2 Food Safety Basic Law
The Food Safety Basic Law established in 2003 has fundamentally changed the legal system for food safety in Japan. The principle of the law is very similar to the EU

This law introduced the method of risk analysis recently elaborated in the EU, the USA and the Codex Commission, and established the Food Safety Commission which independently performs the risk assessments. This law is based on three main principles; “protection of consumers”, “measures based on science” and “from farms to tables”. Several related laws were amended in 2003, according to the principle of “from farms to tables,” which means that measures should be taken in all stages of production and distribution of food and agricultural materials including feed, pesticides and veterinary drugs.

Like EU countries, this law was established, aimed at restoration of consumers’ confidence on food safety policy that was severely deteriorated by the incidence of BSE and cases of false labeling and other violations against laws. Stakeholders considered that the traditional legal system could not any more address well the food safety issue under the recent advanced technology and complexity of food production and distribution processes as well as the globalization of food trade.

3 Health Promotion Law
Nutrition labeling, nutrition claim and health claim are regulated in the Health Promotion Law (2002). This law replaced the Nutrition Improvement Law (1952), which was established to improve the nutrition level of Japanese nationals that was poor due to the shortage of food after the World War II. (Nutrition Improvement Law.

The Voluntary Nutrition Labeling Regulation was introduced in 1995 under the Nutrition Improvement Law, following the nutrition labeling system regulated by the Nutrition Labeling and Education Act of 1990 in the USA and the Directive on the Voluntary Nutrition Labeling of the EC (90/496/EEC). The nutrition labeling and nutrition claim are internationally well harmonized by the Codex. The Japanese regulations are very similar to ones in the EU and the USA.

A variety of health foods began to appear in the Japanese market since late 1980s, as the level of living was improved, the dietary habit changed and consumers’ concern on nutrition and health increased. To prevent misleading labeling on health food, the regulation of “Food for Specified Health Use (FOSHU)”, which is officially allowed to have indication of health function claims, was created in 1991. Then, the system of “Food with Health Claims”, which is composed of FOSHU and Nutrition Functional Food (food with nutrient function claims), was established in 2001.

These regulations are based on the Draft Guidelines for Use of Nutrition and Health Claims of the Codex. However, some differences are observed among Japanese, European and US ones in the health claim.
4 Laws for Fair Trade
The presentation of food (including labeling) is also regulated, aiming at preventing unfair trade practices, by the Unfair Competition Prevention Law (1993) that replaced the old Unfair Competition Prevention Law (1934). And the Act Against Unjustifiable Premiums and Misleading Presentations (1962) regulates the unfair trade practices particularly in the fields of labeling, advertisement and premiums.

Under these laws the Fair Trade Commission is endorsed to investigate and order business operators to cease violation or take necessary measures for violation. This power of the Commission is stronger than corrections and penal measures under the JAS Law. Therefore, these laws have become important tools to control the labeling of food.

Under the Act Against Unjustifiable Premiums and Misleading Representations, voluntary guidelines of representations and premiums for particular products (32 products as of 2005), which member corporations should observe, are approved by the Commission. These are additional guidelines of labeling to the obligatory labeling regulations under the Food Sanitation Law and the JAS Law.

5 New legal system to be elaborated
Japan introduced the method of the risk analysis as a fundamental principle of food safety. However, experiences are needed to be well settled in Japanese conditions of society, culture and tradition. Moreover, new measures should be introduced or elaborated in order to meet high standard of food safety and quality required by consumers, since the existing system could not well address these requirements. Accordingly, various types of traceability, which are supposed to be a compensatory measures for food safety, have been introduced on governmental basis and private basis. GAP (good agricultural practices) is also under elaboration in Japan.

Note:
"Reliability" and "Safety" of food
On one hand « food safety » is necessary to guarantee human health and can be assured by measures based on scientific evidences. On the other part " the food reliability " is assured by additional measures, with a view to obtaining the confidence of consumers. These are, for example, means of controlling the process of production or distribution, informing the product origin, tracing products in the food chain, insuring the accuracy of labelling, etc. In Japan the terms of "security" and "reliability" are often used as a combined expression.

In addition to food safety, consumers are tend to be more interested in food quality which contributes to protection of environment, sustainable agriculture, diversity of natural resources. These measures should be, in principle, based on the intervention in the process of production and distribution. In view of responding to these requirements of consumers, the JAS Law has provided specified JAS standards which are quality certification standards, and is further developing these schemes.
Note:
Madam Veronique Bellemain, Vice Director, National College of Veterinary Services in France, referred to the term “positive quality and negative quality” at the Conference on “foods in the affluent society: a dialogue between the Japanese and the French” which took place in the University of Tokyo in March, 2006. Her definition is as follows;
Negative quality is that of the product which has no defect which is proved by the administrative services or the producers. Positive quality is that of the good quality product which is proved by surveillance on the whole process of production. They are shifting from the absence of defect to the guarantee of positive quality.

6 International Harmonization
Since 1980s the Japanese systems have been influenced by the efforts of international harmonization of measures taken by leading countries such as the EU and the USA and international organizations including the Codex and WTO.

The Sanitary and Phytosanitary Agreement of 1994 is significant for the international harmonization of measures related to food safety. More than 130 countries agreed to the principle that while each member country has right to take necessary measures, those should be based on scientific evidences, and in the occasion of disputes, the member country should prove the scientific need of the measure, when it does not meet the international standard like the Codex.

For example, the risk analysis, HACCP, the organic standard, the nutrition and health claim, the positive list of pesticides, and GAP in Japan are based on the Codex standards or guidelines.

However, international harmonization has not been well achieved for the new measures mentioned above which intervene the process of production and distribution (process defined products). In particular, there is a fundamental discrepancy between European countries and the US in these systems. At the moment, Japanese systems are different from European and US ones, while these seem to have some similarity to European ones.
Structure of Japanese Laws on Food Safety and Quality

1 General (to be applied to all products and services)
       Responsibility of producers and distributors for providing safety goods and providing proper information to consumers
   (2) Unfair Competition Prevention Law (1993) which replaced Old Unfair Competition Prevention Law (1934)
   (3) Act Against Unjustifiable Premiums and Misleading Presentations (1962)
   (4) Measurement Law (1992) which replaced the old Law (1951)
       Uniformed and accurate measurement of goods
   (5) Trademark Law (1959)
       Regional collective mark (geographical indication)

2 Basic Policy for Food Safety
   Food Safety Basic Law (2003)
   General principles of food safety policy
   Food Safety Commission
   Risk assessment and risk communication of food

3 Safety for Food, Additives and Packages
   (1) Food Sanitation Law (1947)
   (2) Law Concerning Amendments to the Food Sanitation Law and Nutrition Improvement Law (1995)
   (3) Law concerning safety Assurance and Quality Improvement of Feed (1953)
   (4) Provisional HACCP Promotion Law (1998)
       Favourable treatment on tax and loan interest on HACCP facilities
   (5) Abattoirs Law (1953)
   (7) Law Concerning Special Measures against Dioxins (1999)
   (8) Law Concerning Special Measures against Sponsiform Encephalopathy (2002)
4 Nutrition and Food for Specified Use

Health Promotion Law (2002) which replaced Nutrition Improvement Law (1952)
  Food for Specified Use
  Food with Nutrition Labelling
  Health Functional Food
  Nutrition Functional Food
  Food for Specified Health Use (FOSHU)

5 Standards and Labelling
(1) Law Concerning Standardization and Proper Labelling of agricultural and Forestry Products (1950) (JAS Law)
(3) Organic Agriculture Promotion Law (2006)

6 Safety of Production Materials
(1) Agricultural Chemicals Regulation Law (1948)
  Registration of pesticides
  Standards of use
(2) Pharmaceutical Affairs Law (1943)
  Approval of veterinary drugs
(3) Law on Securing Safety and Improving Quality of Feed (1953)
  Approval of additives to feed

7 Alcohol Beverages
  Liquor Tax Law (1958)
B Food Safety

II Basic Law and Principles of Food Safety

1 Establishment of Food Safety Basic Law of 2003

1-1 Growing Mistrust of Consumers on Food Safety
After a cow infected with mad-cow-disease was identified in Japan in September 2001, the fundamental change of the law system for ensuring food safety was observed in Japan. Food safety measures have been mainly regulated by the Food Sanitation Law, which was established in 1947, two years later of the end of the Second World War, and have been also regulated partly by the Law Concerning Standardization and Proper Labeling of Agriculture and Forestry Products of 1950 (JAS Law). These laws aimed at preventing the distribution of low-quality food and harmful food to human health in the markets under the severe short supply of food in Japan. In the subsequent years, the laws have been amended for adapting to new circumstances related to food.

During late 1980s and 1990s, several measures were taken in responding the growing interest and concerns of consumers on nutrition and health. One of the measures was the Nutrition Labeling (law or guideline?) of 1996, which regulates labeling of nutritious elements, such as energy, protein, fat, carbon-dioxide, etc. In 2001 labeling of allergens on food became mandatory. However, the core of the food safety regulations in the law has remained almost unchanged for many years, except measures concerning pesticides and food additives. In 1995, a significant change regarding food safety was made. The voluntary HACCP system was introduced in some areas of the food processing industry and regulations on pre-market approval of GMO and labeling of GMO were established.

In 1996, a grave food poisoning by O-157 occurred in primary schools in Okayama Prefecture and the City of Sakai. In that year, 8,314 patients all over Japan were identified as being infected with O-157. In the following several years, many incidents related to food safety were observed. In 1999, a TV station (or program) reported that the green tea in Tokorozawa (Northwest of Tokyo) was contaminated with dioxin. In 2000, more than 15,000 people were suffered from food poisoning by staphylococcus aureus in milk produced by a plant of a factory of a large dairy company. In 2001, non approved GM corn (Starlink) for human consumption was mixed in a food product.

The majority of consumers in Japan were in strong anxiety that food safety may not be able to be ensured by the present system, while it has been meticulously elaborated. They had a fear that they could be infected by a new infectious disease, and they deepened mistrust to the safety of new food, in particular GM food. In addition, consumers have some doubt on
imported food whose share of the total supply in Japan is over 60% on energy basis.

EU countries and America were in the similar situation to Japan in the same years. The situation of Europe was more severe than Japan. BSE, which was found in the UK in 1986, also prevailed in many other countries around 1990. The EU Commission as well as EU countries have examined an appropriate legal and administrative system to effectively ensure food safety. Diseases caused by salmonellae and O-157 could not be effectively prevented in the US. It is reported that even now, the number of patients hospitalized by food poisoning amounts to over 232,000 and people died from food poisoning are approximately 5,000 each year in the US.

Recent Major Cases of Food Poisoning in Japan

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 1996</td>
<td>O-157 food poisoning in Okayama Prefecture and Osaka. The number of patients was around 10,000. Sprouts of Japanese radish were suspected to be an origin of the infection.</td>
</tr>
<tr>
<td>May 1998</td>
<td>O-157 food poisoning in salmon roe dipped in soy sauce in Hokkaido</td>
</tr>
<tr>
<td>March 1999</td>
<td>Food poisoning by salmonellae in processed squid produced by a factory in Aomori Prefecture</td>
</tr>
<tr>
<td>Summer of 1998 and 1999</td>
<td>Many cases of food poisoning by vibrio parahaemolyticus in sea food</td>
</tr>
<tr>
<td>June 2000</td>
<td>Food poisoning by staphylococcus aureus in milk produced by a plant of a milk products company. Patients were over 15,000.</td>
</tr>
<tr>
<td>October 2000</td>
<td>Genetically modified corn “Starlink”, which was under the safety evaluation process, was detected in food.</td>
</tr>
<tr>
<td>March 2001</td>
<td>O-157 food poisoning in beef \textit{tataki} or fresh beef slices with burnt surface in Tochigi Prefecture.</td>
</tr>
<tr>
<td>May 2001</td>
<td>Genetically modified potato “New Leaf Plus”, which was under the safety evaluation process, was detected in snack food products. The products containing this potato were widely withdrawn from the market.</td>
</tr>
<tr>
<td>September 2001</td>
<td>A cow infected by BSE was found in Chiba prefecture.</td>
</tr>
</tbody>
</table>

April 2002, FAO Liaison Office in Japan
1-2 BSE in Japan
In Japan rather loose measures have been taken for prevention of the penetration of BSE into Japan, although the EU, which had many-year experience of BSE, sent a message that there is a possibility of BSE outbreak in Japan through the BSE status study. A cow in Chiba Prefecture was identified as being infected with BSE in September 2001. The beef industry plunged into chaos and consumers refrained from eating beef, even imported beef from Australia and the US.

Statistics shows that the quantity of consumption of beef in a household per month decreased to 160 g in December 2001 from 260g in January 2001.

Inappropriate handlings of measures to be taken against BSE by the administration were revealed and criticized by many persons concerned. Following the BSE incident, several fraud cases in the meat industry were also revealed. To take some examples, a case of January 2002 that imported beef was mixed in packages of domestically produced beef to be purchased by the government as a measure dealing with the BSE disaster, three incidents of false best-before date indications, false labeling on imported chicken and false origin indication of meat in March 2002.

Moreover, during the confusion due to the BSE incident, it was found that imported frozen spinach, in which pesticides remained over the limit of residue standard, had been widely imported in Japan. 10 non-registered pesticides were widely used by farmers.

**Recent Main Fraud and False Labeling Cases in Japan**

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 2002</td>
<td>Imported beef was mixed in packages of domestically produced beef to be purchased by the government.</td>
</tr>
<tr>
<td>March 2002</td>
<td>Chicken imported by a company of chicken foods was labeled as domestically produced chicken.</td>
</tr>
<tr>
<td>March 2002</td>
<td>False best-before date was put on foods produced by a factory in Tokyo.</td>
</tr>
<tr>
<td>March 2002</td>
<td>Beef and pork produced in other regions were mixed in packages of brand beef and pork by food processing companies in Tottori and Ibaraki Prefectures.</td>
</tr>
</tbody>
</table>

April 2002, FAO Liaison Office in Japan

The fundamental reform of regulation systems and administration concerning food safety was regarded as one of the most urgent and important issues in Japan. In this connection, the Commission on Investigation and Examination of BSE Issues was organized as a private advisory body to the ministers concerned in November 2001. The task of the
Commission was to recommend the outline of the reform on food safety policy, based on the findings of the investigation of the reason why the infection of BSE could not be prevented. The report of the Commission issued in April 2002 accused of mishandling of the administration, analyzed the defect of the system, and recommended a fundamental restructuring of the system related to the food safety. The reform recommended was very similar to that taken by the EU in the previous year. The core of the reform is the introduction of the risk analysis, appropriate measures in each stage of the food chain from farm to table. It was recommended that the establishment of an institution to independently perform the risk assessment.

Meanwhile, the government has urgently taken up necessary measures, such as the BSE inspection on all the cattle in abattoirs. At the same time, the government convened the ministerial meetings since April 2002. The Liberal Democratic Party, the ruling party, also held 9 meetings from March 2002 to May 2003.

Reference:

Report of the Commission on Investigation and Examination of BSE Issues
(Summary)

(1) Defaults of the Existing Food Safety Policy
At first, the Report identifies the following malfunctions in the existing food safety policy in Japan.

- Lack of consciousness of crisis and the insufficient crisis management system
- Industry-oriented policy, rather than consumer protection
- Administrative system with opaque process of policy decision
- Insufficient relationship between MAFF and MHLW
- Policies not reflected by opinions of scientists and insufficient information disclosure
- Lack of understanding among consumers

(2) Outline of Proposed Reform
Based on the above assessment on the existing policy, the Report proposes the following three points.

a) Placing Priority on Consumer Protection
A fundamental reform of the existing legislation concerning food safety would be needed. The new legislation should recognize the policy priority on protection of consumers’ health and their rights to access safe food. To achieve this objective, the reformed legislation should stipulate the responsibilities of the government and the business operators concerned.

b) Introduction of the Risk Analysis
The Codex Commission makes it clear that zero risk could not be expected in the food
safety policy, as the scientific knowledge has been accumulated under the progress of the science. A risk is a degree of probability of harmful effect caused by the existence of hazards in food. Based on this scientific notion on food safety, “the risk analysis” should be introduced. Such risk analysis is a system for preventing a possible hazard or for making it as small as possible when a hazard to citizens or groups in the society is expected to occur. The risk analysis is composed of “risk assessment”, “risk management” and “risk communication”. It has been already introduced in laws of the EU and its member countries as a system for ensuring food safety.

A system for tracing and examining food in the food chain would be needed in light of the BSE incidence and the following cases of false labeling. Accordingly, the traceability is considered to be a system that should be applied to all foods in the whole food chain, aiming at ensuring food safety.

c) Reform of the Administrative System
In view of keeping independence and consistency, the risk assessment should be conducted by an organization, which is independent of ministries in implementing risk management. In addition, a coordination system should be established, by examining demarcation of functions of food safety policy among ministries. The function of collecting overseas information and providing the public with the information should be assigned to the organization to perform the risk assessment, while strengthening the function of liaison and coordination with international organizations and foreign countries.

(3) Amendment of Laws
The Report proposes that the following legislative reform should be examined in six months and necessary measures should be taken according to it.

a) A law of the comprehensive food safety policy, aiming at the protection of consumers, should be established and the Food Sanitation Law, the Abattoir Law and other laws concerning food safety should be amended.

b) In reference of the restructuring of food safety agencies in the EU member countries, an organization, which performs independent and consistent risk assessments and has the function of coordination with ministries concerned, should be newly established.

1-3 Establishment of the Food Safety Basic Law
Based on the above report, the proposal of the reform of the legislation and the administrative structure was discussed and the draft bills were made in the government and in the ruling party. The bills were passed in the ordinary diet session of 2003. The Food Safety Basic Law was established, and other laws concerned were established and amended in May and June 2003.

Note:
・Food Sanitation Law (1947),
・Abattoirs Law (1953),
・Poultry Slaughtering Business control and Poultry Meat Inspection Law(1990),
・Health Promotion Law (2002)
were amended.

- Agricultural Chemicals Regulation Law (1948),
- Fertilizers Control Law (1950),
- Pharmaceutical Affairs Law (1960),
- Domestic Animal Infectious Disease control Law (1951)
- Law on Securing Safety and Improving Quality of Feed (1953),
- Provisional HACCP Promotion Law (1998)
- Law on Establishment of the Ministry of Agriculture, Forestry and Fisheries (1999)
were amended.

- Beef Traceability Law of 2003 was established.

1-4 Basic Principles of the Food Safety Basic Law

The law understands that the existing system should be improved to precisely respond to the development of science and technology and the progress of internationalization and other changes in the environment surrounding Japan’s dietary habits (Article 1).

The law says that food safety shall be ensured by taking necessary measures based on the simple recognition that the protection of health of our citizens is a top priority (Article 3). It means that the industry-oriented policies in the past should be changed to consumer-oriented ones. The objective of the direct protection of consumers and the placement of priority to consumers was adopted in the Consumer Fundamental Law of 2004 as well.

The law affirmatively recognizes that food safety shall be ensured by taking necessary measures appropriately at each stage of the food supply process from production to consumption. This policy of “from farm to table” was confirmed in the EU Food Safety Law of 2002. In addition, the law underlines the responsibility of business operators who produce, import and sell food and production materials, underlining that they shall be responsible for appropriately taking necessary measures to ensure food safety at each stage of the food supply process (Article 8). This means that traditional food safety measures based on the check of final products is not sufficient. Appropriate measures should be taken in each stage of the food supply process of production and distribution and the use of production materials such as feed, chemicals and food additives as well as production and distribution of agricultural products and processed food. It implies that the intervention to the production and distribution process would be more necessary. Such new methods in production and distribution are traceability, good agricultural practices (GAP), organic farming, HACCP, etc. These measures will not be well performed without active participation of business operators.

The law says that food safety shall be ensured by taking necessary measures on the basis of scientific knowledge and by sufficiently considering international trends and opinions of citizens on food safety (Article 5).
This is one of the most important parts of the law. The law declared that Japan should introduce the risk analysis, which was elaborated by the Codex based on the original concepts of the US and the EU. Therefore, measures should be based on the scientific principles and taken so as to prevent hazards to human health. It implies a shift from traditional “remedial (or corrective) measures” to “preventive measures”. When we consider the Article 11(provisionary measures), the law seems to have applied “the precautionary principle”, although it is not clearly stated so in it. The law also reiterates that measures should be taken in due consideration of the international trends. In the fact that the international food trade has been enormously increasing, the harmonization of measures is quite important to avoid trade conflicts as far as possible. In this regard, the law appeals that the government should take into consideration standards and guidelines of the Codex and other international standards as well as the SPS and the TBT agreements of WTO at the time of taking measures.

1-5 Basic Directions of the Food Safety Basic Law for Policy Formulation

The law orders that a risk assessment should be made for each measure before it is taken. This assessment is called “the Assessment of the Effect of Food on Health”, which shall be conducted in an objective, neutral, and fair manner on the basis of the state-of-the-art scientific knowledge of the time. In formulating policies to ensure food safety, the risk assessment shall be conducted for the purpose of preventing and restraining the adverse effect on human health, in consideration of the dietary habits of citizens and other circumstances, and on the basis of the results of the assessment of the effect of food on health (Articles 11 and 12). Accordingly, the law seems to adopt the “proportionate principle”.

The law also emphasizes the importance of the risk communication in formulating measures, stating that the mutual exchange of information and opinions between the persons concerned and the authorities should be made by providing information to the persons concerned on the measures and by granting them opportunities to transmit their opinions on those measures, in order to reflect public opinion in the formulation of the measures and to maintain the transparency and fairness of the process (Article 13).

Measures for emergency is regarded as a matter of importance in the law. The law states that necessary measures, such as the establishment of a system to cope with or prevent emergency situations that cause or are likely to cause serious damage to human health, shall be taken to prevent such damages (Article 14).

1-6 Food Safety Commission

The Law orders that the Food Safety Commission shall be established in the Cabinet Office (Article 22). The Commission is to perform risk assessment independently from the ministries responsible for risk management as well as from political (parties?) and industries concerned, and to conduct risk communications and coordination of risk communications made by ministries.
During studies on the reform of the administrative structure for food safety policy, the integration of MAFF’s and MHLW’s duties of risk management into a single agency was studied. However, it resulted in the present risk management system separately performed by the two ministries being maintained, on condition of establishing closer relations between the two ministries.

According to Articles 23 and 24 of the law, the Commission shall pursue the following duties.

(1) To present opinions to the Prime Minister;
(2) To conduct risk assessment;
(3) To make recommendations to ministers concerned through the Prime Minister about policies to be implemented for ensuring food safety on the basis of the risk assessment;
(4) To monitor the implementation of policies performed on the basis of the results of the risk assessment, and to make recommendations to ministers concerned through the Prime Minister if necessary;
(5) To examine and deliberate on important matters regarding policies to be implemented for ensuring food safety, and to give opinions to the heads of relevant administrative bodies if necessary; and
(6) To plan and implement the mutual exchange of information and opinions among persons concerned (Article 23).

In particular, ministries responsible for the risk management should request the Commission for the risk assessment and its opinions, before they take measures related to food safety assigned by the following 13 laws (Article 24).

- Food Sanitation Law (Law No. 233 of 1947)
- Agricultural Chemicals Regulation Law (Law No. 82 of 1948)
- Fertilizer Control Law (Law No. 127 of 1950)
- Domestic Animal Infectious Disease Control Law (Law No. 166 of 1951)
- Law Concerning Safety Assurance and Quality Improvement of Feed (Law No. 35 of 1953)
- Abattoirs Law (Law No. 114 of 1953)
- Waterworks Law (Law No. 177 of 1957)
- Pharmaceutical Affairs Law (Law No. 145 of 1960)
- Agricultural Land Soil Pollution Prevention Law (Law No. 139 of 1970)
- Poultry Slaughtering Business Control and Poultry Meat Inspection Law (Law No. 70 of 1990)
- Law Concerning Amendments to the Food Sanitation Law and the Nutrition Improvement Law (Law No. 101 of 1995)
- Law Concerning Special Measures against Dioxins (Law No. 105 of 1999)
- Law Concerning Special Measures against Bovine Spongiform Encephalopathy (Law No. 70 of 2002)
Ministries may request the Commission for risk assessment on a voluntary basis.

The law stipulates for emergency as follows.

- The obligation of the performance of risk assessment shall not apply to a case where there is no time to conduct an assessment of the effects of food on health in advance in case that the measure is urgently necessary to be taken to prevent or control an adverse effect on human health (Article 11).
- The Commission may request that research institutions would conduct investigation, analysis, or examination necessary for the assessment of the effect of food on health, if it is recognized to be necessary for coping with an emergency situation that cause or are likely to cause serious damages (Article 27.)

Source

- *Food Regulation and Trade (Toward a Safe and Open Global System)*
  Tim Josling, Donna Roberts, David Orden
  The Institute for International Economics 2004
  Translation into Japanese by Jiro Shiwaku Ieno Hikari Association 2005
- *Report of the Commission on Investigation and Examination of BSE Issues (written in Japanese)*
  (2 April 2002)
- *Report on BSE, FAO Liaison Office in Japan, April 2002*
- *Risk analysis and safety of food (written in Japanese)* Yukiko Yamada,
  Research of Agricultural Issues, Volume 38 4 2003
- *Outline of New Food Sanitation Law (written in Japanese)* Jinen Nagase
  Policy of Labour 2003
- *Points and Scope of Food Safety Basic Law(written in Japanese)* Isao Kajii Yoko Niiyama,
  Association of Agricultural and Forestry Statistics, 2003
- *Economic study of safety and reliability of food (written in Japanese)*, Yasuhiro Nakajima, Coop Publish, 2004
- 「食品不安は解消されるか」, Kunitatu Fujiwara, Ryoku-fu Publish, 2004
- *Food Safety Basic Law (Law no 48 23 May 2003)*
- *Droit de la consommation, Jean Calais-Auloy, Frank Steinmetz, Dalloz*, 2003
2 The Precautionary Principle

2-1 Definition of the Precautionary Principle
The precautionary principle means that provisionary risk management measures could be taken to prevent potential hazards to human health, even if uncertainty of scientific evidence remains, while the risk assessment was made based on the available information of the time.

As concern about food security have been growing in recent years, precautionary measures have been considered as a matter of importance. The principle, contents and conditions of the precautionary principle have been discussed in international fora, since measures not based on scientific evidence could be an obstacle to the international trade. The EC has adopted the precautionary principle for many years as one of the principles of the common law (Iwata Nobuto). On the other hand, the USA and some other countries consider that precautionary measures should be a preventive approach which could be taken for an exceptional case. WTO has also the similar opinion to the USA on the precautionary principle (Avis de CNA no 30).

2-2 The Precautionary Principle for the Environmental Development
The precautionary principle has been internationally elaborated in relation with the protection of the environment. At the United Nations Environment Development Conference in 1992, it was agreed that measures could be taken to prevent possible negative impact to the irreplaceable environment, in the event where there is lack of scientific certainty. A clause concerning the precautionary principle in the Treaty Establishing the European Community of 2002 was placed (Title XIX Environment Article 174). In 1995, an article of the precautionary principle for the environment was clearly stated in the Rural Code of France by the Barnier Act. (L.200-1)

The Treaty Establishing the European Community of 2002
Article 174
2. Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.

In the Cartagena Protocol adopted in 2000 concerning bio-safety, the precautionary principle was also agreed regarding the transaction of living modified organism. The Article 10.6 states that lack of scientific certainty shall not prevent a member country importing the
modified living organism from taking an appropriate decision in order to avoid potential adverse effects.

**Cartagena Protocol on Biosafety**

**Article 10. Decision Procedure**

6. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.

2-3 The Precautionary Principle in Relation to Food Safety

For many years, precautionary measures have been taken to prevent hazards to human health as the case may be. However, the precautionary principle has been internationally discussed in association with the risk analysis which fundamentally requires the risk management based on scientific evidence.

The EU considers that the precautionary principle should be incorporated as one of the elements of risk analysis. Therefore, the EU elaborated the contents and conditions of measures to be taken under the precautionary principle. In 2000, the EU released the Communication on the Precautionary Principle (COM/2000/001 final).

Finally, the EU stipulated the precautionary principle in Article 7 of the regulation of 2002 concerning the food safety (Regulation No 178/2002 of the European Parliament and of the Council of 28 January 2002). Article 7 states that in specific circumstances where the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary may be adopted.

Article 7 added that the measures adopted above shall be proportionate and not be restrictive to trade, and the measures shall be reviewed within a reasonable period of time.
EU Regulation of 2002 concerning the food safety

Article 7
Precautionary principle
1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

On the other hand, the USA and some other countries consider that the precautionary measures are to be exceptional ones which should be examined as the case may be. They believe that the precautionary measures not based on scientific evidence could be a substantial obstacle to the international trade. Therefore, they have always been in opposition to the precautionary principle in the international fora.

However, the Sanitary and Phytosanitary Agreement concluded in 1994 seems to adopt the precautionary principle. Article 5 states that a member country may provisionally take measures, in cases where relevant scientific evidence is insufficient.

Sanitary and Phytosanitary Agreement
Article 5

7. In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.
2-4 The Precautionary Principle in Japan

The Commission on Investigation and Examination of BSE Issues clearly reported in 2002 that responsibilities of the government including the precautionary principle should be defined in the new legal system for food safety. However, the term of “precautionary principle” has not been adopted in clauses of the Food Safety Basic Law or the amended Food Sanitation Law. Some articles actually place importance on precautionary or preventive measures and appropriate measures for emergency. Therefore, it is conceivable that the Food Safety Basic Law adopted the notion of the precautionary principle.

In this connection, Mr. Umezu, Secretary General of the Food Safety Commission, responded to a question raised in a Parliament session as follows.

While there is not any clause clearly referring to the precautionary principle in the Food Safety Basic Law, there are 2 clauses related to the precautionary principle. The first one is the Article 11 which allows the risk management authority to take a provisional measure without the prior risk assessment, the second one is the Article 12 which means that a necessary measure may be taken in consideration of the dietary habits of citizens and other circumstances, without the risk assessment.

A la lecture des textes de la Loi, il est difficile de savoir si le Japon a adopté le principe de précaution. Ceux-ci ne comportent aucune précision sur la définition, les modalités et les conditions relatives aux mesures de précaution.
(Implementation of assessment of the effect of food on health)

Article 11
In formulating policies to ensure food safety, assessment (hereinafter referred to as the “assessment of the effect of food on health) shall be made for each policy on the effects that potentially harmful biological, chemical, or physical agents in food or the condition of food have on human health, through the ingestion of the food, provided that this shall not apply to the following cases:
(1) where the assessment of the effect of food on health is explicitly unnecessary in consideration of the contents of the measure;
(2) where the contents and degree of adverse effects on human health are clear;
(3) where there is no time to conduct an assessment of the effects of food on health in advance in cases where the measure is urgently necessary to prevent or control an adverse effect on human health.

2. In cases as cited in (3) of the preceding paragraph, the assessment of the effect of food on health shall be conducted subsequently and without delay.

(Formulation of policies on the basis of the results of the assessment of the effect of food on health in consideration of the conditions of nationals’ dietary habits and other circumstances)

Article 12
In formulating policies to ensure food safety, it shall be conducted for the purpose of preventing and restraining the adverse effect of food ingestion on human health, in consideration of the dietary habits of citizens and other circumstances, and on the basis of the results of the assessment of effect of food on health if conducted in accordance with the provisions of paragraph 1 or 2 of the preceding article.

Source:
- The Treaty Establishing the European Community of 2002
- Code Rural in France (Loi Barnier du 2 février 1995)
- L’Avis no 30 Rapport et avis sur le principe de précaution et la responsabilité dans le domaine alimentaire CNA
- Protocol on Biosafety concerning the safe transfer, handling and use of living modified organisms resulting from modern biotechnology (Cartagena Protocol on Biosafety) 2000
- Sanitary and Phytosanitary Agreement of 1994
- Distant course of food laws in the world Module 4 Michigan State university
- WTO and Precautionary Principle(written in Japanese) Nobuto Iwata Agriculture and Forestry Statistics Association 2004
- Food Safety Basic Law 2003 in Japan
3 Traceability

3-1 Definition and Objective of the Traceability
Definition of the traceability slightly varies depending on countries and international organizations. It is most commonly understood that the traceability is an ability to trace the movements of products in the product chain from production to consumption, by recording their transactions in each stage of the chain. It is usually effective to identify in which stage the hazard has occurred by tracing transaction process.

The Codex’s definition of the traceability, which was agreed in the Committee of the General Principles in April 2004, is the ability to follow the movement of food through specified stage(s) of production, processing and distribution. According to the EU’s definition, which was referred in the Regulation of 2002 (178/2002), the traceability means the ability to trace and follow a food, feed, food-producing animal or substance intended to be or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.

While the recording of transaction has been partly made for many years, objectives and modalities of the traceability have been intensively discussed for securing safety and quality of food, after BSE cases occurred in European and some other countries. At the moment, the traceability is one of the important tools for securing food safety and sometimes for securing reliability of food quality in European countries and some other countries like Japan. It may be regarded as a compensatory system to measures for food safety.

However, many other countries including the USA and Australia consider that the traceability is not an essential tool in securing food safety, and it requires a lot of costs for the industry. Therefore, any official traceability system has not been introduced into these countries.

3-2 Traceability in France
France has a long history of traceability. The system of traceability was incorporated in the distribution of wine of appellation d’origine which was formulated in 1919. The objective of the traceability was to prevent false indication on wine. Under this system, growers shall submit a report of expected harvest and the cultivated area of grapes of the year. At the time of release of wine from the cellar, the tax authorities confirm the quantity to be released and issue a license of distribution. Wholesalers of each stage of distribution shall make a special record of transaction of each wine of appellation. At the request of the authorities of taxation or fair trade, the wholesalers should show them the record of transactions.

Official certification systems of quality and origin in France for AOC (1935), Label Agricole (1960), Certification of Conformity (1990) and Organic Products (1980) provide
the forward traceability within their technical standards (cahier des charges).

Regarding beef, France introduced the individual cattle identification system more than 20 years ago. In 1997, the industry agreed that the place of birth, feeding, the abattoir of the animal, etc, should be indicated on the label. On the basis of this agreement the official regulation (arrêté) was established in 1998. Then, in the following year (1999) this regulation was replaced by the law (décret) for the traceability of bovines.

In 1999, Loi d’Orientation Agricole stipulated that a law shall provide a list of products, whose traceability is to be ensured, and establish procedures for registration of information and identification of products or lot of products. Loi d’Orientation Agricole also states that these procedures would serve to know the origin of the product and the conditions of production and distribution of the product (Article 100). The article of the law was codified in the Code de la Consommation as Article L.214-1-1.

3 -3 Obligation of Traceability in the EU
The EU considered that a traceability system on beef would be needed to restore the consumers’ confidence on the safety of beef. At first, the system for individual identification and indication of origin of beef was established by a regulation in 1997. In 2000, the traceability on beef, which is composed of compulsory traceability and voluntary traceability, became an obligation of the member countries by the EU regulation (1760/2000).
The EU adopted the regulation of food safety in 2002, laying down the general principles and requirements of the food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. This regulation has introduced the obligation of the traceability of all food, feed and materials for the member countries. It means that the EU concluded that the traceability would be an essential element to ensure safety and quality of food under the new policy system of food security. The outline of the traceability adopted in the regulation is as follows (Article 18). The obligation of the traceability came in force in January 2005.

1. The traceability of food, feed and any other substance intended to be incorporated into a food or feed shall be established at all stages of production, processing and distribution.

2. Business operators shall be able to identify any person from whom they have been supplied with a food, a feed, or any substance intended to be incorporated into a food or feed. To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

3. Business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.

4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.

5. Provisions for the purpose of applying the requirements of this Article in respect of specific sectors may be adopted in accordance with the procedure laid down in Article 58 (2).

In 2003, the EU adopted a regulation concerning the traceability and labelling of GMOs (genetically modified foods) and food products derived from GMOs (Regulation (EC) 1830/2003).

Article 4 of the regulation stipulates that at the first stage of the placing on the market of a GMO product, operators shall transmit the information that the product contains GMO in describing the unique identifier of the GMO to the operator receiving the product, and at all subsequent stages, operators shall transmit the information received to the operators receiving the products.

3-4 Traceability Introduced in Japan
In Japan, during the examination on the new policy system for food safety which was
intensively conducted just after BSE was found in 2001, information on measures and activities concerning traceability in the EU and its member countries was collected. The report of the Commission on Investigation and Examination of BSE Issues published in 2002 concluded that the traceability should be an integral element of measures under the new food safety policy. The report declared as follows.

The infection of BSE and false labeling proved that a system for tracing and confirming materials used would be needed. Traceability has an ability of tracking products from materials used to food to be finally consumed. Therefore, the traceability should be adopted in the whole chain of all products, and should be placed as one of important tools in the risk management.

However, any specific clause on the traceability was not mentioned in the Food Safety Basic Law of 2003. It was considered that the traceability should be conducted on the voluntary basis by the food industry, except beef, while the traceability is essential for securing food safety. On the contrary to the EU and its member countries, there is not legal obligation of the traceability in Japan.

Regarding beef, Japan introduced almost the same traceability system as France and the EU by establishing the Beef Traceability Law in 2003 (Law for Special Measures Concerning the Management and Relay of Information for Individual Identification of Cattle). Farmers shall transmit necessary information on their cattle to the MAFF which establishes the individual identification system. All the operators in the distribution chain of beef from slaughterhouses to retailers and restaurants shall indicate the individual identification number of the cattle on their beef to be sold.

Under this understanding of the status of traceability in Japan, the Government, in particular the MAFF, started the promotion activities for the traceability. At first, the MAFF underlined, in the Plan of Revitalization of Food and Agriculture issued in April 2002, that the traceability should be an important challenge. In the Policy Outline for Food Safety and Reliability issued in August 2003, the importance of the traceability is emphasized. Guidelines for Introduction of Food Traceability Systems were issued by the MAFF in March 2003. According to the guidelines, the objective and fundamentals of the traceability are as follows.

Traceability systems can track and trace food and its information at each stage of the food chain, and can achieve the following purposes:

1) Greater reliability of information
Traceability systems can secure the transparency of distribution routes and can provide information to consumers, customers and the competent government agency quickly and positively. The systems also reinforce the verifiability of product labelling by securing the complete agreement between the product managed by an ID number and its label.
(2) Contribution to improvement of food safety
If there occurs an accident related to food safety, traceability systems help trace the cause quickly and easily, and help collect and remove a problem food product correctly and promptly by zeroing in on the product and tracing it to its destination. In addition, the systems make it easier to collect data about unexpected impact on health and long-term effects and help develop risk management techniques.

(3) Contribution to higher business efficiency
Traceability systems help increase the efficiency of product management and quality control work by managing products by ID numbers and by storing and offering information about the origins and characters of products.

In order to assist business operators to formulate appropriate traceability systems, the MAFF established six guidelines from 2004 to 2006;
MAFF also provides subsidies for pilot formulation of traceability systems which are conducted by a group of business operators.

At the moment, business operators provide many types of traceability and are developing new systems by using advanced information technology in Japan. Under the systems developed, for example, consumers can access to the information of traceability through a web site of the product, through a device of the computer placed in stores, or through a portable telephone with camera by reading the bar-code of the product and accessing to the internet with it.

3-5 Different Opinions on the Traceability in the World
The traceability system may have been developed in countries where people tend to assess the total value of products by their origin or sometimes by the process of their production and distribution. In recent years, the definition and modalities have been elaborated to ensure safety and reliability of food in the EU countries and some other countries like Japan. In the case of BSE, almost complete traceability system for beef in the whole chain from production to consumption has been applied to the EU countries and Japan. These countries consider that traceability would serve to support risk management measures and to provide more reliable information on food safety and quality to consumers.

However, some countries including the USA and Australia, which have pursued the most effective system of production and distribution under the market mechanism, avoiding as far as possible the administrative intervention to the process of production and distribution. From this point of view, the traceability is one of unnecessary interventions to the industry,
and requires a large amount of costs. In addition, these countries seem to believe that the traditional method of checking final products would be in principle sufficient enough to ensure food security, the process of production and distribution should not been intervened by the administration to maintain the competition and the effectiveness of the industry. Accordingly, these countries hold the negative opinion to the traceability.

However, the Law on the bio-terrorism of 2002 stipulates, in its section 306, that the government must adopt a text to ask the persons who produce, pack, transport, distribute, receive and import food to record data relating to the entrance and to the exit of the goods in their transaction. This text came into force in 2005. The FDA is endowed with the capacity to trace food in cases where exists a threat for food security. In the United States, the terrorist attacks of September 11th, 2001 had a decisive impact in the adoption of texts aiming at instituting a method of traceability.

Therefore, the USA and some other countries opposed to the idea of traceability for GM food in the Codex discussions at the Task Force on Foods Derived from Biotechnology, 1999–2003. The USA does not have any intention of introducing traceability to the beef industry, although Japan required the measures equivalent to those taken in Japan at the series of consultations, in view of re-opening the Japanese beef market to the USA.

In the situation above, there are problems with the traceability in relation to the international trade between countries providing a traceability system and those without traceability. The present agreement of WTO concerning the application of food safety measures (SPS agreement) prohibits member countries from taking measures not based on scientific proof. The need of traceability may not be justified by any scientific evidence in terms of ensuring food safety. Accordingly, countries introducing the traceability are not able to impose the traceability on exporting countries at the time of import of products.
Source:


- Avis de CNA sur Traçabilité 2002, et 2001

- Code de la Consommation of France


- Codification de la loi du 6 mai 1919 relative à la protection des appellation d’origine

- Décret-loi du 30 juillet 1935 Reconnaissance des Appellation d’ Origine Contrôlée

- Law for Special Measures Concerning the Management and Relay of Information for Individual Identification of Cattle of 2003


- Economic study of safety and reliability of food (written in Japanese), Yasuhiro Nakajima, Coop Publish, 2004

- Study on Food Policy (Written in Japanese) 2002-IV No112 Food and Agriculture Policy Research Centre 3

- Public health security and bio-terrorism preparedness and response act 2002
4 Creation of Consumer Protection Agency

Although the reform of the policy of food security is intervened in 2003, a lot of cases of fallacious and inexact mention in labelling persistently occurred in Japan. In 2007, a Processing company of meat in Hokkaido was accused in June when it had sold, for many years, the bovine ground meat to processing companies food, in spite of this sold meat had been blended with other meat such as chicken, pork and offal. During one year from July, 2006, about 10 cases of the fallacious labellings concerning places of origin, numbers of individual identification of the bovine animals, the parts of meat were detected in the commercial operations of meat. In 2007 several pastries and famous restaurants used ingredients beyond the date of minimal durability and sold their products to the consumers by indicating wrong date of minimal durability. To prevent such fraud in trade, the MAFF ordered the business operators to indicate the names of ingredients and the dates of minimal durability on their products to sell to other business operators. This regulation was disposed by the amendment of the quality labelling standards for perishable foods and processed foods under the JAS Law and came into force in April, 2008.

In situation where measures relating to food reliability such as traceability are not in principle obligatory in the legislation, the JAS law plays a role in securing food reliability by using rules relating to labelling, such as obligatory labelling of GMO, places of origin to consumers, as well as obligatory indications of names of ingredients in all stages of food chain.

In January, 2008, in the city of Kobe and in the prefecture of Tiba, about 10 persons suffered from food intoxication by the consumption of frozen Gyoza dumplings imported from China. These contained a pesticide of organic phosphate definitely above the residue limit. It was assumed that somebody had put intentionally the pesticide during the processing or distribution. Neither the Japanese investigative authorities nor Chinese authorities identified a suspect of intoxication. After this incident, it was noted that several other imported processed products from China had contained some pesticides of organic phosphate above the residue limit. Towards the end of February 2008, 18 distributors of food withdrew 58 types of imported food from the market. The government of Japan made a decision to fulfil the surveillance for all imported processed foods, aiming at confirming residues of pesticides of organic phosphate.

Considering this situation above, the prime minister of Japan, who places an importance on the consumer protection, proposed the creation of a proper agency for the protection of consumers’ interest. After the intensive consultations with relevant ministries, the government of Japan decided to establish the Consumer Agency. Related bills will be proposed in the ordinary parliament session in late 2008. This Agency will integrate control of safety, labeling and transaction. As far as food is concerned, it will cover Food Safety Basic Law, “Food Sanitation Law”(areas of safety), “Product Liability Act”, JAS Law(areas of labeling), Food Sanitation Law(areas of labeling), Health Promotion
Law (areas of labelling), Act Against Unjustifiable Premiums and Misleading Presentations, etc.

**Note:**

This Agency will also cover the Consumer Good Safety Law, the Law on Control of Household Commodity Containing Harmful Substances, the Household Goods Labelling Law, the House Quality Securing Law, the Installment Sales Contract Act, the Money Lending Control Law, the Real Estate Business Law, the Travel Agency Law, the Law on Sales of Financial Products, the Consumer contract Law, etc.
III Regulations for Food Safety

1 The Food Sanitation Law

1-1 History of the Food Sanitation Law
Before the Second World War, food sanitation was controlled by the Food, Beverage and other Related Goods Control Law of 1900, which stipulated only that ministries concerned could prohibit production, sale, transaction or use of food, beverages and other related products that could be injurious to the human health. Therefore, food safety was regulated by various government orders such as the Milk Business Control Regulations, the Soft Drink Business Control Regulations, the Ice Business Control Regulations, the Artificial Sweetener Control Regulations, the Injurious Color Additive Control Regulations, the Anti-decade and Bleaching Substance Control Regulations, the Methyl Alcohol Control Regulations, etc. The controlling measures under these regulations were executed by the police system under the Interior Ministry. However, among these regulations some were not based on the law.

The Law Concerning Effectiveness of Government Orders at the Enforcement of the Constitution of Japan in 1947 stipulated that regulations not based on laws should be abolished. Therefore, the Food Sanitation Law was established in the same year, so as to put these regulations together under the new legal system. In addition, a new comprehensive food sanitation control law was needed to prevent wide distribution of not safety and not sanitary food under the severe shortage of food and to improve the deteriorated public health situation in Japan just after the World War II.

In 1952, the inspection system of food was introduced in the Food Sanitation Law. During the shortage of food, quite a lot of foods that caused food poisoning have been distributed and imported. Before 1952, food was inspected within the Japanese market. However, this inspection system was not sufficient to effectively prevent the circulation of injurious imported food. Regarding meet, the law required the exporting country’s inspection guaranty.

In 1956, considering that food additives have been widely used in processed foods, definitions of food additives to be regulated by the law came to be clearly defined, and the standard of labeling for food, food additives, etc, was established.

In 1995, the law was largely amended to cope with the situation of the development of the food industry and the complexity of the distribution system of food, as well as the increase of the import of food and the consumers’ growing concern to nutrition and health. The HACCP system and the ordered inspection on imported foods were introduced by the amendment of the law. In addition, natural food additives have been regulated, while they were previously not subject to regulations of the law. Since late 1980s, international
harmonization of regulations concerning food safety became important, due to the globalization of trade. Accordingly, new regulations and measures in Japan have been generally taken, following or considering measures adopted in the EU and the US.

In 2001, the legal pre-market approval system and the labeling obligation for GM food were introduced. At the same time, the labeling obligation of allergens in food and the definition of health functional food (health claims) were established, due to the increased consciousness of consumers on the health.

In September 2001, the outbreak of BSE in Japan was confirmed by the identification of an infected cow in Chiba Prefecture. In addition, a lot of incidents of food poisoning and violations against regulations and false labelings were observed in Japan in these years.

Accordingly, the Food Safety Basic Law was established in 2003, and the Food Safety Commission to independently perform risk assessments based on the risk analysis was established. The Food Sanitation Law and other related laws were amended in line with the restructuring of the food safety policy intended by the Food Safety Basic Law.

1-2 Scope of the Food Sanitation Law
The law covers all types of foods, food additives, containers/packages and toys, and almost all aspects related to food safety to human health are covered by the law. Accordingly, the law regulates food labeling, food additives, residue of pesticides, veterinary drugs and additives to feed, import quarantine, inspection, GMO, food with health claims, HACCP, and licenses for carrying on business. However, nutrition labeling, nutrition claim and food for specified use such as food for babies, food for lactating mothers, and food for pregnant mothers are regulated separately under the Health Promotion Law.

Regarding food labeling, the JAS Law under the control of MAFF covers all aspects of food labeling except those related to food safety. Therefore, some duplication and confusion are observed from the viewpoint of consumers in Japan. This problem has been gradually improved since 2003 when closer cooperation between MAFF and MHLW were required at the time of the establishment of the Food Safety Basic Law.

The regulations of the Food Sanitation Law are executed by the government (state) and prefectures. In principle, prefectures are responsible for monitoring and inspection (except import inspection), appointment of monitoring officer and order of withdrawal of violating products from the market, as well as licensing for business. To perform these duties, each prefecture has public health centers. However, import quarantine and related inspection at the point of import are performed by the state.

1-3 Structure of the Food Sanitation Law
The Food Sanitation Law is very comprehensive law, which covers all types of foods, food additives, apparatus and containers/packages, and almost all aspects relating the safety of these products. The composition of the regulations is as follows.
1-3-1 Duties of the state and prefectures and business persons
(1) Duty of the state and prefectures (Article 2)
(2) Duty of businessperson of food (Article 3)

1-3-2 Prohibition of sales of goods which are injurious to human health
(1) Food and food additives whose sales are prohibited (Article 6)
   - Those which are rotten, decomposed or immature
   - Those which contain toxic or injurious substances
   - Those which are contaminated with pathogenic microorganisms
   - Those which may injure human health due to uncleanness or any other causes
(2) Prohibition of sales of newly developed food (Article 7)
(3) Prohibition of sales of meat derived from diseased livestock and poultry (Article 9)
(4) Prohibition of sale of food additives (Article 10)
   Any person shall not sell food additives, unless the minister designates them as not injurious to human health.
(5) Prohibition of sales of injurious or toxic apparatus, containers/packages (Articles 16 and 17)

1-3-3 Specifications and standards
(1) Establishment of specifications and standards for food and food additives (Article 11)
   The minister may establish specifications or standards for food and food additives.
   Any person shall be prohibited from manufacturing food and food additives not in conformity with standards, or from selling those not complying with the specifications.

   Note:
The positive list system of agricultural chemicals including feed additives, veterinary drugs, GM food,
and Health Functional Food (including FOSHU) are regulated under this article.

(2) Establishment of specifications and standards of apparatus, containers/packages (Article 18)

1-3-4 HACCP
The comprehensive sanitation-controlled manufacturing process, HACCP, (Article 13)
   The minister may give approval for manufacturing based on HACCP for manufacturing plant, when the minister receives a petition.

1-3-5 Labeling and advertising
Establishment of standards of labeling (Articles 19 and 20)
   The minister may establish standards of labeling for food, food additives, apparatus and containers/packages. No person shall sell those goods, unless those bear labeling complying with the established standard. No person shall falsely or exaggeratedly label or advertise.
1-3-6 Japanese standards for food additives (Article 21)
The minister shall compile the Japanese Standards for Food Additives.

1-3-7 Inspections and examinations
(1) Plan of inspection of and guidance on imported food (Article 23)
The minister shall establish every fiscal year a plan of inspection of and guidance on imported food, food additives, apparatus and containers/packages.
(2) Plan of inspection of and guidance on food sanitation by prefectures (Article 24)
The governor of prefecture shall establish every fiscal year a plan of inspection of and guidance on food sanitation of prefecture.
(3) Product examination and prohibition of sales of food not labeled with certification (Article 25)
(4) Order for examination (Article 26)
The minister may order a person who imports to allow examinations performed by the ministry or registered laboratories. The governor of prefecture may order a person having manufactured or processed products to allow examinations performed by the prefecture or registered laboratories.
(5) On-site inspection and collection of samples (Article 28)
The minister or the governor of prefecture may request necessary documents from businessperson and require the officials concerned to visit the business places in order to inspect the facilities.

1-3-8 Import notifications
A person who wishes to import shall notify at each import (Article 27)

1-3-9 Registered laboratories

1-3-10 Establishment of preventive measures against contamination of toxic or injurious substances
Minister may establish standards for the course of manufacturing and processing of food and food additives. Each prefecture may establish standards for public health measures including cleanliness of inside and outside of business facilities. Each prefecture shall establish standards by types of business for facilities of restaurants and other business. (Articles 50 and 51)

1-3-11 Licenses for carrying on business
A person who wishes to carry on any business shall obtain a license from the governor of the prefecture (Article 52).

1-3-12 Invitation of comments of the public (Risk communication)
(1) In case of taking certain measures under the law (standards of food and food additives, plan of examination on imported food, etc), the minister has to announce the contents and reasons to the public and hear opinions of the people (Article 64).
(2) The minister and the governor of prefecture have to announce to the public the actual
state of practices of food sanitary measures, and have to hear widely to opinions of the people, in order to reflect opinions on measures concerned, and in order to undertake the promotion of exchange of information and opinions (Article 65).

1-3-13 Penal provisions (Articles 71-79)

1-4 Amendment of the Food Sanitation Law in 2003
1-4-1 From Public Health to Protection of Consumers’ Health
Following the Food Safety Basic Law placing priority on protection of consumers’ health, the objective of the law was amended for the first time since the establishment of the law in 1947. The law was promulgated only 2 years after the Second World War ended. Under the low hygiene conditions in the situation of severe shortage of food, the main purpose of the law was to ensure public health by preventing distribution of very low quality food and harmful food. In 1995, the law was amended to respond to the developing situations such as very advanced technology in the food industry, complex production and distribution systems, increase of imported food and change of dietary habits. However, the objective of the law has not been changed.

In the amendment of the law in 2003, the objective of the Food Sanitation Law has been changed as follows.

Article 1 The purpose of this law is to prevent the occurrence of health hazards arising from human consumption of food, by making necessary regulations and taking any measure so as to work for the protection of the health of the people.

1-4-2 Responsibilities of the Government and Business Operators
The law requires business operators to perform the responsibility as follows.

“Any businessperson shall voluntarily make efforts to get knowledge and techniques related to securing the safety of food intended for sale, securing the safety of the raw materials and the practice of self-imposed examination, and shall make efforts to take any necessary measure.
Any businessperson of food shall make a record of the list of suppliers of food intended for sale and its raw materials, and shall make efforts for its maintenance. And the list shall be provided to the state and the prefecture, where necessary for prevention of a food sanitation hazard (Article 3).”

The above responsibilities of business operators are very general efforts to be made by them, except efforts to make a list of transactions. Therefore, appropriate measures, together with measures under the Food Sanitation Law, should be taken by business operators under regulations of other laws in each stage of the supply process. Ensuring food safety and food quality could be achieved by the combination approach of measures in the
process of food production and those to be taken under the Food Sanitation Law. This is the notion of “from farm to table”.

1-4-3 Promotion of Risk Communication
The law urges the state and the governors of prefecture in particular to promote two sorts of risk communication, as the Food Safety Basic Law places importance on the risk communication.

In case of taking certain measures under the law (standards of food and food additives, plan of examination on imported food, etc), the minister of MHLW has to announce the contents and the reasons to the public and hear opinions of the people (Article 64). Then, the minister and a governor of prefecture has to announce to the public the actual state of practices of food sanitary measures, and has to hear widely to opinions of the people, in order to reflect the opinions in the measures concerned, and in order to undertake the promotion of exchange of information and opinions (Article 65).

1-4-4 Regulations to Food Additives and Residue of Pesticides
The positive list system of food additives has been introduced in Japan in earlier stage, compared with the US and European countries. However, natural food additives were not subject to the registration of food additives. In 1995, listing these natural food additives in the list of registration became obligatory, while the safety assessment is not necessary as a provisional treatment. These items are called “Existing Additives” which number 489. Consumer groups, however, claimed that some of them are harmful to human health, and these items should be removed from the list by undertaking safety assessment.

In 2003, the law established a procedure to withdraw from the list an item which was assessed as a substance with a possibility of adverse effect to the human health (Articles 2 and 3 of the Law Concerning Amendments to the Food Sanitation Law and Nutrition Improvement Law). The assessment of items in the existing list should be actively performed. By February 2005, the “madder red color additive” was removed from the list, and other 38 items that had not actually been used were also removed from the list.

A food additive is designated through an application from a corporation developing it or its importer. The designated food additive could be used by any person, although a huge amount of costs is needed to supply necessary scientific data on safety at the time of application. By this reason, there are some number of food additives which have not been applied in Japan. Accordingly, these food additives are prohibited to use in Japan, while they are approved as safe in foreign countries. To break through this constraint, a system that the government could register an additive without an application from a petitioner was introduced. These additives number 46 items. By February 2005, an additive has been already designated and 19 food additives are under examination.

Regarding agricultural chemicals (pesticides, veterinary drugs and feed additives), the law introduced the positive list system, a system to prohibit the distribution of foods that
contain agricultural chemicals above a certain level if maximum residue limits (MRLs) have not been established. The system will take effect within three years after the publication of the revised law (refer to the section of pesticides).

1-4-5 Ensuring Safety of Imported Food

(1) Introduction of the Comprehensive Ban of Import
In March 2002, frozen spinach imported from China was found containing insecticides. The inspections and examinations identified many cases of contamination of residue of pesticides over the residue standards. Despite of the subsequent strengthened inspections and examinations, the government could not effectively prevent such violation. There was no way other than inspection or examination on lots of goods to prohibit the import, according to the existing system. Accordingly, a need of introducing a comprehensive ban of import was recognized, as the EU introduced this kind of import ban in the food safety law (regulation) of 2002.

The law was proposed by members of the Parliament in the emergency situation and approved in August 2002 (Amendment of Food Sanitation Law for the prohibition of sales, production and import of food from specified countries and regions where there are repeated violations in export, sales and production of the food concerned).

(2) Prohibition of Sales of Unfamiliar Food which may Injure Human Health
There have been some cases that special food containing condensed substance for diet injured human health. In 2002, persons who took a diet food imported from a country (China) happened to die. This incident triggered the addition of a clause that the government may prohibit sales of unfamiliar or suspected food which may injure human health to the law. According to the Article 7, the following two types of food could be prohibited to sell.

a) Articles generally served, and in case it is served for consumption in a quite different recipe from ordinary way, which could possibly injure human health,

b) A food suspected to contain a substance that has never been served for human consumption, when it causes a serious hazard.

Note:
The original Article 7 prohibits only the sales of products that never have generally served for human consumption, which could possibly injure human health.

(3) Quick Execution of Ordered Examination
The system of order for examination was introduced by the amended law of 1995, aiming at effective examination on imported food. The government could order importers to undergo examinations at the registered examination facilities at importers’ expense, when the government considers it necessary. The law of 1995 stipulated that the types of foods to be ordered to conduct self examinations by order of the Cabinet were limited to foods which had high possibility of violation, such as vegetables, fruits, beef, pork, poultry, fish paste products, etc. By the amendment of the law, the limitation of types of food being
subject to ordered self-examinations was abolished. Therefore, the government can order self examinations on any types of foods at this moment (Article 26).

(4) Others
In addition to the above amendments, a suspension of import operation by the government (Article 55), entrustment of the conduct of the examinations to registered examination facilities (Article 28), change of the designation system of examination facilities to the registration system, and establishment and publication of a guideline of examination and a plan of examination were introduced.

1-4-6 Limitation of the Validity of HACCP Approval
During the several years since the introduction of the approval system of HACCP facilities, some food safety accidents have happened at the HACCP-approved facilities. Therefore, the law has changed to limit the term of validity of the approval, in view of introducing the periodical review of effectiveness of approved HACCP facilities. The term is within 3 years (Article 14).

In addition, the Provisional HACCP Promotion Law, which provides favorable treatment of tax and loan interest rate to HACCP-approved facilities, was prolonged for another 5 years. At the application for the HACCP approval, an operation plan should be submitted, in addition to a facility improvement plan based on the standards for progress operations.

Source:
- Statement of the Minister at the parliament on the proposal of the Food Sanitation Law on 3 December 1947
- Statement of the Minister at the parliament on the proposal of the amendment of the Food Sanitation Law on 3 July 1952
- Statement of the Minister at the parliament on the proposal of the amendment of the Food Sanitation Law on 17 April 1956
- The Outline of the New Food Sanitation Law, Jinen Nagase, K. K. Labor Administration, 2003 (written in Japanese)
- Commentary on the Amendments of the Food Sanitation Law and Other Laws in 2003, Research Institute for Food Sanitation, Chuohoki Publishers, 2004 (written in Japanese)
2 Pesticides

2-1 Improvement of Regulations on Agricultural Chemicals
The Food Safety Law of 2003 underlined that appropriate measures should be taken in each stage of food supply process (from farm to table). Accordingly, a clause that policymaking on food safety in the process of production is one of the MAFF’s roles was added to the duties and responsibilities of MAFF by the amendment of the MAFF’s establishment law of 2003 (Article 4, 15).

In 2003, regulations for safety of agricultural materials such as pesticides, veterinary drugs, feed additives, etc. were strengthened by the amendments of the related laws. The laws stipulated that cooperation between MAFF and MHLW should be enhanced in deciding measures for food safety.

2-2 Prohibition of the Use of Non-Registered Pesticides
When food safety was a crucial issue due to the outbreak of BSE in Japan, an actual use of two prohibited pesticides, Difolatan and Plictran, which were imported, was revealed in Yamagata Prefecture on 4 April 2002. According to an intensive survey conducted by MAFF, 10 non-registered pesticides were found to have been sold by 270 business facilities, and have been used by approximately 4,000 farmers.

This illegal use of pesticides was considered as a very serious threat to food safety. The existing Agricultural Chemicals Regulation Law prohibited sales of non-registered pesticides. However, import by non-commercial people and use of non-registered pesticides by farmers were not prohibited by the law. To prevent import and use of non-registered pesticides, the Agricultural Chemicals Regulation Law (1948) was revised in December 2002 and came into force in March 2003. Then, sales, use and import of non-registered pesticides are prohibited (Articles 9 and 11).

Note:
Registration, labeling, prohibition and restriction of sales, prohibition of use, standards of use, inspection, registration of imported pesticides, etc. are regulated in the Agricultural Chemicals Regulation Law (No 82 1 July 1948)

In the amendment law, an advertisement for encouraging import of non-registered pesticides by traders was also regulated (Article 10-2). In addition, the law orders that standards of the use of pesticides should be introduced so as to prevent residue problems of pesticides in food, and should be obligatory by introducing the penalty to the violation (Article 12).

An important problem to be solved was the legal definition of pesticides in association with the ban of use of non-registered pesticides. Farmers could not use salt or vinegar to kill insect, if these substances are not registered as pesticides. Accordingly, a category of
pesticides as “Specified Pesticides”, which are not subject to the regulations of the law, was decided to be established (Article 2). According to a study so far, weed controlling sheet, goose, dug, cattle, carp, etc. are excluded from “pesticides”, while sodium bicarbonate, vinegar, natural enemies in particular regions are designated as specified pesticides. Other approximately 700 items are under examination.

2-3 Introduction of the Positive List System of Agricultural Chemicals
A pesticide is registered after a standard of use and a “standard of withholding” have been set through examinations on its safety and effect to the environment by MAFF and Ministry of Environment. A residue standard (MRL) concerning the safety of human health is set by MHLW under the Food Sanitation Law. Residue standards have actually been set neither for all the registered pesticides nor for all the pesticides distributed in the world. Therefore, there have been certain number of pesticides being used without residue standards. Moreover, it is not possible to regulate the import and distribution of food containing pesticides for which residue standards were not set.

Note:
Registered pesticides: 350, Pesticides for which residue standards are set: 229, Globally distributed pesticides: approximately 700, as of January 2005.

In many overseas countries, a registration is to be set after or at the same time of the establishment of a residue standard. The report of the Commission on Investigation and Examination of BSE Issues recommends that a registration should be made at the same time of the establishment of a residue standard. By the amendment of the Food Sanitation Law and the Agricultural Chemicals Regulation Law and other relevant laws in 2003, the positive list system of agricultural chemicals (including veterinary drugs and feed additives) was introduced. Accordingly, food containing pesticides without residue standards is, in principle, prohibited to be distributed. The positive list system shall come into force after 3 years of the publication of the laws (in 2006). In addition, food containing pesticides, for which residue standards are not set, shall not be distributed, if the residue of the pesticides is above an uniform level.

In the implementation of the positive list system, the government should establish as many residue standards as possible for pesticides internationally distributed. Otherwise, it may cause serious obstacles for the international trade. Accordingly, the intensive preparation work for establishing residue standards was made by the government, so that those can be established before the enforcement of the positive list system in 2006.
Provisional Translation of the Article 11, Paragraph 3, of the revised Food Sanitation Law (newly established provision)

Any food that contains, as a residue, an active ingredient of an agricultural chemical defined in the Agricultural Chemical Control Law, a feed additive defined in the Feed Additives Safety Control Law, or a veterinary drug defined in the Pharmaceutical Affairs Law (including a substance produced by a chemical change in the active ingredient and excluding any substance specified by the Minister of Health, Labour and Welfare as not posing any adverse health effects) at a level exceeding the amount that is established by the Minister of Health, Labour and Welfare as not posing any adverse health effects after hearing the opinion of the Pharmaceutical Affairs and Food Safety Council, shall not be produced, imported, processed, used, prepared, or stored for the purpose of sale, or sold. However, this provision shall not be applied in the case that the maximum residue limit is established for the chemical on the food, in accordance with the provision of Paragraph 1 in this article.

Translated by MHLW

2-4 Provisional Residue Standards
The government studied the establishment of provisional residue standards (MRLs). The method of establishment is firstly to adopt MRLs of the Codex, secondly to adopt national withholding standards if there are not MRLs of Codex for the substances, thirdly to set standards, considering other countries’ standards such as the US, the EU, Australia, etc. if neither MRLs of Codex nor national withholding standards are established.

- The current established MRLs will remain unchanged and continue to be applied.
- Provisional standards for approximately 715 chemicals, which should be in principle applied to perishable products, will be established.
- Provisional MRLs for processed food were established, only when Codex MRLs are established (61 chemicals).
- Provisional MRLs for mineral water were established (34 chemicals), based on the WHO guideline.
- When an ADI cannot be established due to carcinogenesis or other reasons, provisional MRLs were established as “Not Detected” (15 chemicals).
- An uniform limit was set as a limit of the amount which has no harmful effect to human health. The limit will be 0.01 ppm, the same as that in the EU.
- The specified chemicals, which are considered as harmless and are not to be subject to the regulations, were fixed.
## Introduction of the Positive List System of Pesticides, Veterinary Drugs and Feed Additives

### Present Regulations

<table>
<thead>
<tr>
<th>Pesticides whose MRLs exist</th>
<th>Pesticides whose MRLs do not exist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Residue standards for 229 Pesticides and 26 veterinary drugs</td>
<td>In principle free distribution of food which has residues of pesticides</td>
</tr>
<tr>
<td>Ban of distribution of food which has residues over the MRLs</td>
<td></td>
</tr>
</tbody>
</table>

Approximately 350 pesticides were registered in Japan, and around 700 pesticide are distributed in the world.

### After the Enforcement of the Positive List System (2006)

<table>
<thead>
<tr>
<th>Pesticides whose residue standards are established</th>
<th>Pesticides whose residue standards do not exist</th>
<th>Specified pesticides</th>
</tr>
</thead>
<tbody>
<tr>
<td>By the enforcement of the positive list, provisional MRLs will be established in reference to Japanese, international (Codex), American and European standards of residue. Establishment of MRLs at the same time of new registration</td>
<td>An uniform limit to be announced by the minister (0.01 ppm)</td>
<td>Pesticides to be announced by the minister as no harmful to human health</td>
</tr>
<tr>
<td>Ban of distribution of food which has residues over the MRLs of pesticides</td>
<td>Ban of distribution of food which has residues over the uniform limit</td>
<td>Not to be subject to the positive list</td>
</tr>
</tbody>
</table>

Source: MHLW
2-5 Strengthened Safety Regulations on Veterinary Drugs, Feed Additives, etc.
In addition to the regulations on pesticides, safety regulations on fertilizer, veterinary drugs, feed and feed additives were improved, such as the establishment of standards of use, the prohibition of use of non-registered veterinary drugs, the establishment of manuals for the prevention of animal infectious diseases. When MAFF takes these measures, MAFF should hear opinions of MHLW. The positive list system was introduced on veterinary drugs and feed additives. Accordingly, residue standards of these chemicals should be set at the same time of the resignation of feed additives and the approval of veterinary drugs.

Source:
- Commentary on the Amendments of the Food Sanitation Law and Other Laws in 2003, Research Institute for Food Sanitation, Chuohoki Publishers, 2004 (written in Japanese)
- The Recent Amendment of the Agricultural Chemicals Regulation Law and Its Influences, Nippon Soda Co., Ltd., Mitsuo Hattori, 2004 (written in Japanese)
- The Website of the MHLW (Request for Comments on the Second Draft of Provisional Maximum Residue Limits for Agricultural Chemicals in Foods)
3 Food Additives

3-1 Legal Status of Food Additives
Food and food additives are equally regulated by many articles of the Food Sanitation Law. For example, Article 6 of the Law stipulates that no person shall sell or handle, manufacture, import, process, use, prepare, store, or display with intent to sell any food or food additive given as below.

(1) Those which are rotten, decomposed or immature.
(2) Those which contain toxic or injurious substances or, which are suspected to contain such substances.
(3) Those which are contaminated or suspected to be contaminated with pathogenic microorganisms
(4) Those which may injurious to human health due to uncleanness.

However, any food additive (excluding natural flavoring agent and usual food or beverage which is used as food additives) shall not be sold, unless the Minister of MHLW designates it as not injurious to human health (Article 10). From the beginning of the establishment of the Food Sanitation Law in 1947, this designation system (positive list system) was introduced in Japan, when the USA and European countries still adopted the negative list system.

The MHLW may establish specifications and standards for food and food additives by Article 11 of the Law, which stipulates that Minister, from the viewpoint of public health, may establish standards for methods of manufacturing, processing, using, preparing, or preserving food or food additives intended for sale, or may establish specifications for components of food and food additives intended for sale. The Minister shall compile “the Japanese Standards for Food Additives” which contain the standards and specifications for food additives (Article 21).

Labeling of food additives and those contained in food is regulated by Article 19 and 20 of the Food Sanitation Law. Article 21 of the enforcement regulations of the Law stipulates the details of the labeling requirements (Refer to IV 3-3 Labeling standards for food additives).

3-2 Categories of Food Additives
There are following 4 categories of food additives in Japan.

(1) Designated Food Additives (325 items as of 2005)
This category of food additives includes those which are designated by the Minister as not injurious to human health. Food additives other than designated food additives, except existing food additives, natural flavoring and food additives of usual food and beverage are prohibited to be sold.
In principle, manufacturers or distributors (including importers) submit a petition to the Minister with documents concerning safety. The petition is examined by the Pharmaceutical Affairs and Food Sanitation Council. The Minister registers the food additives, when the Council has reached a positive conclusion. Then, the Minister may establish a standard for methods of manufacturing, processing, using, preparing or preserving it. The standard has not been established for all food additives registered.

The designated food additive could be used by any person, although a huge amount of costs is needed to supply necessary scientific data on safety at the time of the petition. By this reason, there are some numbers of food additives which have not been applied in Japan, and are prohibited to use in Japan, while those are approved as safe in foreign countries. To break through this constraint, a system that the government could register an additive without any application of a petitioner was introduced. Such additives account to 46. By February 2005, an additive was already designated and 19 food additives are under examination.

(2) Existing Food Additives (489 items as of 2005)
Natural food additives were not subject to the designation system of food additives. Consequently, they had been freely produced and used for many years. Consumers claimed that these substances should be regulated by the Food Sanitation Law. In 1995, by the amendment of the Law, these natural food additives became listed in the list of registration, while the safety assessment would not be necessary as a provisional treatment (Food Sanitation Amendment Law of 1995, Additional Clauses Articles 2 and 3). These items are called “existing additives” which account to 489. Consumer groups, however, claimed that some of them were harmful to human health, and these items should be removed from the list by undertaking safety assessments.

In 2003, the law established a procedure to withdraw an item assessed as a substance that has a doubt of adverse effect to the human health from the existing list (Article 2-3 of the Law Concerning Amendments to the Food Sanitation Law and Nutrition Improvement Law). As a result, the assessment of items in the existing list became actively performed. By February 2005 “madder red color additive” and other 38 items which had not been actually used were removed from the list.

(3) Natural Flavoring
Flavoring agents which are produced from any natural animal or plant. They are freely produced and sold.

(4) Food Additives of Usual Food and Beverage
This category of food additive includes foods usually consumed, which is used as food additives. For example, when a juice is used for coloring, it is treated as a food additive. When wheat flour is used in the process of filtration, it is regarded as a food additive. These food additives are not prohibited to be produced or to be sold.
Source

- Food Sanitation Law (1947)
- Enforcement regulations of the Food Sanitation Law (Ministerial Ordinance of MHLW 1958)
- Web site of the MHLW
4 Import Procedures and Inspection

4-1 Import Procedures under the Food Sanitation Law

To ensure the safety of imported foods and related products, Article 27 of the Food Sanitation Law obliges importers to submit import notification. As Article 27 states that "Those who wish to import food, food additives, apparatuses, or container/packages for sale or for use in business shall notify the MHLW on each occasion as prescribed by the Ministerial Ordinance "the imported foods and related products must not be used for sale without an import notification."

The "Notification Form for Importation of Foods" is submitted to a Quarantine Station of the MHLW. At the quarantine station, food sanitation inspectors carry out documentary examinations and inspections to see if the foods and products comply with the Food Sanitation Law.

4-1-1 Import Notification

Importers have to fill out the Notification Form for Importation of Foods providing all the required information. The import of some food items such as meat, meat products and swellfish (puffy fish) requires a "sanitary (health) certificate" issued by the governmental organization of the exporting country.

The importers, then, submit the completed Notification Form to the quarantine station responsible for the port of import. A submission through electronic information processing system is also available. To submit the notification through the electronic system, importers are required to register their computer terminal along with the necessary information to the MHLW beforehand.

4-1-2 Document Examination of the Notification Form for Importation of Foods and Inspection at the MHLW Quarantine Station

After the submission of the notification, the food sanitation inspector at the quarantine station inspects the product to examine whether the item meets the regulations under the Food Sanitation Law.

During the documentary examination, the food sanitation inspector validates the following points based on the information reported in the Notification Form. The judgment will be made based on the information, such as the country of export, the imported items, the manufacturer, the place of manufacture, the ingredients and materials, the methods of manufacturing and the use of additives.

- Whether the imported food, etc. complies with the manufacturing standards regulated under the Food Sanitation Law.
- Whether the use of additives complies with the standards.
- Whether poisonous or hazardous substance is contained.
- Whether the manufacturer or the place of manufacturing has a record of sanitation problem in the past.
When the cargo is judged to need to be inspected, an inspection order, a public inspection or other kinds of inspection will be carried out in order to confirm the compliance of the cargo with the law.

There are following three types of inspection as follows.

**a) Inspection Order System**  
When the examination of the document and information on the sanitary situation of the exporting country, the nature of the food and related items, or the record of incompliance of the similar items in the past indicates that the food concerned is highly suspected of violating with the Food Sanitation Law, the inspection order will be issued by the MHLW, and the import procedure will be suspended until the compliance of the food concerned is proved. This system is called "Inspection Order System" and the importer is responsible for the cost of the inspection.

**b) Monitoring Inspection System**  
"Monitoring inspections" are carried out at a MHLW’s Quarantine Station for the food and related items that are unlikely to be incompliant with the Food Sanitation Law. Every year, the items to be subject to monitoring inspections are designated based on the annual import amount and the record of incompliance in the past for each item.

The purpose of the monitoring inspection system is to collect information data on sanitation statuses of the diverse food items that are brought into Japan, as well as to promote the smooth distribution of these items. While the MHLW food sanitation supervisors carry out sample inspections, the import procedures can be proceeded without waiting for the inspection results.

**c) Other Inspection Systems**  
In addition to monitoring inspections, the MHLW food sanitation inspectors conduct other kinds of inspections, such as inspections for foods that are imported to Japan for the first time, inspections to examine the items that are incompliant with the Food Sanitation Law, and inspections to examine the food and related items that have experienced an accident during transportation.

Also, in some cases of first-time imports or regular imports, the MHLW quarantine station requires the importers to conduct an inspection of the cargo on some necessary items, based on the idea that importers also have an obligation to secure the food sanitation and safety.

When that the cargo is found in compliance with the law through the documentary examination and cargo inspection (the cargo "passed" the inspection), a "Certificate of Notification" will be issued to the importer by the MHLW quarantine station where the notification was first submitted. The import procedures, then, will proceed to the next step.

The cargo that has been judged not to comply with the law (the cargo that "did not pass" the inspection) cannot be imported into Japan. The MHLW quarantine station will notify the
importer how the cargo violates the Food Sanitation Law, and the importer will take necessary measures by following the instructions from the station.

In order to simplify and expedite the import procedures, simplified systems of import notification are also available.

**Systems for Simplified and Expedited Systems of Import Procedures of Food and Related Items**

<table>
<thead>
<tr>
<th>Name</th>
<th>System</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Advance Notification System</strong></td>
<td>For all food and related products, the import notification form can be submitted up to 7 days in advance of the estimated date of cargo's arrival. Except for the cargo that needs an inspection, a copy of certificate of notification is issued immediately, either before the arrival of cargo or after the cargo is unloaded to the bonded area.</td>
</tr>
<tr>
<td><strong>Planned Import System</strong></td>
<td>If a certain food or related item is planned to be imported repeatedly, an import plan can be submitted at the time of the first import. When the plan is found satisfactory, the submission of import notification is exempted for a certain period.</td>
</tr>
<tr>
<td><strong>Inspection Results by Public Inspection Organizations in Other Countries</strong></td>
<td>When a cargo is inspected by a public inspection organization in the exporting country prior to the export, and a report of the result of the inspection is attached to the cargo, the inspection for the cargo at the quarantine station may be exempted. Inspection items whose results are subject to change during transportation (due to bacteria, mycotoxin, etc.) are excluded.</td>
</tr>
<tr>
<td><strong>Continuous Import of Same Items</strong></td>
<td>When certain foods and related products are imported repeatedly and inspection results are attached to the import notification form at the initial import, provided a documentary examination founds no problem, inspection can be exempted on the upcoming occasions of import for a certain period.</td>
</tr>
<tr>
<td><strong>Advance Approval of Imported Foods and Related Products</strong></td>
<td>When the imported foods are confirmed to be in compliance with the Food Sanitation Law, the items and the manufacturers may be registered. Inspection at the upcoming import is exempted for these items for a certain period of time and the certificate of notification is issued immediately after the submission of the import notification.</td>
</tr>
</tbody>
</table>

Source: MHLW
Procedures of the Import of Food

Source: MHLW
4-2 Importance of Import Quarantine, in View of Securing Food Safety

Japan depends on large amount of the imported food. In recent years, the self-sufficiency rate of food has been decreased to less than 40% on energy (calorie) basis.

In 2003, 27 million tonnes of grain has been imported, and the self-sufficiency rate is around 30%. The quantity of import of meat (beef, pork and poultry) was 1.70 million tonnes. 800 thousand tonnes of vegetables have been imported, while there was almost no import of vegetables 2 decades ago.

Therefore, securing food safety for imported food whose share in the total supply is more than 60% in Japan is very important. The main method for securing food safety of imported food is the import quarantine system. However, by this system, it is almost impossible to check how the food safety is secured in the production and distribution process. Food safety is pursued by the jurisprudence of the exporting country.

The quantity of import on the basis of import notifications was 34 million tonnes in 2003, while in 1957 the figure was 25 million tonnes. The numbers of import notifications has increased dramatically from 250 thousand in 1975 to 1700 thousand in 2003. In this situation, one of the important challenges is to perform the quarantine as effectively as possible. In addition, Japan has been requested from many exporting countries for quicker quarantine procedures. In view of prompt quarantine, the procedures have been improved many times in the past.
Number of import notifications and volume of imported food
From 1975 to 2000

Source: MHLW

4-3 Evolution of Quarantine System
The quarantine system for imported food was introduced in 1956. The inspection ratio (cases of inspection/total notification number) has been gradually decreased. It was 10.2% in 2003, while it was 18.1% in 1989, which was the highest. One of the reasons is the very rapid increase of notifications since 1990. In this trend, it would be difficult to increase the inspection ratio. Therefore, the effective (efficient?) inspection system has been continuously examined and pursued.

Previously, state quarantine offices conducted inspections for cases that the inspection was considered to be necessary. In 1995, ordered inspection, which is to be executed by registered institutions by the importers’ expense, was introduced, in view of effective and rapid inspections. The ordered inspection is not conducted by the government, but is conducted by the expense of importers who received an order from the government for foods which are highly expected to commit a violation. On the other hand, the state mainly conducts monitoring inspections, and the number of administrative inspections by the quarantine station was reduced. The objective of the monitoring inspection is to identify
cases which are needed to undergo ordered or administrative inspections.

The food could not be distributed, until the ordered inspection is finished, while the food is allowed to be distributed in the case of the monitoring inspection.

By the amendments of the Food Sanitation Law in 2002 and 2003, the comprehensive ban of import system was introduced, and sales of unfamiliar food which may injure human health could be prohibited. In addition, import operation of a corporation could be suspended, if necessary, by the discretion of the government. The introduction of the positive list system for agricultural chemicals, which will be enforced in 2006, is very significant to secure safety of imported. All foods to be imported which have residue of agricultural chemicals could be controlled under the new regulation. Previously, foods which have residue of agricultural chemicals are freely imported, if there is not the residue standard of the chemicals.
Table Import Notification, Inspection and Rejection according to Category of Food Items (Year 2000)

<table>
<thead>
<tr>
<th>Category of Food Items</th>
<th>Import Notification</th>
<th>Inspection</th>
<th>Rejection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Notification (cases)</td>
<td>Weight (tons)</td>
<td>Notification (cases)</td>
</tr>
<tr>
<td>Livestock Products</td>
<td>211,446</td>
<td>2,362,496</td>
<td>7,228</td>
</tr>
<tr>
<td>Processed Livestock Products</td>
<td>130,869</td>
<td>650,044</td>
<td>6,579</td>
</tr>
<tr>
<td>Marine Products</td>
<td>230,490</td>
<td>1,967,787</td>
<td>17,762</td>
</tr>
<tr>
<td>Processed Marine Products</td>
<td>135,011</td>
<td>1,074,064</td>
<td>19,594</td>
</tr>
<tr>
<td>Agricultural Products</td>
<td>201,267</td>
<td>18,041,162</td>
<td>18,102</td>
</tr>
<tr>
<td>Processed Agricultural Products</td>
<td>221,967</td>
<td>3,380,707</td>
<td>16,317</td>
</tr>
<tr>
<td>Other Foods</td>
<td>114,224</td>
<td>714,922</td>
<td>12,094</td>
</tr>
<tr>
<td>Drinks</td>
<td>149,226</td>
<td>1,051,989</td>
<td>9,925</td>
</tr>
<tr>
<td>Food Additives</td>
<td>26,968</td>
<td>250,850</td>
<td>504</td>
</tr>
<tr>
<td>Apparatuses</td>
<td>112,011</td>
<td>452,821</td>
<td>3,854</td>
</tr>
<tr>
<td>Containers/Packages</td>
<td>6,896</td>
<td>55,981</td>
<td>170</td>
</tr>
<tr>
<td>Toys</td>
<td>10,550</td>
<td>31,000</td>
<td>152</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1,550,925</strong></td>
<td><strong>30,033,823</strong></td>
<td><strong>112,281</strong></td>
</tr>
</tbody>
</table>

Source: MHLW

4.4 Challenges in the Future
Many people express their concerns that the effectiveness of the import quarantine has been gradually degraded for many years, since the inspection ratio has been decreased, the number of inspectors has decreased as well, and simplified and expedited systems have been introduced. However, it is not realistic to increase the number of inspectors.

In the future, measures other than the quarantine system, such as the development and dissemination of international standards which are applied to food to be exported to Japan, and the transfer of technology for producing safety food to developing countries, will be more important. The EU places importance on the international assistance in the new package of sanitary regulations of food and feed which was adopted in April 2004. In addition, consultations with countries which tend to export foods that do not meet standards should be intensified.
Article 4 of the Food Safety Basic Law clearly states that the words “At each stage of supply process” should include the external food supply process, when an appropriate measure is taken. This is added by a proposal of members of the parliament during discussions on the Bill.

It is obvious that the role of business operators and importers is crucial for securing safety of imported food. In this connection, a system of the private sector like EurepGap and Fair Trade, which could impose standards on foods in exporting countries, would be effective by imposing producers and distributors of exporting countries standards for food safety. Many tools other than quarantine should be elaborated and applied for securing safety of imported food in the future.

Source:

- “Food Safety and Quality Labeling”, Edited by Academic Society on Japan Agriculture Market, Published by K.K. Tsukuba Shobo, 2001
5 GMO Regulations

5-1 Approval and Assessment Procedures

5-1-1 Regulations Concerning Bio Safety
As the Cartagena Protocol on Biosafety to the Convention on Biological Diversity was adopted in 2000 and come into force in September 2003, Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Law No. 97 of 2003) was established as the implementation law of the Protocol in 2003 and came into force in February 2004. The GMO (living modified organism) to be used for cultivation, processing, storage, transportation, etc, are regulated under this law.

Accordingly, the guidelines for evaluating the ecological and environmental effects of cultivation of rDNA plants, which have been applied since 2000 in Japan, were replaced by new guidelines under the implementation law of the Protocol.

Note: Guidelines for Industrial Application
- Guidelines for Application of rDNA Organism in Agriculture, Forestry, Fisheries, the Food Industry and Other Related Industries (Guideline for rDNA Organisms [MAFF])
- Guidelines for Safety assessments of Application of rDNA Organisms in Feed” (Guideline for Feed [MAFF])
- Guidelines for Safety assessments of Application of rDNA Organisms in Feed Additives (Guideline for Feed Additives [MAFF])
- Guidelines for Foods and Food Additives Produced by the rDNA Techniques (Guideline for Foods [MHLW])
- Guidelines for the Manufacture of Pharmaceuticals, Etc., Utilizing rDNA Technology - (Guideline for Pharmaceuticals [MHLW])
- Guidelines for the Industrialization of RDNA Technology (Ministry of International Trade and Industry (MITI) Guideline)

According to the law, the regulations concerning approval of the use of living modified organisms, the import and the export of them are as follows.

(1) A person who wishes to create or import and make Type 1 Use (use in an open system) of living modified organisms or other persons who wish to make Type 1 Use of living modified organisms must stipulate regulations for the Type 1 Use for each type of living modified organism, and must obtain the approval of the competent minister (article 4).

(2) A person who makes Type 2 Use (use in simulated model environment) of living modified organisms must, when containment measures to be taken in connection with the Type 2 Use are stipulated in the ordinance of the competent ministries, take the
containment measures (article 12).

(3) When there is a high likelihood that living modified organisms that could not be considered not to give rise to adverse effect on biological diversity are imported without knowledge of that fact, a person who wishes to make imports must notify the competent minister to that effect on each occasion (article 16). The competent minister may order a person who has made notification to undergo testing of organisms pertaining to import by that person by the competent minister or a person registered by the competent minister (article 17).

(4) A person who wishes to export living modified organisms shall, notify the importing country of the names of the types of living modified organisms to be exported, and other related matters (article 27).

5-1-2 Pre-market Approval Regulation for GM Food
The pre-market approval system based on the safety assessment guideline was introduced for GM food and GM food additives in 1991, which was not legal obligation. However, in 2000 the legal pre-market approval regulation was established, in consideration that the development of GM foods would be further progressed, and that the number of developed GM foods which were sold in the market place would be rapidly increasing. The procedure for the approval from the point of view of food safety was established under the Food Sanitation Law.

The MHLW examines the necessary documents for application on safety assessment of foods and food additives when it receives the documents from applicant. The MHLW shall receive the opinion of the Food Safety Commission which conducts the risqué assessment. And the MHLW shall publish the announcement in official gazettes, indicating the fact that their safety assessment has been examined, unless there are certain risks as injurious to human health.

5-1-3 Approved Agricultural Products and Food
As of the middle of 2006, GM foods approved in Japan are those developed in foreign companies. There is no GM crop cultivated in Japan. Accordingly, GM foods in the Japanese market are imported agricultural products or food made of imported GM ingredients.

As of August 2006, 76 food items were approved from the point of view of food safety. 8 items for potato, 4 items for soybean, 3 items for sugar beet, 25 items for maize, 15 items for rapeseed, 18 items for cotton and 3 items for alfalfa. Developers are American, German and Swiss companies. 13 food additives were also approved. Developers are Danish, American, Swiss and Dutch companies.

5-2 Labeling Standard for GM Food
In 2001 the labeling standard was introduced in Japan. The same labeling regulations on
GM food are stipulated under the Food Sanitation Law (Article 21 of the ministerial ordinance for the implementation of the Food Sanitation Law No. 23, 13 July 1948) and the Japan Food Standard Law (Quality Labeling Standard of Genetically Modified Foods, the ministerial notification No. 517, 31 March 2000), respectively, in Japan.

According to the regulation, GM food should be labeled, indicating that the food is produced by recombination of DNA. However, the products which are subject to obligatory labeling are limited to “designated genetically modified agricultural products”, which are soybean, corn, potato, rapeseed, cottonseed, alfalfa and beet (Table 1), and are limited to 32 processed foods which contain soybean, corn and potato, alfalfa and beet (Table 2 and Table 3), in which recombinant DNA or the resulting protein still exists even after processing.

Note: Processed food which the recombinant DNA or protein are dissolved in or removed from, are not necessary to be labeled, even if their ingredients are produced by recombinant DNA technique. These processed foods are, for example, soy sauce, soybean oil, corn flake, millet jelly, corn oil, rapeseed oil, cottonseed oil, etc.

According to the Quality Labeling Standard of Genetically Modified Foods (Ministerial Notification of MAFF), the labeling regulation is as follows.

5-2-1 Labeling Standard for Processed Food in Table 2

<table>
<thead>
<tr>
<th>Items subject to labeling</th>
<th>Ingredient to be labeled</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Tofu (soybean curd) and fried tofu</td>
<td>Soybean</td>
</tr>
<tr>
<td>2. Dried soybean curd, soybean refuse, and yuba</td>
<td>Soybean</td>
</tr>
<tr>
<td>3. Natto (fermented soybean)</td>
<td>Soybean</td>
</tr>
<tr>
<td>4. To-nyu (soy milk)</td>
<td>Soybean</td>
</tr>
<tr>
<td>5. Miso (soybean paste)</td>
<td>Soybean</td>
</tr>
<tr>
<td>6. Cooked soybean</td>
<td>Soybean</td>
</tr>
<tr>
<td>7. Canned or bottled soybean</td>
<td>Soybean</td>
</tr>
<tr>
<td>8. Kinako (roasted soybean flour)</td>
<td>Soybean</td>
</tr>
<tr>
<td>9. Roasted soybean</td>
<td>Soybean</td>
</tr>
<tr>
<td>10. Item containing food of items 1 to 9 as a main ingredient</td>
<td>Soybean</td>
</tr>
<tr>
<td>11. Item containing soybean (for cooking) as a main ingredient</td>
<td>Soybean</td>
</tr>
<tr>
<td>12. Item containing soybean flour as a main ingredient</td>
<td>Soybean</td>
</tr>
<tr>
<td>13. Item containing soybean protein as a main ingredient</td>
<td>Soybean</td>
</tr>
<tr>
<td>No.</td>
<td>Item containing edamame (green soybean) as a main ingredient</td>
</tr>
<tr>
<td>-----</td>
<td>---------------------------------------------------------------</td>
</tr>
<tr>
<td>14</td>
<td>Edamame</td>
</tr>
<tr>
<td>15</td>
<td>Item containing soybean sprouts as a main ingredient</td>
</tr>
<tr>
<td>16</td>
<td>Corn snacks</td>
</tr>
<tr>
<td>17</td>
<td>Corn starch</td>
</tr>
<tr>
<td>18</td>
<td>Popcorn</td>
</tr>
<tr>
<td>19</td>
<td>Frozen corn</td>
</tr>
<tr>
<td>20</td>
<td>Canned or bottled corn</td>
</tr>
<tr>
<td>21</td>
<td>Item containing corn flour as a main ingredient (except corn</td>
</tr>
<tr>
<td>22</td>
<td>flakes)</td>
</tr>
<tr>
<td>23</td>
<td>Item containing corn grits as a main ingredient (except corn</td>
</tr>
<tr>
<td>24</td>
<td>Item containing food items 16 to 20 as a main ingredient</td>
</tr>
<tr>
<td>25</td>
<td>Frozen potato</td>
</tr>
<tr>
<td>26</td>
<td>Dried potato</td>
</tr>
<tr>
<td>27</td>
<td>Potato starch</td>
</tr>
<tr>
<td>28</td>
<td>Potato snacks</td>
</tr>
<tr>
<td>29</td>
<td>Item containing potato (for cooking) as a main ingredient</td>
</tr>
<tr>
<td>30</td>
<td>Item containing potato (for cooking) as a main ingredient</td>
</tr>
<tr>
<td>31</td>
<td>Item containing alfalfa as a main ingredient</td>
</tr>
</tbody>
</table>

**Note: Identity preserved handling (IP handling)**

Management method in which segregation between genetically modified agricultural products and non-GM agricultural products is accomplished under the care of a good manager at each stage of production, distribution and processing. Further, it must be verified by using documents clearly indicating that segregation has been made.

b) In the event that the product has been produced, distributed, or processed without segregation between genetically modified agricultural products and non-GM agricultural products, it shall be declared that such segregation has not been made for the ingredient by printing words representing “CM not segregated,” etc.
c). In the event that an ingredient is a non-GM agricultural product and it is confirmed that it has been treated under an identity preserved handling:
   - The name of the said ingredient shall be declared;
   - In the case that it is made of only one ingredient, the name of the said ingredient should be omitted; or
   - It may be declared that the ingredient is a non-GM agricultural product treated under an identity preserved handling by printing words representing “non-GM segregated from GM”, “not genetically modified”, etc.

d) For ingredients of processed foods listed in the Table 2 and 3, designated agricultural products or processed foods that contain designated agricultural products but are not main ingredients, the “labeling concerning GM” is not necessary.

**Note: Main ingredients**
Ingredients that are ranked within the top three constituents in terms of the ratios of weight they occupy, and the weight ratios of which account for five or more percent of the total.

**5-2-2 Labeling Standards for Processed Food in Table 3**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Items subject to labeling</th>
<th>Ingredient to be labeled</th>
</tr>
</thead>
<tbody>
<tr>
<td>High oleic acid</td>
<td>1. Item containing soybean as a main ingredient (except those lose a characteristic listed in the left column as the result of defatting)</td>
<td>Soybean</td>
</tr>
<tr>
<td></td>
<td>2. Item containing food of Item 1 as a main ingredient</td>
<td></td>
</tr>
</tbody>
</table>

Soybean containing high oleic acid which is produced by recombination of DNA is classified as specific genetically modified product, whose composition, nutritional value, etc, are significantly different from those of corresponding existing products. Accordingly, the labeling regulation is different from the processed food in Table 2 above.

a) In the event that a ingredient is a specific genetically modified agricultural product listed in the right column of Table 3 and it is confirmed that it has been treated under a specific identity preserved handling: it shall be declared that the ingredient is a specific genetically modified agricultural product by printing words representing “GM segregated from non-GM”, “genetically modified”, etc. following the name of the ingredient.

b) In the event that a ingredient is a designated agricultural product listed in the right
column of Table 3 and it is an intentional mixture of specific genetically modified agricultural products and non specific genetically modified agricultural products: it shall be declared that the ingredient is an intentional mixture by printing words representing “GM mixed”, etc. following the name of the ingredient.

5-2-3 Labeling Standard for the Designated Agricultural Products in Table 4

<table>
<thead>
<tr>
<th>Table 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Soybean (including green soybeans and soybean sprouts)</td>
</tr>
<tr>
<td>2. Corn</td>
</tr>
<tr>
<td>3. Potato</td>
</tr>
<tr>
<td>4. Rapeseed</td>
</tr>
<tr>
<td>5. Cottonseed</td>
</tr>
<tr>
<td>6. Alfalfa</td>
</tr>
<tr>
<td>7. Beet</td>
</tr>
</tbody>
</table>

a) In the event that a designated agricultural product is a genetically modified agricultural product and it is confirmed that it has been treated under an identity preserved handling: it shall be declared that the designated agricultural product is a genetically modified agricultural product which has been treated under an identity preserved handling by printing words representing “GM segregated”, “genetically modified”, etc.

b) In the event that a designated agricultural product has been produced or distributed without segregation between genetically modified agricultural products and non-GM agricultural products: it shall be declared that segregation has not been made by printing words representing “GM not segregated”.

c) In the event that a designated agricultural product is a non-GM agricultural product and it is confirmed that it has been treated under an identity preserved handling:
- The name of the designated agricultural product shall be declared; or
- It may be declared that the designated agricultural product is a non-GM agricultural product which has been treated under an identity preserved handling by printing words representing “non-GM segregated from GM”, “not genetically modified”.

Note:
Agricultural product listed in Table 3 shall be declared “GM segregated”, “genetically modified” or “GM mixed” according to the segregation procedure.

5-2-4 Adventitious Commingling
Where there is a possibility that a certain amount of adventitious commingling of genetically modified agricultural products or non-GM agricultural products though an
identity preserved handling has been performed, the product shall be regarded as treated under an identity preserved handling, as far as the confirmation procedures have been properly followed. According to the Director General’s Note, if the amount of adventitious commingling is 5% or less than 5%, labeling concerning GM is not necessary. This regulation is applied to corn and soy beans and their products.

5-3 Traceability
There is not any regulation on traceability of GM food in Japan.

Source:
- Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Law No. 97 of 2003)
- Notification No. 517 of the Ministry of Agriculture, Forestry and Fisheries of March 31, 2000, Established: March 31, 2000, Revised: September 28, 2001
- Règlement (CE) No 1829/2003 du parlement européen et du conseil du 22 septembre 2003 concernant les denrees alimentaires et les aliments pour animaux genetiquement modifives
- Règlement (CE) No 258/97 du parlement européen et du conseil du 27 janvier 1997 relatif aux nouveaux aliments et aux nouveaux ingrédients alimentaires
- FDA Proposes Draft Guidance for Industry for New Plant Varieties Intended for Food Use, November 19, 2004
- Les biotechnologies agricoles, Une réponse aux besoins des plus démunis,
6 Beef and BSE

6-1 Measures for Preventing from Penetration of BSE and the Infection of BSE in Japan

As the WHO and the EU addressed a warning to Japan that there was a possibility of outbreak of BSE (bovine spongiform encephalopathy) in Japan, the MAFF started active surveillance in April 2001. 300 cattle were subject to the surveillance which was conducted based on the standard established by the OIE (Office International des Epizooties). The objective of the surveillance was said to verify that Japan is clean country where there is no outbreak of BSE, and to prevent from spreading a harmful rumor caused by the suspicion of the outbreak. However, a cow in Chiba Prefecture was found to be infected with BSE on 9 October 2001.

In 1986, BSE was identified in England for the first time. Feeding meat and bone meal to ruminants was banned in 1988, for the reason that the possible source of the disease was meat and bone meal. In 1994, the EU made a decision for an absolute ban of use of meat and bone meal. In 1996, the British authorities officially recognized that the human could be infected with BSE, acknowledging the relation between vCJD (variant Creutzfeldt-Jakob Disease) and BSE.

Note:
167 patients of vCJD were observed in the world as of January 2005. Among these 153 are patients in Britain. In Japan, a patient was found on 4 February 2005. He has been in Britain for a month in 1989.

In Japan, the import of live cattle from infected countries was banned and heat treatment of meat and bone meal became compulsory in 1990. In April 1996, the Conference of the WHO recommended a ban of feeding meat and bone meal. Following the recommendation, Japan introduced a ministerial guideline for the ban, instead of legal prohibition. In 1997, the USA and Australia introduced a legal ban of feeding meat and bone meal, replacing the previous voluntary restriction. Japan remained maintaining the guideline without penalty.

Since 1998, the EU conducted the status assessment of BSE for countries which had an interest in exporting beef and its products to EU countries. The EU’s interim assessment of BSE for Japan, which was transmitted to the Japanese government in 2000, indicated that there was a possibility of outbreak of BSE in Japan, as Japan had imported meat and bone meal from infected countries. However, the MAFF requested the EU for the suspension of the BSE status assessment for Japan, since the EU did not accept the Japan’s views on this matter. The MHLW had not extended any opinion on this request. The MAFF was said to be afraid of serious confusion both in the meat industry and consumers caused by the suspicion of outbreak, if the EU assessment was open to the public in Japan.

Japan did not introduce the ban of import of meat and bone meal from infected countries until January 2001.
 Shortly after Japan had requested the suspension of the EU’s BSE assessment, a cow was identified to be infected with BSE in Japan.

6-2 Serious Confusion Caused by BSE
Due to the identification of a cow infected with BSE in October 2001, the consumption of beef has been drastically decreased, and the consumption of the imported beef from Australia and the USA, where were free from BSE, also have lowered. Costumers refrained from going to Korean barbeque restaurant and to first food restaurants of Gyudon (bowl of rice with cooked beef on the top), which were popular to young people, and those restaurants did not sell well. The beef industry faced unprecedented chaos in Japan. The survey of the household consumption showed that the consumption of beef of 260g/ person/month in January 2001 had decreased to 160g in December 2001.

Persons concerned and consumers severely criticized the government for mismanaging the BSE issues, underlining that the government had not taken any effective measures to prevent from feeding meat and bone meal, although it had many chances to take appropriate actions. The MAFF and the MHLW were also accused of lack of close collaboration for dealing with this matter. Meanwhile, the criticism of the mal-performance of the food safety policy has been growing in Japan.

Following the BSE incident, several fraud cases in the meat industry were also revealed in 2002. For example, there were two cases that imported beef was falsely mixed in packages of domestically produced beef to be purchased by the government in a scheme of measures for relieving the beef industry affected by the BSE incident, a case of false labeling as if the products were high-quality beef, and two cases of false labeling on chicken meat as if the products were produced in Japan.

6-3 Urgent Measures Taken in Japan against BSE
The government of Japan immediately took measures against BSE, with a view to securing safety of beef and to regaining consumers’ trust in beef. These measures were taken, following those taken in the EU and England. The main measures for food safety are as follows. In addition, measures for relieving the beef industry were introduced.

6-3-1 BSE Inspection for All Cattle at the Abattoirs
All cattle to be slaughtered should be inspected prior to and after slaughter. Cattle suspected of being infected with BSE at the prior inspection shall not be slaughtered. Cattle and meat diagnosed BSE shall be incinerated, and the abattoir shall be disinfected.

6-3-2 Remove of SRM (Specified Risk Materials)
The person who runs the abattoir shall remove the SRMs (head, spinal cord distal, ileum (two meters from connection to caecum)), etc, avoiding the infection in SRMs to carcass and offal. The person who runs the abattoir shall keep SRMs in containers exclusively used for this purpose, and shall incinerate them.
6-3-3 Ban of Feeding Meat and Bone Meal to Ruminants
Feed for ruminants shall not contain protein derived from mammals, fowls and fish. To ensure this regulation, standards to be applied in processing, storing, labeling and using shall be established under the Law on Securing Safety and Improving Quality of Feed (1953).

Up to February 2005, approximately 4,200,000 cattle were inspected, and 16 cattle have been found infected with BSE as of March 2005.

6-4 Establishment of the Law Concerning Special Measures against Spongiform Encephalopathy
In association with the establishment of the Food Safety Basic Law, the law concerning special measures against BSE was promulgated in 2002. Three measures mentioned above (6-3-1, 6-3-2, 6-3-3) became legal obligations under this law. A regulation was added and this stipulates that a veterinarian shall inform the prefecture of the death of a cattle whose age is over 24 months, or the holder of the cattle shall inform of the death of the cattle when it is not inspected by a veterinarian (Article 6).

In addition to these measures, the following measures were stipulated in the law.

   Establishment of a basic plan of measures to be taken by the government and the prefectures where BSE outbreak is anticipated (Article 4); a system for identification of individual cattle and traceability in the distribution system (Article 8); assistance measures to producers, processors, distributors and restaurants concerning cattle and beef when they are in difficulties caused by BSE (Article 9); dissemination of appropriate knowledge on BSE to consumers (Article 11); and promotion of research (Article 12).

6-5 Beef Traceability Law of 2003
Facing the serious decrease of consumption of beef, traceability has been studied in view of regaining the trust of consumers on the safety of beef. The study was conducted on the basis of the systems of the EU and France. France introduced the traceability on beef in 1997 and the Loi d’ Orientation Agricole of 1999 encouraged the traceability on other products, which influenced the EU’s traceability regulation of 2000 to be applied to all member countries.

In Japan, the Beef Traceability Law was established within the framework of the fundamental reshuffle of the structure of food safety policy in 2003. The system is composed of individual cattle identification and traceability in the distribution process. The former came into force in November 2003, and the latter came into force in December 2004.
6-5-1 Outline of the Law for Special Measures Concerning the Management and Relay of Information for Individual Identification of Cattle (Beef Traceability Law)

6-5-1-1 Objective
The objective of this law is, by taking special measures concerning the proper management and relay of information designed to identify individual cattle, to make the foundation for implementing measures aiming at preventing the spread of BSE, and also to promote the provision of information designed to identify individual cattle related to beef and to promote the sound growth of the livestock and related industries, as well as the interests of consumers (Article 1).

6-5-1-2 Individual Cattle Identification Register
(1) The MAFF prepares an Individual Cattle Identification Register, and records the following items for each head of cattle (Article 3).
(i) Individual identification number
(ii) Date of birth or import
(iii) Gender
(iv) For cattle other than imported cattle, the individual identification number of the maternal parent
(v) For imported cattle, the name or title and address of the importer
(vi) The name or title and address of the Manager and the date on which management by the Manager commenced.

Note: “Manager” means the owner of cattle or others who manage cattle.

(vii) The location of the raising facilities and the date on which the raising in the facilities commenced
(viii) Date of slaughter, death or export
(ix) Other items stipulated by the Ordinance

Note: The work of the register is commissioned to the National Livestock Breeding Center

(2) The MAFF publicly discloses items recorded in the individual cattle identification register using the internet or other method (Article 6).

6-5-1-3 Notification from Cattle Managers and Management of Ear Tags (Article 8)
(1) When a calf is born, its Manager must immediately notify the MAFF of the date of birth, gender, the individual identification number of the maternal parent, the name or title and the address of the Manager, the location of the raising facilities, and other items.
When cattle are imported, their Importer must immediately notify the MAFF of the date of import, gender, the name or title and the address of the Importer, the location of the raising facilities, and other items (Article 9).

The MAFF, on receiving notification, decides an individual identification number for the cattle related to the notification, and immediately notifies the individual identification number to the Manager or Importer who made the notification.

Managers or Importers of cattle must, on receiving the notification, attach ear tags bearing the individual identification number to both ears of the cattle.

6-5-1-4 Indication of Designated Beef by Slaughterers (Article 14)
(1) Slaughterers must, on delivering Designated Beef derived from cattle to another person after the slaughter of the cattle, indicate the individual identification number of the cattle on the designated beef.

Note: “Designated Beef” means bovine meat supplied as food (except that which has been manufactured, processed, or cooked using this as a raw material or ingredient, or others stipulated by the Ordinance) which has been derived from cattle registered with the individual cattle identification register. Accordingly, imported beef is not subject to the Law.

(2) Slaughterers may use an alternative method of identifying cattle using numbers or codes other than the individual identification number. In such cases, slaughterers must issue documentation clarifying the individual identification number of the cattle corresponding to the numbers or codes to the person receiving delivery of the designated beef.

(3) Slaughterers may provide the items to be specified in the documentation via a method that uses an electronic data processing organization, or another method that uses data communication technology, instead of the issue of documentation.

6-5-1-5 Indication of Individual Identification Numbers by Sellers (Article 15)
(1) Sellers must, when selling designated beef, indicate the individual identification number of the cattle on its container, packaging, or invoice, or in an easily visible location in the retail establishment.

Note: “Seller” means a person who engages in the business of selling beef.

(2) In the case of the preceding paragraph, Sellers must indicate one individual identification number for one item of designated beef, provided, however, that when selling designated beef that fulfills any of the following requirements, more than one individual identification number may be indicated for one item of designated beef.
(i) When it is difficult to identify which cattle the designated beef was derived from.
(ii) When it is designated beef derived from not more than the number of cattle stipulated by the Ordinance.
(3) In the case of Paragraph 1 above, Sellers may indicate a lot number (meaning a number or code other than the individual identification number that corresponds to the individual identification number) in place of the indication of the individual identification number.

(4) In the case of the preceding paragraph, Sellers must also indicate the name or title of 何の？, as well as clarifying the individual identification number corresponding to the lot number in response to requests from the other party of the sale of the designated beef, consumers or other persons, provided, however, that when indicating a lot number determined by a third party, this requirement shall not apply provided that the name or title of the third party has been indicated.

6-5-1-6 Indication of Individual Identification Numbers by Suppliers of Designated Cuisine (Article 16)
Suppliers of Designated Cuisine must, when supplying designated cuisine (limited to cuisine that has designated beef as its principal ingredient), indicate the individual identification number of the cattle related to the designated beef that is the principal ingredient of the designated cuisine, or in an easily visible location in the restaurant.

Note: Designated cuisine is “yakiniku”, “sukiyaki”, “shabu-shabu”, and “steak”.

6-5-1-7 Maintenance of Ledgers (Article 17)
Slaughterers, Sellers and Suppliers of designated cuisine must maintain ledgers (including those prepared by means of magnetic disk), in which they must enter or record items concerning the delivery or sale of designated beef or the supply of designated cuisine, and must retain the same.

6-6 Ban of Import of Beef from the USA where BSE was Found in December 2003
On 26 December 2003, Japan prohibited the import of beef and its products from the USA, as BSE was found in the country on the same day. An investigation mission was dispatched to the USA, and reported that the import of cattle which were raised together with infected cattle in Canada and the import of meat and bone meal which was given to the infected cattle in Canada might be a cause of BSE outbreak in the USA. The mission also underlined that the beef industry in the USA and Canada has been highly integrated, the ban of feeding cattle with meat and bone meal has not been totally effectively managed in the USA, and the cross contamination was not totally denied.

Japan has imported beef of 240,000 tonnes per year from the USA, which was equivalent to approximately 30% of the total consumption of beef in Japan. Accordingly, the abrupt prohibition of import of beef significantly affected Japan. The very popular restaurant chain of gyudon or cooked beef on the top of rice, whose main ingredient was imported beef ribs, could not any more serve this dish since February 2004.
After the first meeting was held on 29 December 2003, several meetings were held between Japan and the USA, and experts and working level officials meetings started. At these meetings, the US reiterated that the inspection of all cattle would not be needed to resume export of beef to Japan from the USA. It is actually impossible to inspect all cattle in the USA, since 35 million cattle are annually slaughtered in the country. Measures taken in the USA were prohibition of import of live cattle, active surveillance, and BSE inspection in association with the active surveillance, ban of use and import of meat and bone meal. After BSE was found, the USA introduced additional measures such as ban of slaughtering cattle which can not normally walk, ban of distribution of beef before it is confirmed to be BSE negative, and removal of SRMs of cattle of over 30 months of age.

6-7 Relaxation of BSE Inspection on All Cattle
Japan introduced the most severe BSE inspection system in the world. As the consumption of beef was recovered and the confusion of the industry was calmed down, the need of the BSE inspection on all cattle became a matter of discussion. In October 2004, the MAFF and the MHLW officially submitted a request for a risk assessment to the Food Safety Commission whether it would be appropriate to apply the BSE inspection to cattle of 21 months of age or older, instead of all cattle. According to almost 3 year experience of the BSE inspections, it would be possible to find a prion in the cattle of 21 months of age or older with the present inspection method. Actually, a cattle of 21 months of age and a cattle of 23 months of age were identified as BSE positive respectively in the past inspections. However, the Commission could not reach the conclusion for several months.

6-8 Agreement on Reopening of Japanese Market to US Beef
At the meeting of October 2004, Japan and the USA agreed that Japan would resume the import of beef from the USA on condition that SRMs should be removed, and the government of the USA should guarantee that the beef is derived from cattle of 20 months of age or younger on the basis of a record of age of the cattle. The outline of the agreement is as follows.

The USA will establish a marketing programme. The operational details of Beef Export Verification Programme (BEV) managed by USDA will be further worked out by Japanese and US experts on the following points.

1. SRMs must be removed from animals of all ages.
2. Beef items including offals and variety meats must be derived from bovine animals verified to be 20 months of age or younger.
3. Beef included in the BEV must be traceable to live animal production records which indicate that they are 20 months of age or younger at the time of slaughter.
4. Experts of both countries will continue to consult on carcass grading with a view to verifying physiological age to evaluate carcasses to be 20 months of age or younger.
However, the important issue remained on how the age of cattle could be surely verified, because the USA has not introduced any age verification system for individual cattle such as the individual cattle identification system. On 8 February 2005, both countries agreed that it could be confirmed by a beef grading system that the beef is derived from a cattle of 20 months or younger.

The US authorities and some congressmen were upset on the delay of studies in Japan toward the resumption of beef import from the USA. They strongly claimed that American beef is safe by the scientific criteria. In this relation, the USA urged Japan to conclude as soon as possible the risk assessment on the relaxation of inspection on all cattle conducted by the Food Safety Commission, which is the pre-condition for realizing the above agreement between the two countries.

On 28 March 2005, the Commission reached the conclusion that it is not necessary to apply the BSE inspection to cattle of 20 months age or younger. It took approximately a half year to reach this conclusion. However, a risk assessment of the Commission is needed on the method of verification of beef derived from cattle of 20 months age or younger as agreed between Japan and the USA. In December 2005, the Japanese government took a decision to reopen the Japanese market for beef from the United States and Canada, based on the conclusion of the Commission in December of the same year. However, in January 2006, the import of beef from the United States was banned again, due to the fact that one of the SRMs was mixed in the imported beef. It was in July 2006 when Japan lifted the ban of import of beef from the United States following the intensive consultations between two countries. It was in July, 2006 when Japan lifted the ban of the importation of beef from the United States after intensive consultations between both countries.

source:
- The Report of the Research and Examination Committee on the BSE Issue, 2 April 2002
- “Science for Measures against BSE”, The Open Forum of the Science Council of Japan, 30 October 2004
- “Information on Stock Raising (Domestic Edition)”, November 2004 and December 2004 Issues, Agriculture & Livestock Industry Corporation
- “Food Safety and Quality”, Edited by Academic Society on Japan Agriculture Market, Published by K.K. Tsukuba Shobo, 2001
7 HACCP and ISO

7-1 HACCP Principles
HACCP is one of the quality management systems to be applied to food, whose method is to identify critical control points in the process of production of each category of food in view of preventing hazards to food safety, and to establish appropriate control measures on each critical control points. Historically, food safety was assured by sample inspection of finished products. However, such an inspection system became ineffective in recent advanced processing technologies, the mass production system and the complex process of production. In particular, purchasers of products came to check the production process and management method of producers.

Standardization of quality management system was promoted within each country. However, international harmonization became gradually needed according to the development of globalization. The HACCP system was established in these circumstances.

The HACCP system is one of interventions to the process of production, which assures an effective quality management system in a facility. However, it does not certify the quality itself of the products. In this sense, products made under the HACCP system is not “process-defined ones”, to be exact.

7-2 Development of HACCP
The origin of HACCP was a management system for producing safety food for astronauts in the space. The principle of HACCP was announced by General Mills, Inc. (Pillsbury はブランド名のようです), which provided food for astronauts in 1971. While HACCP was introduced as Good Manufacturing Practices for low-level acidity canned food in 1973, it has not been popular until 1980s when food poisoning cases caused by O-157, salmonella and lead contamination in food occurred in the USA.

In 1985, the Science Academy recommended the USDA (US Department of Agriculture) to introduce HACCP to meat, in view of preventing food hazards. In 1995, FDA introduced the compulsory HACCP, which was applied to large-size production facilities of fish and fish products. In 1998, USDA introduced compulsory HACCP for meat and poultry which was also to be applied to large-size facilities. In 2001, the HACCP system became compulsory for fruit and vegetable juice.

The EU ordered member countries to oblige all facilities to adopt the HACCP principle by the Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs. Therefore, the HACCP principle is regarded as a standard to be observed by any facility in EU countries.

In light of such development of HACCP in the USA and the EU, the Codex Commission
adopted a guideline for HACCP in 1993.

7-3 Establishment of the HACCP System in Japan
The examination on introducing the HACCP system substantially started, when a Japanese processing plant was refused to export some fish products to one of the EU countries, since this product did not meet the equivalent sanitation standard regulated by the EU Directive on hygiene of food stuffs. Food poisoning cases of O-157 and others, which occurred in 1980s, accelerated the establishment of the HACCP system in Japan.

The HACCP system was introduced by the amendment of the Food Sanitation Law in 1995 as “Integrated Sanitation Management of Process of Manufacturing”.

According to Article 13 of the Law, the Minister approves a food on the basis of an application of a manufacture. The duration of the approval is limited to 3 years. The areas to be applied to the HACCP are also limited to 6 categories of products by the government ordinance as follows.

Milk; Milk products; Meat products; Fish paste products; High pressured, heated, sterilized food in containers/packages; and Soft drinks

(As of 2005)
Food Sanitation Law

Comprehensive Sanitation-controlled Manufacturing Process

**Article 13.** When the Minister of Health, Labour and Welfare has received an application for approval concerning a food for which standards for manufacturing or processing methods have been established pursuant to the provisions of Article 11 Paragraph 1 and which has been designated by the Cabinet Order No. 299 from a person (including a person wishing to manufacture or process such food as abroad) who wishes to manufacture or process the food based on comprehensive sanitation-controlled manufacturing process (hereinafter in this Law, such process means a process of manufacturing or processing methods and sanitation controlled methods, to prevent the occurrence of food sanitation hazards), the Minister of Health, Labour and Welfare may give approval for such manufacturing and processing based on the comprehensive sanitation controlled manufacturing process, for each type/kind of food and each manufacturing plant.

**Term of Validity of Approval of Comprehensive Sanitation-controlled Manufacturing Process**

**Article 14.** Any person who wishes to apply for the renewal of the approval prescribed in Paragraph 1 of the preceding Article shall lose the validity after elapse of not less than 3 years specified by the Cabinet Order, unless he applies the renewal every time when necessary.

Provisional translation by JETRO

To promote the HACCP system, the HACCP promotion Law (Provisional Law for Effective Management of Process of Manufacturing) was created. The objective of the Law is to provide reduced interest rate of loans and preferential tax treatment on HACCP-approved facilities of the manufacturers.

Approved HACCP facilities and items in Japan

(As of 31 December 2004)

<table>
<thead>
<tr>
<th></th>
<th>Facilities</th>
<th>Items</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Milk</strong></td>
<td>156</td>
<td>264</td>
</tr>
<tr>
<td><strong>Milk products</strong></td>
<td>186</td>
<td>270</td>
</tr>
<tr>
<td><strong>Meat Products</strong></td>
<td>85</td>
<td>158</td>
</tr>
<tr>
<td><strong>Fish paste products</strong></td>
<td>24</td>
<td>32</td>
</tr>
<tr>
<td><strong>High pressured, heated, Sterilized food in containers/packages</strong></td>
<td>39</td>
<td>46</td>
</tr>
<tr>
<td><strong>Soft drinks</strong></td>
<td>56</td>
<td>93</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>546</td>
<td>863</td>
</tr>
</tbody>
</table>

Source: MHLW
7-4 Problems of HACCP in Japan

The number of approved facilities is very limited and has not remarkably increased in Japan. Japan established the HACCP system as a voluntary management system. Manufacturers who have received approval of HACCP do not have any significant benefit, due to this reason. Their products cannot sell at higher prices, while they spent large amount of investment for HACCP.

On the other hand, the EU and the USA introduced HACCP as an obligatory management system for food safety. This is the minimum standard to be respected by all manufacturers concerned. In this case, the additional costs for HACCP may be recovered by raising the prices of products, which can be born by consumers.

Therefore, the HACCP system in Japan is adopted by manufactures to show their general corporate performance for food safety, which could be regarded as one of the advertisement methods. Small-size manufacturers who cannot afford to invest including small-size operators have not generally applied for HACCP. Manufactures sometimes use the HACCP system for export of products to the EU countries or the US, which sometimes require the assurance that the products have produced under the HACCP system or equivalent.

In June 2000, a serious food poisoning case occurred. It was contamination by staphylococcus aureus of processed milk produced by a plant which received an approval of HACCP. More than 15,000 people were infected with the bacteria through those products. Consumers and people concerned in the industry came to have some doubt on the effectiveness of the HACCP system. The government reduced the duration of approval of HACCP to 3 years by the amendment of the Food Sanitation Law in 2003. Every 3 years the approval will be revised (Article 14 of the Food Sanitation Law), in view of assuring the effectiveness of HACCP.

7-5 ISO 9000

ISO 9000 is an international standard for quality of products, which was established in 1987. It is an international standard of management system on the private basis. In Japan, the certification organization is the Japan Accreditation Board for Conformity Assessment (JAB), and registered certification organizations account to approximately 40, and the number of registered facilities is 48,698 as of 2004. Among these facilities, 107 for agriculture and fisheries, and 1188 for food, drinks and tobacco (according to JAB).

While the total number of registered facilities is quite large, there is a doubt on the effectiveness of ISO 9000 in Japan. Each facility prepares the quality management system according to the standard. However, the actual operation under the system does not well work in some cases. Like HACCP, there is not significant business benefit for ISO facilities in Japan.
7-6 ISO 22000
Considering that the food safety hazards may occur in any step of the food chain, the International Standardization Organization prepared a new standard for food safety which could be applied to agricultural material industry such as fertilizer, agricultural chemicals, feed, agriculture, food processing industries and the food distribution industry.

The new standard is a food safety management system based on the HACCP principle which has been developed from the Codex in combination with Prerequisite Programmes (PRPs). The existing GMP (Good Manufacturing Practice), GAP (Good Agriculture Practice), GDP (Good Distribution Practice), GVD (Good Veterinary Practice), GPP (Good Production Practice) or GTP (Good Trade Practice) could be an alternative of PRPs according to the step of the food chain.

The new standard, which is called ISO22000, came into force in September 2005. The Japanese food industry, which is composed of a large number of small-size operators, may be incapable of running well such advanced standard. Therefore, ministries concerned have an opinion that it is important to make efforts to adopt the idea of the new management system in its own way, instead of hastening application for ISO 22000.

Note:
BRC : British Retail Consrclium
CIES : Comité international d’intrprises à succursales
Source

- Mouvement Francais pour la Qualite HACCP 1998

- HACCP Procedures for the Safe and Sanitary Processing and Importing of Juice: Final Rule Federal Register; January 19, 2001 FDA
- Federal Register: December 18, 1995 (Volume 60, Number 242)
- Rules and Regulations. Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products FDA
  - Federal Register Vol 61 No 144 25 July 1996
  - Final draft of SO/FDIS 22000:2005 (E), International Standardization Organization 2005

- Better Understanding of HACCP, Satoki Kurosawa, Kazuo Hisa, PHP Institute, 1998 (Written in Japanese)
- Food Sanitation Law (1947)
IV. Food Labeling Regulations for Food Safety and Health

1 General Principle for Food Labeling

Regulations on labeling of food are established in light of four points; securing food safety, promoting health, providing information on food quality, and ensuring fair trade. Appropriate labeling protects consumers’ interest through providing them with better choice of goods and services, as well as facilitates the fair competition.

In Japan, labeling regulations are controlled by the Food Sanitation Law from the viewpoint of food safety, by the Health Promotion Law from the viewpoint of nutrition and health, by the JAS Law from the viewpoint of food quality, and by the Unfair Competition Prevention Law and the Act against Unjustifiable Premiums and Misleading Representations from the viewpoint of fair trade. In addition, the Measurement Law regulates indications of weight and volume in the labels.

In Japan, legal regulations of labeling started with the standards by the JAS Law of 1950, which succeeded the standards of foods under the Government Inspection Law of Agricultural and Forestry Products in association with the Supply and Demand Adjustment Policy including the Government Procurement and Ration System. The government needed standards including labeling requirements in controlling distribution of food including the ration system.

Although the Food Sanitation Law was promulgated in 1947, the law did not establish labeling standards at the beginning. It was in 1956 when the labeling standards were established under the Food Sanitation Law from the viewpoint of securing food safety.

Due to this historic reason, the food labeling has been separately managed and developed by the JAS Law under the control of the MAFF and by the Food Sanitation Law under the control of the MHLW. Therefore, industry people placing food in the market had to carefully watch standards of both the JAS Law and the Food Sanitation Law, and consumers faced some confusion about differences of terminology and duplications of the indications.

In the 1960s, consumer movements have been intensified in Japan. These movements in Japan were influenced by those in the USA, in particular by President Kennedy’s message to the Congress concerning the protection of consumers in 1962, and by those in European countries. These movements resulted in the establishment of the Consumer Protection Fundamental Act in 1968, which was proposed by some members of the parliament.

The Act defined the government’s responsibilities to take necessary measures for avoiding any danger in goods and services, ensuring observance of exact weights and measures, establishing proper standards, establishing systems for indication of quality and other elements, and ensuring fair and free competition.

Regarding the labeling, the law stipulated the government’s responsibility as follows in the Article 10.
Article 10  So that consumers do not make wrong choices in the purchase or use of goods or in the utilization of services, the state shall take the necessary measures to establish a system for indicating the quality and other elements of the substance of goods and services and also take the necessary measures to regulate false and exaggerated indications.

Translated by Economic Planning Agency

Following the Consumer Protection Fundamental Act, the Food Sanitation Law paid further attention to the protection of consumers in formulating and reviewing the labeling regulations.

During the 1980s and 1990s, consumers have become much more interested in food safety, health and nutrition in the course of improvement in living standards. In responding such growing interest and concerns of consumers on nutrition and health, several measures were taken. One of the measures was the Nutrition Labeling Ordinance of 1996 under the Nutrition Improvement Law, which regulates labeling of nutritious elements, such as energy, protein, fat, carbon-dioxide, etc. In 2001, labeling of allergens in food became mandatory. In the same year, an approval system for food with health claim was introduced.

In the late 1990s and early 2000s, many incidents of false indications in labeling occurred. Therefore, securing reliability of labeling has become another important task in the labeling regulations. In this situation, the importance of labeling for ensuring food safety was recognized in the Japanese society. Representing such recognition, the Food Safety Basic Law established in 2003 stated as follows in the Article 18.

(Ensuring appropriate labeling)

Article 18

In formulating policies to ensure food safety, necessary measures for accurately conveying the information on food, such as ensuring the appropriate operation of a food labeling system, shall be taken in consideration that food labeling plays an important role in ensuring food safety.

Translated by the Food Safety Commission

Source:

- Explanatory Notes on Laws, Chapter 12 on JAS Law, MAFF (written in Japanese)
- Comprehensive Explanatory Documents on Laws and Regulations No. 259 (written in Japanese)
- Explanation of the Amendment of Food Sanitation Law in 2003, Research Group of Food Sanitation, Chuo Houki, 2004 (written in Japanese)
- JAS Law (1950)
- Food Sanitation Law (1947)
- Consumer Protection Fundamental Act (1968)
2 Labeling Standards for Food Safety under the Food Sanitation Law

The Food Sanitation Law stipulates labeling and advertisement regulations on food, food additives and containers/packages in the Chapter 3, as follows.

Chapter 3  Labeling and advertising

[Establishment of standards for labeling]
Article 19 Minister of MHLW, from the viewpoint of the public health, may establish after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council necessary standards for food, food additives intended for sales, or of apparatus, or containers/packages for which specifications have been established pursuant to the provisions of Paragraph 1 of the preceding article.

2 No person shall sell, or display with intent to sell, or in use any food, food additive, apparatus or container/package for which labeling standards have been established pursuant to the preceding paragraph, unless it bears labeling complying with the established standard.

[Prohibition of false labeling, etc.]
Article 20 No person shall falsely or exaggeratedly label any food, food additive, apparatus, or container/package in any manner which may injure public health.

Based on the Article 19 of the Food Sanitation Law, the Article 21 of the HMLW ordinance of the implementation of the Food Sanitation Law was established to regulate labeling of food and food additives except milk and milk products. For the milk and milk products, a specific MHLW ordinance has been introduced, due to special importance of securing food safety, and due to technical reasons of these products. This ordinance regulates standards of products and labeling of these products.

2-1 Labeling Standards under the Ministerial Ordinance of the Law
At first, the article specifies items to be labeled, which are applied to all foods. These are the product name, the use-by-date or best-before-date, the name of manufacturer, the address of the plant, the names of food additives, and the method of storing.

Secondly, specific statements to be labeled for specific products are required from the point of view of securing food safety. These products are mineral water, frozen fruit juice, canned food, meat, dried meat product, unheated meat product, specifically heated meat product, heated meat product, whale meat, fish sausage, fish ham, product obtained by freezing food, frozen food requiring heating before consumption, raw oyster, filleted fish, food treated with ionizing radiation, egg with shell, liquid egg, boiled crab, instant noodle, and food
containing allergen(s).

The Article 21 also stipulates labeling standard for GM food, and health claim in association with food for specified use (FOSHU) and food with nutritional function. In this relation, the Article 21, in principle, prohibits use of health claim for food other than food with health claim, as follows.

3) In the cases of foods other than foods for specified health uses and food with nutritional function (shall be called hereinafter as food for special dietary use), names misleading to food for dietary use, labeling that function of nutritional components and purpose of specified health use can be expected, shall be prohibited; while in the case of food with nutritional function that is not belonging to foods for specified health uses labeling of expectation for specified health use shall be prohibited.

Translated by the MHLW

2-2 Labeling Requirements by the MHLW Ordinance on Standards of Milk and Milk Products

The Article 7 of this ordinance specifies statements to be labeled on milk and milk products classifying them into 3 categories, which are milk, milk product and food whose main ingredient is milk.

2-3 Labeling Standards for Food Additives

The labeling regulation of food additives contained in food is regulated by the Article 21 of the MHLW Ministerial Ordinance of the Enforcement Regulations of the Food Sanitation Law (MHLW Ministerial Ordinance of 1948) and a related notice of the MHLW.

2-3-1 Declaration of Food Additives

Food additives shall be declared by the following methods.

(1) Declaration by Substance Name
   a) The designated food additives shall be declared by the substance name (a substance listed in the Table 1 of the ordinance shall be declared by one of 345 names listed in the same table and 1051 names of natural substances).

   b) However, food additives whose names have been widely used may be declared by those names. And food additives such as organic acid or amino acid which are ubiquitously distributed in food may be declared by the following collective names or category names which describe collectively such functions.

      Acidity regulator, bittering agent, chewing gum base, “chomiryo” (flavoring for taste-related purposes), coagulant for “Tofu” (soybean curd), emulsifier, enzyme, flavouring, food acid, glazing agent (additive for glossy or protective coatings),
“kansui” (alkaline agent for preparation of Chinese noodles), plasticizer for chewing gum, raising agent, and yeast nutrient.

c) Regarding the food additives derived from wheat, buckwheat, egg, milk and groundnut, they should be also declared that the food additives are derived from the food(s).

d) In case citrus fruits and banana are sold loose, imazalil, o-phenyl phenol, sodium o-phenyl phenate, diphenyl or thiabendazole used shall be indicated at the sales place.

(2) Declaration of Substance Name and of Function by Using Category Name for Use
A food additive shall be declared by both substance name and category name for use when it is used for one of the following 8 purposes.

Antimolding agent, antioxidant, bleaching agent, color, color fixative, preservative, sweetener, or thickener/stabilizer/gelling agent.

(3) Natural Flavoring
Natural flavoring agents shall be declared by names of source substances or synonyms mentioned in the Document 2 of the Notice. Besides, words of “Flavoring Agent” are required to be attached. Food additives not mentioned in the Document 2 shall be declared by scientifically appropriate names by which the food additives can be identified.

(4) Substances Generally Provided as Food
Substances which are generally provided as food and used as food additives shall be declared by names or abbreviated names mentioned in the Document 3 of the Notice. Food additives not mentioned in the document shall be declared by scientifically appropriate names by which the food additives can be identified.

2-3-2 Exemptions for Labeling
Food additives for processing aids, carry-over and dietary supplements are not necessary to be declared.

(1) Processing Aid
Processing aids are substances,
• that are added to a food during processing the food, but are removed from the food before it is prepared in its finished food,
• that are added to a food during processing, but are converted to components ubiquitously present in the food, and do not significantly increase the level of the constituents naturally found in the food, or
• that are added to a food for technical or functional effect in the processing, but are
present in the finished food at the insignificant level and do not have any technical or functional effect.

(2) Carry-Over
Carry-overs are food additives carried over into a food in insignificant level to perform a technological function in the food as a result of the use of food additives in raw materials or other ingredients for the food.

(3) Food Additives for Dietary Supplements
Food additives for dietary supplements are those which may be considered to be used as dietary supplement, and which are described in the Notice.

2-3-3 Notice in the Labeling
(1) In any case, it is prohibited to claim “natural” or any impression implying “natural.”
(2) が抜けている
(3) For preparation of food containing aspartame, a statement of effect that the product is an L-phenylalanine compound shall be done.

2-4 Labeling Standards for Allergens
Since late 1980s, consumers’ concerns and interest on health and nutrition became growing in Japan. People concerned drew attention that some health hazards found to be caused by foods containing allergens (substances known to cause allergies, other hypersensitivities or allergosis). At the session of the Joint FAO/WHO Codex Alimentarius Commission in June 1999, it was agreed that foods containing eight tracts of ingredients known as allergens must indicate that the food contains such substances. It was also agreed that the member countries are required to study concrete methods of labeling adapted to the respective national systems.

In Japan, a report on "Labeling of Genetically Modified Foods and Foods Containing Allergens", which was presented by a Special Subcommittee on Labeling of the Food Sanitation Investigation Council on 13 July 2000, recommended "legally requiring labels to indicate that allergens are contained in foods to prevent health hazards.

Therefore, it was decided that a legal requirement of labeling of these foods be established. The regulation came into force on 1 April 2001, and the grace period was one year, including products manufactured (or imported) on 31 March 2002.

The labeling requirements, which is stipulated in Article 21 of the Enforcement Regulations of the Food Sanitation Law (1948), are as follows:

2-4-1 Products to be Subject to the Regulation
Prepackaged processed foods and food additives, including ingredients.
2-4-2 Types of Labeling
The specified ingredients subject to labeling are defined according to the Japan Standard Commodity Classification.

The 24 items proposed by the subcommittee on labeling are classified into two stages of labeling – mandatory and recommended – according to the number of occurrences and the severity of danger.

a) Products subject to mandatory labeling established by a ministerial ordinance
   Seven items: egg, milk, wheat, buckwheat, shrimp/prawn, crab and peanuts
b) Products for which labeling is recommended by a notice
   18 items: common abalone, squid, salmon roe(ikura), orange, kiwifruit, beef, tree nuts(walnut), salmon, mackerel, soybean, chicken, pork, matsutake mushroom, peach, yam, apple, gelatin and banana

Source:
- Food Sanitation Law (No 23, 3 24 December 1947)
- Enforcement Regulations of the Food Sanitation Law (Ministerial Ordinance of MHLW No 23 13 July 1948)
- Standards of Milk and Milk Products (Ministerial Ordinance of MHLW No52, 27 December 1951)
- Enforcement Regulations of the Food Sanitation Law Ministerial Ordinance of MHLW, 1948 (Translated into English by JETRO)
- Handbook of Regulations on Agricultural, Forestry and Fisheries Products to be Imported, JETRO, February 2004
- Enforcement Regulations of the Food Sanitation Law (Ministerial Ordinance of MHLW, 1948)
3 Labeling Standards under the Health Promotion Law

3-1 Nutrition Labeling and Nutrition Claims
As the standard of living became higher, consumers’ consciousness to nutrition of food increased. The USA introduced compulsory nutrition labeling on processed food (the labeling is voluntary for perishable food) by the Nutrition Labeling and Education Act of 1990. The EU also adopted a directive on the voluntary nutrition labelling (90/496/EEC) in the same year, while a directive on the nutrition claims is still under examination.

Following the standards established in the EC and the USA and considering discussions in Codex on this subject, Japan decided to establish standards on the nutrition labeling and nutrition claims to be applied to processed food by amendment of the Nutrition Improvement Law (Present Health Promotion Law) in 1995. Then, the standards were established by the MHLW ministerial notification in the following year (1996). The nutrition labeling and nutrition claims are voluntary in Japan, while any person shall comply with standards in the notification, when they intend to put nutrition labeling or nutrition claim on their products.

These standards are applied to any person who has an intention of selling food with nutrition labeling and claims, and to any person who imports food with nutrition labeling and claims. However, food with health claims (FOSHU and Nutrition Functional Food) are not subject to these standards.

In Japan, nutrition labeling and claims are regulated under the Health Promotion Law (partly regulated under the Food Sanitation Law), since these are not regarded as a matter of food safety, all of which are regulated under the Food Sanitation Law.

The Standard of the Nutrition Labeling (Ministerial Notification of the MHLW, No 146, 20 May 1996) regulates nutrition labeling and nutrition claims as follows.

3-1-1 Standard of Nutrition Labeling
Items to be labeled are weights of protein, fat, carbohydrate and natrium as well as calorie contained in the unit of the food (for example, per 100g, per 100ml, per pack or per dose in one meal). Items should be labeled in the descending order as mentioned above. However, calorie per unit should be labeled on the top.

3-1-2 Standard of Nutrition Claim
a) In case of claiming “high content”
For the nutrients in the first column in the table below (Table 2), the claim of “high” shall not be made in the label, unless the weight of the nutrient per 100g of the food is equal or more than the weight described in the second column (for soft drink, weight per 100ml described in the second column), and unless the weight of the nutrient per 100 Kcal of the food is equal or more than the weight described in the third column.
<table>
<thead>
<tr>
<th>Nutrients</th>
<th>g /100g</th>
<th>g /100ml</th>
<th>g /100Kcal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protain</td>
<td>12g</td>
<td>6g</td>
<td>6g</td>
</tr>
<tr>
<td>Dietary Fiber</td>
<td>6g</td>
<td>3g</td>
<td>3g</td>
</tr>
<tr>
<td>Calcium</td>
<td>210mg</td>
<td>105mg</td>
<td>70mg</td>
</tr>
<tr>
<td>Iron</td>
<td>3.6mg</td>
<td>1.8mg</td>
<td>1.2mg</td>
</tr>
<tr>
<td>Niacin</td>
<td>4.5mg</td>
<td>2.3mg</td>
<td>1.5mg</td>
</tr>
<tr>
<td>Pantothenic Acid</td>
<td>1.50mg</td>
<td>0.75mg</td>
<td>0.50mg</td>
</tr>
<tr>
<td>Biotin</td>
<td>9.0μg</td>
<td>4.5μg</td>
<td>3.0μg</td>
</tr>
<tr>
<td>Vitamin A</td>
<td>162μg</td>
<td>81μg</td>
<td>54μg</td>
</tr>
<tr>
<td>Vitamin B₁</td>
<td>0.30mg</td>
<td>0.15mg</td>
<td>0.10mg</td>
</tr>
<tr>
<td>Vitamin B₂</td>
<td>0.33mg</td>
<td>0.17mg</td>
<td>0.11mg</td>
</tr>
<tr>
<td>Vitamin B₆</td>
<td>0.45mg</td>
<td>0.23mg</td>
<td>0.15mg</td>
</tr>
<tr>
<td>Vitamin B₁₂</td>
<td>0.72μg</td>
<td>0.36μg</td>
<td>0.24μg</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>30mg</td>
<td>15mg</td>
<td>10mg</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>0.75μg</td>
<td>0.38μg</td>
<td>0.25μg</td>
</tr>
<tr>
<td>Vitamin E</td>
<td>3.0mg</td>
<td>1.5mg</td>
<td>1.0mg</td>
</tr>
<tr>
<td>Folic Acid</td>
<td>60μg</td>
<td>30μg</td>
<td>20μg</td>
</tr>
</tbody>
</table>

b) In case of claiming “containing”
For the nutrients in the first column in the table below (Table 3), the claim of “containing the nutrient” shall not be made, unless the weight of the nutrient per 100g of the food is equal or more than the weight described in the second column (for soft drink, weight per 100ml described in the second column), and unless the weight of the nutrient per 100 Kcal of the food is equal or more than the weight described in the third column.
Table 3

<table>
<thead>
<tr>
<th>Nutrients</th>
<th>g /100g</th>
<th>g /100ml</th>
<th>g /100Kcal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein</td>
<td>6g</td>
<td>3g</td>
<td>3g</td>
</tr>
<tr>
<td>Dietary Fiber</td>
<td>3g</td>
<td>1.5g</td>
<td>1.5g</td>
</tr>
<tr>
<td>Calcium</td>
<td>105mg</td>
<td>53mg</td>
<td>53mg</td>
</tr>
<tr>
<td>Iron</td>
<td>1.8mg</td>
<td>0.9mg</td>
<td>0.9mg</td>
</tr>
<tr>
<td>Niacin</td>
<td>2.3mg</td>
<td>1.1mg</td>
<td>0.8mg</td>
</tr>
<tr>
<td>Pantothenic Acid</td>
<td>0.75mg</td>
<td>0.38mg</td>
<td>0.25mg</td>
</tr>
<tr>
<td>Biotin</td>
<td>4.5μg</td>
<td>2.3μg</td>
<td>1.5μg</td>
</tr>
<tr>
<td>Vitamin A</td>
<td>81μg</td>
<td>41μg</td>
<td>27μg</td>
</tr>
<tr>
<td>Vitamin B1</td>
<td>0.15mg</td>
<td>0.08mg</td>
<td>0.05mg</td>
</tr>
<tr>
<td>Vitamin B2</td>
<td>0.17mg</td>
<td>0.09mg</td>
<td>0.06mg</td>
</tr>
<tr>
<td>Vitamin B6</td>
<td>0.23mg</td>
<td>0.11mg</td>
<td>0.08mg</td>
</tr>
<tr>
<td>Vitamin B12</td>
<td>0.36μg</td>
<td>0.18μg</td>
<td>0.12μg</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>15mg</td>
<td>8mg</td>
<td>5mg</td>
</tr>
</tbody>
</table>

**c) In case of claiming “fortified” (comparative claim)**

For the nutrients in the first column in the table above (Table 3), the comparative claim shall not be made, unless the fortified weight of the nutrient per 100g of the food, compared with other foods is equal or more than the weight described in the second column (for soft drink, weight per 100ml described in the second column), and unless the fortified weight of the nutrient per Kcal of the food compared with other foods is equal or more than the weight described in the third column.

Necessary description to identify other food to be compared shall be stated, and the fortified quantity or percentage compared with other food shall be stated in the label.

**Note:**

In case of a comparative claim, the standard degree to be compared is usually determined by the association of producers of the product concerned.

**d) In case of claiming “not containing”**

For the nutrients or energy in the first column in the table below (Table 4), the claim of not containing the nutrient or energy shall not be made, unless the weight of the nutrient or energy per 100g of the food is less than the weight or energy described in the second column (for soft drink, weight or energy per 100ml).
Table 4

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Saturated Fatty Acid</td>
<td>0.1g</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>5mg</td>
</tr>
<tr>
<td>Saccharide</td>
<td>0.5g</td>
</tr>
<tr>
<td>Natrium</td>
<td>5mg</td>
</tr>
<tr>
<td>Calorie</td>
<td>5Kcal</td>
</tr>
</tbody>
</table>

e) In case of claiming “low content”
For the nutrients or energy in the first column in the table below (Table 5), the claim of low content shall not be made, unless the weight of the nutrient or energy per 100g of the food is less than the weight or energy described in the second column (for soft drink, weight or energy per 100ml described in the third column).

Table 5

<table>
<thead>
<tr>
<th></th>
<th>3g</th>
<th>1.5g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fat</td>
<td>3g</td>
<td>1.5g</td>
</tr>
<tr>
<td></td>
<td>1.5g</td>
<td>0.75g</td>
</tr>
<tr>
<td>Saturated Fatty Acid</td>
<td>1.5g</td>
<td>0.75g</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>20mg</td>
<td>10mg</td>
</tr>
<tr>
<td>Saccharide</td>
<td>5g</td>
<td>2.5g</td>
</tr>
<tr>
<td>Natrium</td>
<td>120mg</td>
<td>120mg</td>
</tr>
<tr>
<td>Calorie</td>
<td>40Kcal</td>
<td>20Kcal</td>
</tr>
</tbody>
</table>

f) In case of claiming “reduced” (comparative claim)
For the nutrients in the first column in the table above (Table 5), the comparative claim shall not be made, unless the reduced weight of the nutrient per 100g of the food, or reduced energy, compared with other foods is less than the weight or energy described in the second column (for soft drink, weight per 100ml described in the second column).

Necessary description to identify other foods to be compared shall be stated, and the reduced quantity or percentage compared with other food shall be stated in the label.

Source:
- Standard of the nutrition labeling (Ministerial Notification of the MHLW, No 146, 20 May 1996)
- Understanding labeling of Food, Kiyoshi Masuo, Nousangyoson Bunka Kyokai, 1991
3-2 Health Claims and Health Food

3-2-1 Labeling Guidelines on Health Food
Along with the improvement of the level of living and the change of dietary habit, consumers’ concern on nutrition and health has been increasing since late 1980s. In light of this trend, variety of health foods began to appear in the Japanese market. While the MHLW did not formulate a clear definition of health food, a guideline of labeling on health foods was introduced for the first time in 1988. This guideline standardized indications about the appropriate quantity and method of consumption of the health food to avoid excessive intake.

The role of the health food in selecting the food became gradually important. Then, a more comprehensive guideline for appropriate labeling on health food was established in view of preventing confusion of consumers in taking health food in 1989.

The system of “Food for Specified Health Use” (FOSHU), which is officially allowed to make health function claim, was created under the Nutrition Improvement Law of 1952 in 1991. Each FOSHU should be approved through the examination on safety and function at a designated research institution. In 1998, the approval procedure of FOSHU was relaxed. The labeling regulations have been changed, so as to treat vitamins, mineral and herb as food instead medicinal drugs.

3-2-2 Review of Demarcation between Drugs and Food, and the Introduction of the System of Food with Health Claims
According to the review of the definition of medicinal drugs, vitamins, minerals, etc. became freely distributed in the market. Accordingly, capsules and tablets with health functions became treated as food. This category of food includes not only vitamin, mineral or herb but also substances related to physiological functions. And it had a variety of functions. Inappropriate labeling and use of these foods may cause an adverse effect to human health, while appropriate intake contributes to maintain and promotes the health. Actually, too exaggerated advertisements and labels appeared in the market.

In these days, discussions have been continued in view of introducing a standard on the health food on an international basis. The health claim on the label was examined in the Codex Commission. In this situation, the MHLW started studying to categorize these health foods and legal treatment for them in line with the review of the definition of medicinal drugs. Then, the system of “Food with health claims”, which is composed of FOSHU and nutrition functional food (food with nutrient function claims), was established under the Nutrition Improvement Law (presently the Health Promotion Law) and the Food Sanitation Law in 2001. By the establishment of the system, the definition of the health food has been clearly given, and the labeling standard on health claim was established for the food with
health claims.

Position of the Food with Health Claims

<table>
<thead>
<tr>
<th>Medicinal drugs</th>
<th>Food with health claims</th>
<th>Ordinary food</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>FOSHU (Food for specified health use)</td>
<td>Nutrition functional food</td>
</tr>
<tr>
<td></td>
<td>Pre-market approval</td>
<td>Obligation of respecting the established standard</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Including various health foods</td>
</tr>
</tbody>
</table>

3-2-3 Review of the System of Food with Health Claims of 2005

While the demand of food with health claims has been increasing in a steady manner, functions demanded widely varied. Based on the progress of research and technology, various functions have been identified and many types of foods have been developed. On the other hand, consumers has begun receiving too much information on health and food. Inappropriate information, which may induce excess of consumption, over diet and unbalanced dietary habit, has become observed in the market.

In light of this trend, the MHLW considered that appropriate, necessary and sufficient information should be provided so as that consumers could appropriately choose foods to meet their needs in changing eating habits. A committee on the orientation of health food in the future was established in April 2003. Then, the system of the food with health claims was revised in 2005, based on the report of the committee which was issued in June 2004.

Note: Amendments of related regulations

- Amendment of the ministerial ordinance of the health promotion law (Ministerial ordinance of the MHLW No. 9, 2005)
- Amendment of the ministerial ordinance of the food sanitation law (Ministerial ordinance of the MHLW No. 10, 2005)
- Amendment of the ministerial notification of standard of nutrition labeling (Ministerial announcement of the MHLW No. 16, 2005)

In the revised system, the Qualified FOSHU and the Standardized FOSHU were created. And an indication of reducing risk of disease was allowed in FOSHU. Regarding the nutrition functional food, an indication of nutritive substances other than those designated by the minister was prohibited. The indication of names of nutritional element became compulsory.

In addition, the words stating that the balanced intake of food among staple food, main sub-food and sub-food would be important should be labeled on the food with health claims.
This kind of expression is highly recommended to be labeled on health foods other than the food with health claims as well.

3-2-4 Standards of FOSHU
According to the definition in the ministerial ordinance, FOSHU is a food claiming that specified beneficial effect(s) to the health is expected for those who consume it.

FOSHU has been controlled under the Nutrition Improvement Law (the present Health Promotion Law), however, it has been partly controlled under the Food Sanitation Law since 2001.

Before a FOSHU is placed in the market, it should receive an approval on the contents of labeling from the MHLW, through the examination of scientific evidence(s) on physiological functions, specific health functions and safety. However, in 2005 a system for Standardized FOSHU was introduced. This type of FOSHU, whose scientific evidences have been accumulated through experiences of the past approvals, is not necessary to undergo the examination. It has to only receive the confirmation that it meets the standards by the MHLW.

In 2005, a system for Qualified FOSHU was also added. This type of FOSHU, whose beneficial effect(s) to the health have been already confirmed, although the scientific evidence is not complete as required in the previous cases, could be approved with conditions. One of reasons of the creation of the Qualified FOSHU system is that the prohibition of labeling of benefits to the health on health foods other than the food with health claims has caused the increase of misleading, confusing or vague indications on other health foods.

In addition, an indication of decreasing risk of disease is allowed for FOSHU whose scientific evidence has been widely recognized from the medical and nutritive points of view.

The following information should be labeled on FOSHU in addition to labeling requirements to be generally applied to food.

- Being a FOSHU;
- Approved indications related to beneficial effect(s) to the health and others;
- Weight of each nutritive substance and total calorie;
- Names of ingredients;
- Total weight;
- Recommendable daily intake quantity;
- Usage and cautions;
Percentage of each nutritive substance in the recommendable daily intake quantity to the necessary total quantity of the corresponding substance per day; and

Cautions regarding methods of cooking and storing, if necessary.

Apart from the above information, the indication about the importance of the balanced intake of food among staple food, main sub-food and sub-food should be labeled.

The regulation of the form of FOSHU was abolished in 2001. Accordingly, tablet and capsule and other forms are possible for FOSHU.

### Number of Approved FOSHU and Their Health Use

**As of March 2005**

<table>
<thead>
<tr>
<th>Health Claim</th>
<th>Functional Factors</th>
<th>No. of Products Approved</th>
<th>Number of Approved Products/Total Approved Products Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improves gastrointestinal conditions</td>
<td>Origosaccharides, lactulose, bifidobacterium, lactobacillus, dietary fiber (indigestible dextrin, polydextrose, cyamoposis gum, psyllium husk)</td>
<td>196</td>
<td>47.6</td>
</tr>
<tr>
<td>Blood sugar level</td>
<td>Indigestible dextrin, wheat albumin, guava leaves polyphenols, L-arabinose</td>
<td>52</td>
<td>12.6</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>Lactotripeptide, casein dodecapeptide, tochu leaves glycoside (geniposidic acid), sardine peptide</td>
<td>40</td>
<td>9.7</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>Chitosan, soy protein, low molecular weight sodium alginate</td>
<td>34</td>
<td>8.3</td>
</tr>
<tr>
<td>Teeth</td>
<td>Palatinos, maltitol, erythritol</td>
<td>29</td>
<td>7.0</td>
</tr>
<tr>
<td>Cholesterol + gastrointestinal conditions, serum triacylglycerol + cholesterol</td>
<td>Low molecular weight sodium alginate, dietary fiber of psyllium husk</td>
<td>23</td>
<td>5.6</td>
</tr>
<tr>
<td>Bones</td>
<td>Isoflavone,(乳塩基性タンパク質 major basic protein)</td>
<td>15</td>
<td>3.6</td>
</tr>
<tr>
<td>Serum triacylglycerol</td>
<td>Diacylglycerol, globine digest</td>
<td>12</td>
<td>2.9</td>
</tr>
<tr>
<td>Mineral absorption</td>
<td>Calcium citrate malate, casein phosphopeptide, heme iron, fructo-oligosaccharide</td>
<td>11</td>
<td>2.7</td>
</tr>
</tbody>
</table>

Source: MHLW

Reference: National Centre of Excellence in Functional Foods
3-2-5 Standards of Nutrition Functional Food

According to the ministerial ordinance, the nutrition functional food is a food which claims a function(s) of specified nutrient(s) contained in the food, in line with the standards of the MHLW. The nutrition functional food is not necessary to receive a pre-market approval by the MHLW. 4 minerals and 12 vitamins which meet the standards could be labeled on the nutrition functional food.

Minerals: Zink, Calcium, Iron, Copper, Magnesium

Vitamin: Niacin, Pantothenic acid, Biotin, Vitamin A, Vitamin B1, Vitamin B2, Vitamin B6, Vitamin B12, Vitamin C, Vitamin D, Vitamin E, Folic acid

By the revision of the system in 2005, labeling about the function(s) of nutritive elements other than the above-mentioned minerals and vitamins is prohibited.

The quantity of nutritive elements in a recommendable intake quantity of the food should be within the limits specified. The cautions in consuming the nutritive element(s) should be also labeled.

**Note:** The nutrition functional food in Japan corresponds to the Nutrient Function Claims defined in 2.2.1 of the Draft Guidelines for Use of Nutrition and Health Claims of the Codex.

### Limits of Quantity of Nutritive Substances and Cautions to be Labeled in the Nutrition Functional Food (Ministerial Notification of the MHLW of 2004)

<table>
<thead>
<tr>
<th>Nutrients</th>
<th>Minimal limit</th>
<th>Functions</th>
<th>Maximum limit</th>
<th>Cautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zink</td>
<td>3mg</td>
<td>Is necessary in maintaining the normal function of palate. Helps to maintain skin and mucosa healthy. Helps to maintain healthy conditions in relating with the metabolism of protein and nucleic acid.</td>
<td>15mg</td>
<td>Excess intake of this product may cause a risk of disturb the absorption of copper. Take only the optimum amount. Prevent babies and infants from taking this product.</td>
</tr>
<tr>
<td>Calcium</td>
<td>250mg</td>
<td>Is necessary in tooth and bone development.</td>
<td>600mg</td>
<td>Excess intake of this product neither cures your diseases nor promotes your health. Take only the optimum amount.</td>
</tr>
<tr>
<td>Iron</td>
<td>4mg</td>
<td>Is necessary in red blood cell formation.</td>
<td>10mg</td>
<td>Excess intake of this product neither cures your diseases nor promotes your health. Take only the optimum amount.</td>
</tr>
<tr>
<td>Nutrient</td>
<td>Amount</td>
<td>Purpose</td>
<td>Maximum Amount</td>
<td>Precautions</td>
</tr>
<tr>
<td>---------------</td>
<td>--------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>----------------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Copper</td>
<td>0.5mg</td>
<td>Is necessary in helping the red blood cell formation. Helps the normal function of enzymes in the body and for developing bones.</td>
<td>5mg</td>
<td>Excess intake of this product neither cures your diseases nor promotes your health. Take only the optimum amount. Prevent babies and infants from taking this product.</td>
</tr>
<tr>
<td>Magnesium</td>
<td>80mg</td>
<td>Is necessary in tooth and bone development. Is necessary for the normal function of enzymes in the body and for producing energy. Is necessary in maintaining the normal circulation of blood.</td>
<td>300mg</td>
<td>Excess intake of this product neither cures your diseases nor promotes your health. Take only the optimum amount. Excess intake of this product may loosen the bowels. Prevent babies and infants from taking this product.</td>
</tr>
<tr>
<td>Niacin</td>
<td>5mg</td>
<td>Helps to maintain skin and mucosa healthy</td>
<td>15mg</td>
<td>Excess intake of this product neither cures your diseases nor promotes your health. Take only the optimum amount.</td>
</tr>
<tr>
<td>Pantothenic acid</td>
<td>2mg</td>
<td>Helps to maintain skin and mucosa healthy.</td>
<td>30mg</td>
<td>Excess intake of this product neither cures your diseases nor promotes your health. Take only the optimum amount.</td>
</tr>
<tr>
<td>Biotin</td>
<td>10μg</td>
<td>Helps to maintain skin and mucosa healthy</td>
<td>500μg</td>
<td>Excess intake of this product neither cures your diseases nor promotes your health. Take only the optimum amount.</td>
</tr>
<tr>
<td>Vitamin A</td>
<td>180μg (600IU)</td>
<td>Helps to maintain vision in the dark Helps to maintain skin and mucosa healthy</td>
<td>600μg (200IU)</td>
<td>Excess intake of this product neither cures your diseases nor promotes your health. Take only the optimum amount. Women who are pregnant within 3 month or who want to expect should be careful not to intake over the optimum amount.</td>
</tr>
<tr>
<td>Vitamin B₁</td>
<td>0.3mg</td>
<td>Helps to produce energy from carbohydrate and to maintain skin and mucosa healthy.</td>
<td>25mg</td>
<td>Excess intake of this product neither cures your diseases nor promotes your health. Take only the optimum amount.</td>
</tr>
<tr>
<td>Vitamin B₂</td>
<td>0.4mg</td>
<td>Helps to maintain skin and mucosa healthy.</td>
<td>12mg</td>
<td>Excess intake of this product neither cures your diseases nor promotes your health. Take only the optimum amount.</td>
</tr>
<tr>
<td>Vitamin B₆</td>
<td>0.5mg</td>
<td>Helps to produce energy from protein and to maintain skin and mucosa healthy.</td>
<td>10mg</td>
<td>Excess intake of this product neither cures your diseases nor promotes your health. Take only the optimum amount.</td>
</tr>
<tr>
<td>Vitamin</td>
<td>Amount</td>
<td>Description</td>
<td>Recommended</td>
<td>Excess intake of this product neither cures your diseases nor promotes your health. Take only the optimum amount.</td>
</tr>
<tr>
<td>-----------------</td>
<td>--------</td>
<td>------------------------------------------------------------------------------</td>
<td>--------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Vitamin B₁₂</strong></td>
<td>0.8μg</td>
<td>Aids in red blood cell formation.</td>
<td>60μg</td>
<td></td>
</tr>
<tr>
<td><strong>Vitamin C</strong></td>
<td>35mg</td>
<td>Have an antioxidizing effect. Helps to maintain skin and mucosa healthy.</td>
<td>1000mg</td>
<td></td>
</tr>
<tr>
<td><strong>Vitamin D</strong></td>
<td>0.9μg (35IU)</td>
<td>Promotes the absorption of calcium in the gut intestine and aids the development of bones.</td>
<td>5.0μg (200IU)</td>
<td></td>
</tr>
<tr>
<td><strong>Vitamin E</strong></td>
<td>3mg</td>
<td>Helps to protect fat in the body from being oxidized and to maintain cells healthy.</td>
<td>150mg</td>
<td></td>
</tr>
<tr>
<td><strong>Folic acid</strong></td>
<td>70μg</td>
<td>Aids in red blood cell formation and contributes to the normal growth of the fetus</td>
<td>200μg</td>
<td></td>
</tr>
</tbody>
</table>

Source: MHLW
Reference: National Centre of Excellence in Functional Foods

The following information should be labeled on the nutrition functional food, in addition to labeling requirements to be generally applied to food.

- Being a nutrition functional food;
- Indications related to beneficial effect(s) to the health in line with the standards established by the MHLW;
- Functions of each nutritive substance which meets the standard;
- Weight of each nutritive substance and total calorie;
- Recommendable intake quantity per day;
- Usage and cautions;
- Percentage of each nutritive substance in the recommendable daily quantity to the necessary total quantity of the corresponding substance per day (Daily value);
- Cautions regarding methods of cooking and storing, if necessary; and
- Statement that the food is not individually approved by the MHLW.

Apart from the above information, the indication about the importance of the balanced
intake of food among staple food, main sub-food and sub-food should be labeled.

Demarcation of the Competence of the Laws

<table>
<thead>
<tr>
<th>The Health Promotion Law</th>
<th>The Food Sanitation Law</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Food for Specified Use</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Food with Health Claims</strong></td>
<td>Food with Health Claims</td>
</tr>
<tr>
<td>Food of Specified Health Use</td>
<td>Food of Specified Health Use</td>
</tr>
<tr>
<td>Items to be filled in the petition</td>
<td>Standards of labeling</td>
</tr>
<tr>
<td>Items to be labeled</td>
<td>Procedures of examination</td>
</tr>
<tr>
<td><strong>Nutrition functional Food</strong></td>
<td>Nutrition functional Food</td>
</tr>
<tr>
<td>Items to be labeled</td>
<td>Standards of labeling</td>
</tr>
<tr>
<td>Method of labeling</td>
<td></td>
</tr>
<tr>
<td><strong>Nutrition Labeling Regulations</strong></td>
<td></td>
</tr>
</tbody>
</table>

3-2-6 Market Size of Health Foods
The market size of all types of foods for health, including FOSHU, functional foods (functional sweeteners), health supplements, and nutrition functional foods is estimated to be 1.3 trillion yen in 2000 (the Report of the New Economic Growth Policy Committee of the Council of the Industrial Structure). And it is estimated to be 3.2 trillion yen in 2010 (the Outline of Biotechnology Strategy of the Government in 2003).

Source:
- Ministerial Ordinance of the Health Promotion Law (No. 86, 2003)
- Standard of the nutrition labeling (Ministerial Notification of the MHLW, No 176, 2003)
- Amendment of the Ministerial Ordinance of the Health Promotion Law (Ministerial Ordinance of the MHLW, No. 9, 2005)
- Amendment of the Ministerial Ordinance of the Food Sanitation Law (Ministerial Ordinance of the MHLW, No. 10, 2005)
- Amendment of the Ministerial Notification of the Standard of Nutrition Labeling (Ministerial Notification of the MHLW, No. 16, 2005)
- MHLW Web site (the Committee on the Orientation of the System for Health Food)
- Web site of the National Centre of Excellence in Functional Foods
6 Act against Unjustifiable Premiums and Misleading Representations

6-1 Outline of the Law
This law was promulgated in 1962. Its objective is to secure fair competition and to protect consumers’ interests by preventing inducement for customers by means of premiums and misleading representations on goods and services (Section 1).

Misleading representation in connection with transactions of goods and services is prohibited. The Section 4 defines misleading representations as follows.

(1) Any representation misleading customers to believe that the quality, standard and other matter relating substance of good or service is much better than the actual one, and likely impeding fair competition.

(2) Any representation misleading customers to believe that the prices and any other terms of transactions of goods or services are much more favorable than the actual one, and likely impeding fair competition.

(3) Any representation which is designated by the Fair Trade Commission, finding it likely to induce customers unjustly and to impede fair competition.

In this law, "representation" means advertisement or any other descriptions which a person uses as means of inducement for customers, with respect to the substance of the good or service which he supplies or the terms of sale or any other matter concerning the transaction.

Note: The Fair Trade Commission’s notifications on misleading representations concerning food
1. Misleading Representations on Soft Drinks without Juice, etc.
   (FTC Notification No. 4 of 1973)
   (FTC Notification No. 34 of 1973)

The Fair Trade Commission may, in the event there is an act violating the prohibition of misleading representations, order the person concerned to cease such an act, or to take the measures necessary to prevent the resurgence of the act (Section 6).

6-2 Voluntary Guidelines of Fair Trade
Under this law a group of producers may establish a voluntary guideline of representations and premiums for their products, which shall be observed by participating member corporations. The guideline shall be approved by the Fair Trade Commission. This is an additional guideline of labeling to the obligatory labeling regulated by the standards under the Food Sanitation Law and the JAS Law. The outsiders of the guideline are to be controlled by the Fair Trade Commission and the prefectural government in implementing the regulations of this law.
As of May 2005, the Fair Trade Guidelines of Labeling are established for following 33 processed foods and meat as well as 5 alcoholic products.

**Foods**

Drinking milk, Fermented lactic acid milk, Sterilized lactic acid milk drink, Cheese, Ice cream, Honey, Royal jelly, Sea urchin food, Seasoned cod raw, Dried bonito, Seaweed, Canned food, Processed tomato food, Powdered horse radish, Fresh noodles, Biscuit, Chocolate, Food using chocolate, Chewing gum, Frozen soybean curd, Vinegar, Fruit drink, Coffee drink, Synthetic lemon, Soybean milk, Margarine, Regular coffee, Ham, Sausage, Meat, Packed bread, Instant noodles, soybean paste,

**Alcoholic beverages**

Beer, Imported beer, Imported whisky, Shochu “otsu” grade, Awamori

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**Sec. 4 [Prohibition of misleading representations]**

(1) No entrepreneur shall make such representation as provided for in any one of the following paragraphs in connection with transactions regarding a commodity or service which he supplies:

(i) Any representation by which the quality, standard or any other matter relating to the substance of a commodity or service are shown to consumers in general to be much better than the actual one or much better than that of other entrepreneurs who are in competitive relationship with the entrepreneur concerned contrary to the fact and thereby which is found likely to induce customers unjustly and to impede fair competition;

(ii) Any representation by which price or any other terms of transaction of a commodity or service will be misunderstood by consumers in general to be much more favorable to the consumer in general than the actual one or than those of other entrepreneurs who are in competitive relationship with the entrepreneur concerned, and thereby which is found likely to induce customers unjustly and to impede fair competition; or

(iii) In addition to those stipulated in the preceding two paragraphs, any representation by which any matter relating to transactions as to a commodity or service is likely to be misunderstood by consumers in general and which is designated by the Fair Trade Commission as such, finding it likely to induce customers unjustly and to impede fair competition.

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Tentative translation of the law by the Fair Trade Commission

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**Source:**

- Act against Unjustifiable Premiums and Misleading (Law No. 134 of 1962)
- Fair Trade Commission Homepage
C  Food Quality

V  Measures for Food Quality

1 JAS Law

1-1 Purpose and Structure of the JAS Law

The objective of the JAS Law of 1950 is to improve the quality of food, to rationalize the production, use or consumption and to achieve fair-trading by establishment of standards, and to help proper selection of food by consumers through the proper quality labeling.

It is very obvious that the Law has two purposes. One is the promotion of the food industry including agriculture through transactions of standardized products, and the other is the protection of consumers. The original objective of the Law was the facilitation of the sound development of agriculture and the food industry. However, the purpose of the consumer protection has been gradually intensified, as the information gap became widened between consumers and producers, due to the advancement of technology and increasing complexity of the production and distribution in the food industry. The JAS standards for forestry products are still serving the forestry industry.

(Purposes of Law)

**Article 1** The purposes of this Law are to achieve the improvement of quality, the rationalization of production, the simplification and fair trading, and the rationalization of use or consumption of agricultural and forestry products by establishing proper and reasonable standard for the agricultural and forestry products and disseminating it and to help general consumers select products by obligating the proper labeling which concerns the quality of the agricultural and forestry products, thereby contributing to the promotion of public.

Translated by MAFF

The Law covers a wide range of issues concerning food labeling and quality. The component of the regulation of the Law is as follows.

(1) Standards of products for 53 foods and 21 forestry items (as of 2003)
(2) Specified Standards for 7 food items
(3) General quality labeling standards for 5 items
(4) Quality labeling standards of indication of place of origin of ingredients of processed food for 6 items
(5) Quality labeling standards for 55 specified items (as of 2005)
1-2 History of the JAS Law

1-2-1 Creation of the JAS Law
In Japan, legal regulations of labeling started with standards by the JAS Law of 1950, which succeeded standards of foods under the Government Inspection Law of Agricultural and Forestry Products in association with the supply and demand adjustment policy including the government procurement and ration system. Just before the Second World War, Japanese government imposed on suppliers an obligation to sell certain major foods to the government intending the equitable supply of food to consumers. Towards the end of the war, the number of products to be sold to the government has increased. After the war ended, the inspection system within the framework of the government procurement continued for several years in the severe food shortage. The government needed standards including labeling requirements in controlling distribution of food in the ration system.

1-2-2 JAS Law before 1969
JAS standards have contributed for many years to facilitating smooth transactions among producers and distributors. JAS standards were set by prefectures and the government regional offices, mainly for perishable products. However, the need for standards of processed food was recognized, as the share of processed food in the food consumption became increasing in line with the increase of income of households in the late 1950s.

In 1960, an incidence of false canned beef occurred. A consumer group revealed that the contents were meat of horse or whale. In those days, beef was very precious in Japan. Through this incidence, food quality and labeling happened to be one of the important issues in the society of Japan. Accordingly, the government studied to establish appropriate measures to response to this social matter. In 1962, “Act against Unjustifiable Premiums and Misleading Representations” was promulgated, and “Law of Quality Labeling on Goods for Households” was also promulgated in the same year.

The JAS Law was also amended in the same year. The law introduced the system of certified manufacturer, which allow a manufacturer of processed food to conduct sampling and labeling of a JAS product by itself, if the manufacture is certified by the Minister in recognition that it has sufficient ability. The objective of this system was to efficiently grade the JAS mark for processed foods. The Law also introduced a mark of JAS which allow consumers to easily distinguish JAS products. Previously, the methods of labeling widely varied according to types of food, since the JAS standards were those for the industry concerned.

1-2-3 Establishment of the Consumer Protection Fundamental Act and Amendment of the JAS Law in 1969
Around 1965, the consumer protection movement started to be intensively discussed as one of important social issues. In these days, the rural population migrated into cities due to the remarkable development of the industry in Japan. There has been sometimes the shortage of
food supply for rapidly increased population in large cities. In particular, city dwellers suffered from high prices or excessive fluctuation of prices of vegetables. The government adopted the price stabilization policy as one of the most important challenges of Japan. It was also recognized that law-quality foods, harmful foods or foods with false labeling came to appear in the market under the condition of food shortage and high prices, and that consumers were not provided with sufficient information to distinguish those products. The common understanding that the consumers are vulnerable compared with producers and distributors has been formulated in the society.

In these circumstances, the establishment of a law for the protection of consumers had been studied in Japan. It was stimulated by the consumer movement in the USA and European countries. In the USA, President Kennedy sent a message on the protection of consumers to the Congress in 1962. In addition, the international harmonization of consumer protection started. In 1962, the Codex Commission of FAO/WHO was created, aiming at fair trade of food and consumer protection. In 1969, a consumer policy committee was established in the OECD. And the International Organization of Consumer Union (IOCU) started the exchange of information on this matter.

The draft of the Consumer Protection Fundamental Act was submitted to the parliament as a joint proposal of the Liberal Democratic Party, the Communist Party, the Social Democratic Party and the Komeito in 1968. The law was passed in the following year.

The Consumer Protection Fundamental Act cited measures to be taken by the government; prevention of danger, ensuring correct weight and measures, establishing proper standards, proper labeling, securing fair and free trade, promotion of education, reflection of public opinions, establishment of facilities for testing and inspection, and establishment of a system for dealing with complaints.
Consumer Protection Fundamental Act (Law No. 78, enacted May 30, 1968)

Section 2 Measures Concerning Consumer Protection

(Prevention of Danger)
Article 7 To prevent goods and services from causing danger to life and to the property of the people in their consumer lives, the state shall establish necessary standards for the prevention of danger and take the necessary measures to maintain them.

(Ensuring Correct Weights and Measures)
Article 8 So that consumers may not suffer a disadvantage in their dealing with businesses, the state shall take the necessary measures to ensure observance of correct weights and measures concerning goods and services.

(Establishing Proper Standards)
Article 9 To contribute to the rationalization of consumer life, the state shall establish proper standards concerning goods and services and take the necessary measures to popularize them.

2. The establishment of standards referred to in the preceding paragraph shall be carried out in accordance with the progress of technology and with a rise in the standards of consumer life.

(Proper Labelling)
Article 10 So that consumers do not make wrong choices in the purchase or use of goods or in the utilization of services, the state shall take the necessary measures to establish a system for indicating the quality and other elements of the substance of goods and services and also take the necessary measures to regulate false and exaggerated indications.

(Securing Fair and Free Competition)
Article 11 The state shall take the necessary measures to regulate activities that unreasonably restrict fair and free competition concerning such as prices of goods and services. With regard to prices of goods and services that are particularly important to the consumption life of the people and that also require state-level decision, approval or other measures in those forms, the state shall endeavor to take that influence on consumers fully into consideration in its executing the above policies.

Translated by the Ministry of General Affairs

The parliamentary decision made in relation to the Fundamental Act recommended that the system of standards should be improved so as to be suitable to processed food including imported food, and that a proper labeling system to protect consumers should be established in the JAS Law.
In 1969, the JAS Law was amended and the title of the Law was changed from “Law Concerning Standardization of Agricultural and Forestry Products” to “Law Concerning Standardization and Proper Labelling of Agricultural and Forestry Products”. The purpose of facilitating consumers’ selection of products by providing proper quality labeling was added in the Law.

1-2-4 Amendment in 1983 to Open the Market to Foreign Countries
The Standard Code, which was agreed at the GATT Tokyo Round and was enacted in 1980, obliged the participating countries to ensure that domestic certifying systems should be opened to foreign people on the same conditions as domestically applied, and that foreign products should be treated in the same manner as domestic products in applying inspection and administrative procedures.

In those days, the trade conflicts between Japan and the USA and/or European countries became intensified, as the export of Japan was well over the import. The government of Japan created an organization for coordinating standard and certification systems. As the result of the coordination of this organization, amendment of 16 relating laws was proposed to achieve the further free access to the Japanese market. The JAS Law was one of them. The main amendments were as follows

a) The system of certified manufacturer should be open to foreign producers.

b) Legal requests are applied to foreign producers, instead of legal orders applied to domestic producers.

c) The penalties are not applied to foreign producers, while the cancellation would be applied.

1-2-5 Introduction of the Specific JAS Standard in 1993
Consumers’ requirements on food gradually shifted from quantity to quality, as the income of households has grown, along with the development of the economy. Consumers began to place importance on safety, health and quality of food. Regarding the food quality, consumers became interested in organic products, region-specific food and traditional food which are characterized in the production process. Such products could not be distinguished by their appearances. Therefore, many types of indications trying to attract consumers emerged in the market. These indications sometimes misled consumers.

To cope with such problems of labeling, the government established a guideline for labeling of organic fruits and vegetables in 1992. In addition, the JAS Law created a new category of JAS standards, which is called as “Specific JAS”, by the amendment of the Law in 1993. The quality or characteristic of products categorized as Specific JAS are defined by the process or method of production.
However, the confusion of labeling of organic products still remained as a large problem, since the guideline of 1992 was only a guidance without any legal penalty. The Food, Agriculture and Rural Community Basic Law (the new agriculture basic law) (Law No. 106, 16 July 1999), which underlined the enhancement of natural recycling function of agriculture, was promulgated in 1999. Then, the system of organic agriculture was arranged as one of JAS standards by the amendment of the JAS Law in 1999. In 2000, the standards of JAS organic agricultural products and JAS organic processed food were established, based on the Codex guideline of organic food adopted in 1999.

According to the amendment of the JAS Law and the standards, the certification by a third party is compulsory, and the labeling as an organic product is prohibited to other products than those produced following the procedures of the standards. Organic JAS standard is one of the Specific JAS standards.

1-2-6 Amendment of 1999
By the amendment of JAS Law in 1999, the organic products were arranged as a category of JAS standards. Other important changes as follows were made in the amendment of the Law.

a) The JAS standards shall be revised every 5 years. In the process of the revision, un-necessary standards should be abolished and standards should be revised in consideration of the international standards like the Codex.

b) Private organizations shall be encouraged to be registered certification organizations or registered grading organizations.

c) Producers and manufacturers shall be allowed to grade their own products and attach JAS marks by themselves, if they are certified as certified manufacturer or certified production process manager by a registered certification organization.

d)

1-2-7 Amendment of 2005
The Law provided a new category of Specific JAS standards. Products which are distributed in a special method and whose value is added due to the distribution method may be graded as a product of Distribution JAS, which is one of Specific JAS standards (Article 2). One of purposes of the Distribution JAS is to promote the traceability. In this relation, distributors, wholesalers or retailers may grade the Distribution JAS, if they are certified (Article 14).

The system of grading by registered certification organizations was abolished. Therefore, products will be graded only by certified manufacturers or certified production process managers.
Prefectures and the statutory organization would not be any more an organization to perform grading. Instead, the Law arranged procedures of registration of private entities as certification organizations, so as to encourage them to be registered certification
organization of JAS standards (Article 17).

1-3 Recent Trend of JAS Standards and Quality Labeling
In responding to the increasing interest of consumers in food safety and food quality as well as health, the nature of JAS standards have been changing in recent years.

In older times, the JAS standards played an important role to facilitate the smooth transaction of products in the industry and to provide quality and safety products to consumers in the low developed society. As high-quality products are generally produced in the recent advanced industry, many JAS standards have lost their original objective. Therefore, the government encourages the industry to abandon rather meaningless JAS standards and restore JAS standards so as to secure the quality by emphasizing characteristics of methods of production in response to various requirements of consumers.

In order to certify the quality of food, so as to ensure the reliability of food in meeting consumers’ requirements, Specific JAS standards, which guarantee the targeted quality of products by regulating the process of production or distribution of the products, have been gradually expanded, such as Organic JAS standards, Production Disclosure JAS standards, JAS standard for aged ham. Although the Specific JAS standards are not perfectly elaborated in Japan, compared with signes de qualité in France or geographical indications in the EU, they could be considered as “process defined products”.

Regarding the labeling system in Japan, the indication of place of origin has been dramatically intensified. The original purpose of the obligation of the indication of origin was to distinguish the domestic products from imported ones whose safety sometimes were uncertain. In the recent trends of consumers to require the high level of safety and reliability of food, the indication of place of origin has become applied to many products. It is obligatory to all perishable foods and to the main ingredients of certain processed foods. In 2005, the MAFF established a guideline of the indication of origin for ingredients of dishes served in restaurants, since there have been appeared some restaurants which place the indication of origin of ingredients.

Such system of indication of place of origin in Japan seems to have been elaborated on the basis of a combination of the tradition of identification of products by their origin and the new trend of demand for the reliability of food.

Although the reform of food safety policy has been intervened in 2003, a lot of cases of fallacious and inexact indications in labelling persistently occurred in Japan. In the situation where measures for food reliability such as the traceability are not in principle obligatory in the legislation relating to food security, JAS Law plays a role mattering for food reliability by using regulations relating to labelling, such as obligatory labelling of OGM and places of origin. An obligation to the operators of all food chain to provide information on ingredients of a transformed product was introduced in 2008 under the JAS Law, to struggle against frequent fraud.
2 JAS Standards

2-1 Scope of JAS Standard (Article 2)
JAS standards shall be established for agricultural and forestry products, except liquors as well as drugs, quasi-drugs and cosmetics provided in the Pharmaceutical Affairs Law (Law No. 145 of 1960).

An Article of the JAS Law related to JAS Standards

(Establishment of the Japanese Agricultural Standard)

Article 7 If the Minister of Agriculture, Forestry and Fisheries judges it necessary for attaining the purposes provided in Article 1, he shall designate the category of any agricultural and forestry product and establish the Standard relating it.
2. The Standard mentioned in the preceding Paragraph shall be established with respect to the current situation and future forecast of quality, production, transaction, use or consumption of the agricultural and forestry product covered by the Standard as well as international trend of standard, and to reflect the intent of the persons having substantial interests, and further, in the implementation, so as not to unfairly put discrimination against any person present in similar conditions.

2-2 Four Categories of JAS Standards
JAS standards are composed of 4 categories. The first one is the JAS standard related to grade, performance and composition, additives and others related to quality of the product. The second one is the JAS standard related to process of production or distribution of the product, which was introduced by the amendment of the JAS Law of 1993. Products of Specific JAS Standards are classified as “process defined”. The third one is organic JAS standards. The forth one is the production information disclosure JAS.

The second category of JAS standard is called as “Specific JAS standard”. JAS standards for aged ham and for “Zidoriniku” are ones of Specific JAS standards. In occasion of the establishment of Specific JAS standard, the law provided a system that a certified farmer (production process manager) may carry out the grading its product and attach the label to the product, and a certified subdivider of products may attach a label to subdivided products, since products of the Specific JAS standards.

In addition, a certified distributor of products of the distribution JAS standard, which was added in the amendment of the JAS Law of 2005, may carry out the grading and attach a label to its products.

2-4 Establishment of the JAS Standard (Article 7, 8 and 13)
a) The Minister designates a category of any agricultural and forestry product and establish
a Standard relating it. If the Minister intends to establish a Standard, he must obtain in advance the resolution of the Council.

b) A Prefecture or an interested person may propose to the Minister that a JAS Standard should be established by designating a category of product and preparing its original draft. When the Minister has received the proposal, he judges that a JAS Standard should be established concerning the product covered by such proposal, and he shall present the original draft to the Council for deliberation. If he judges that it is unnecessary to do so, he must notify it the proposer with the reason.

c) The Minister may hold a public hearing to listen opinions of interested persons on a draft of a JAS standard. A person having substantial interest in a JAS standard may request the Minister to hold a public hearing, which concerns that the JAS standard would, or not, reflect the intention of all the interested or it would, or not, unfairly put discrimination against any person present in similar conditions in its application.

**Agricultural and processed products to which JAS standard is applied**

**As of September 2008**

**Canned and bottled food**
(1) Canned and bottled agricultural products, (2) Canned and bottled livestock products, (3) Canned and bottled marine products

**Beverages**
(4) Fruit drinks, (5) Apple strait and pure juice, (6) Carbonated drinks, (7) Soy bean milk, (8) Carrot juice and mixed carrot juice

**Meat products**

**Cereal products**
(17) Dried noodles, (18) Instant noodles, (19) Non-dried instant noodles, (20) Macaronis, (21) Vegetable protein, (22) Powdered bread,

**Processed agricultural products**
(23) Pickled agricultural products, (24) Processed tomato food, (25) Jams,

**Marine products**
(26) Kezurubushi (shaved dried food), (27) Dried fish and powdered dried fish.

**Sweatners**
(28) Dextrose, (29) High fructose corn syrup and sugar mixed high fructose corn syrup,

**Seasoning**

**Oil and fats**
(36) Edible vegetable oils and fats, (37) Refined lard, (38) Margarine, (39) Shortening, (40) Edible, refined and processed oils and fats,
Others
(41) Prepared frozen food,

Processed food to which specific JAS standard is applied
(1) Aged ham products, (2) Aged sausage products, (3) Aged bacon products, (4) Hand made dried noodles, (5) Jidoriniku (native poultry)

Products to which organic JAS standard is applied
(1) Organic agricultural products, (2) Organic agricultural processed food, (3) Organic feed, (4) Organic livestock products

Products to which production information disclosure JAS is applied
(1) Beef, (2) Pork, (3) Agricultural products, (4) Processed food, (5) Aquaculture fish

Source: MAFF

2-5 Prohibition of Reference to the JAS Standard (Article 11)
No one shall use the Japanese Agricultural Standard or any other name confusing it for any standard for agricultural and forestry products other than the Japanese Agricultural Standard.

2-6 Procedure of Grading
(1) Grading by Manufacturer and Production Process Manager (Article 15)
a) A manufacturer may carry out the grading of his products, by obtaining in advance the certification of the Minister of MAFF or a Registered Certification Organization. Then, the manufacturer may attach the label of grading to the product.

b) A person who manages or controls production process of an agricultural product, and is certified by the Minister of MAFF or a Registered Certification Organization (“Production Process Managers”) may carry out the grading of the products which he manages or controls production process. Then, the Production Process Manager may attach the label of grading to the product.

c) The manufacturer or a production process manager who has obtained the certification may, if it is especially necessary for carrying out the labeling efficiently, attach the label of grading to the product, prior to the grading.

d) The product attached the label of grading must not be transferred, consigned for transfer or displayed for transfer before the grading is carried out.

Note: Registered Certification Organization
Any private organization may apply to the registration as Registered Certification Organization to the Minister of MAFF, and will be registered, if the organization meets the technical standard provided by the Minister.
(2) Labeling of Grading by Subdivider (Article 15-6)
A person who divides a product for his business (subdivider) may attach the same label of grading to the subdivided product, by obtaining in advance the certification of the Minister of MAFF or the Registered Certification Organization.

(3) Labeling of Grading by Importer (Article 15-7)
An importer of any specified agricultural and forestry product (specified product) may attach the label of grading to the specified product imported by him, by obtaining in advance the certification of the Minister of MAFF or the Registered Certification Organization.

The certificate issued by the governmental organizations or those designated as quasi-governmental organizations by the ministers of agriculture, forestry and fisheries of foreign countries is needed. In this case, the country must be judged by the Minister of MAFF as a country having an equivalent grading system to the JAS system.

(4) Foreign Grading
a) Grading by Registered Foreign Grading Organization (Article 19-2-2)
If a Registered Foreign Grading Organization has carried out in a foreign country the grading of an agricultural and forestry product in accordance with the Japanese Agricultural Standard, it may attach the label of grading to such a product.

b) Grading by Foreign Manufacturer and Foreign Production Process Manager (Article 19-3)
A Foreign Manufacturer may, for an agricultural and forestry product manufactured or processed by him, carry out the grading in accordance with the Japanese Agricultural Standard and attach the label of grading to such a product, by obtaining in advance the certification of the Minister of MAFF, a Registered Certification Organization or a Registered Foreign Certification Organization.

A Foreign Production Process Manager may, for any agricultural and forestry product which is managed or controlled by him, carry out the grading and attach the label of grading to such a product, by obtaining in advance the certification of the Minister of MAFF, a Registered Certification Organization or a Registered Foreign Certification Organization.

c) Labeling of Grading by Foreign Subdivider (Article 19-3-2)
A foreign subdivider may, for an agricultural and forestry product covered by the certification concerned to which the label of grading has been attached, attach the same label of grading to subdivided products, by obtaining in advance the certification of the Minister of MAFF, Forestry and Fisheries, a Registered Certification Organization or a Registered Foreign Certification Organization.
3 Organic Products

3-1 Establishment of the Standard for Organic Products
Around 1970, the movement of organic agriculture started in Japan. In those years, organic products were sold by the method of direct contracts between producers and consumers, which was different from the distribution through the market dominating the distribution of agricultural products. Then, the organic production has been developed by collaboration between consumers and producers.

Organic agriculture had been neglected by the authorities for many years, and any policy was not adopted, even when organic products have been recognized to some extent in the Japanese society in 1980s. The government was unwilling to promote organic products which was distributed outside of the market system promoting agricultural products supplied by the agricultural cooperative system.

Therefore, many types of indication concerning organic products, which might mislead consumers, happened to appear in the market. To cope with such confusion of labeling, the government established a guideline for labeling of organic fruits and vegetables in 1992. However, the confusion of labeling still remained as a serious problem, since the guideline was only guidance without any legal penalties.

The system of organic agriculture has been developed as national legal systems in European countries and the USA in early 1990s. Even Japanese consumers considered that organic products in these countries were much more reliable than those in Japan. Moreover, foreign certification organizations started certifying Japanese organic producers.

In 1999, the New Agriculture Basic Law, which underlines the enhancement of the natural recycling function of agriculture, was promulgated. Then the system of organic agriculture was arranged as one of the JAS standards by the amendment of the JAS Law in 1999. In 2000, the standards of JAS organic agricultural products and JAS processed food were established, based on the Codex guideline of organic food adopted in 1999.

According to the amendment of the JAS Law and the standards, the certification by the third party is compulsory, and the labeling of organic products is prohibited to other products than those produced following the procedures defined by the standards. Standards of meat, milk products and their processed foods have not yet been established in Japan. These standards are expected to be established in 2005.

3-2 Juridical System
The legal procedures for certification, grading and modalities of import are almost the same as those for other JAS standards, since organic products are classified as one of JAS standards. However, a certified production process manager (a farmer), instead of the certified manufacturer, carries out grading of organic agricultural products. The system
of certified subdivider was created due to the situation which organic agricultural products are often subdivided by wholesalers or retailers.

Organic products are defined as “specified products”. Article 19-10 of the law states that with regard to the food which is specified by a Government Ordinance as one especially necessary to achieve proper labeling of name because the name provided in the JAS Standard is being used also for any other product by a method other than that provided by the JAS Standard and if left as it is, this would likely cause grave hindrance to consumers’ choice, any person must not indicate the name provided by the JAS Standard or any name confusing on any such specified food.

Then the Government Ordinance specifies an organic product as a “specified product”. This means that specified products are given a special status with exclusive right of use of the indication of product.

3-2-1 Principles of Production of Organic Products

a) Principle of Production of Organic Agricultural Products
The principle of production of organic agricultural products is that the productivity of farmland derived from soil properties shall be generated by avoiding usage of chemical synthetic fertilizers and agricultural chemicals, in view of sustaining and enhancing the natural recycling in agriculture, and the method of agricultural practices shall be managed so as to reduce negative impacts on the environment as much as possible.

b) Principle of Production of Agricultural Processed Food
The principles of the production of organic agricultural processed foods is that the characteristics of organic agricultural products used as raw materials in the manufacturing and processing processes shall be preserved, the processing methods applying the physical and biological functions shall be used basically, and any use of food additives and drugs synthesized chemically shall be avoided.

3-2-2 Certification and Grading
a) Registration of Registered Certification Organizations
Receiving an application, the minister registers a certification organization.

b) Certification of Certified Producers (Production Process Manager)
A registered certification organization, when it has received an application from a farmer of organic agricultural product or a producer of organic agricultural processed food, certifies it through an examination, based on the technical criteria.

c) Investigation on Certified Producers
A registered certification organization shall investigate certified producers at least once a year, in view of verifying that the producers are producing the product in conformity with the JAS organic standard.
d) Grading Products by the Certified Producer
A certified producer grades its own product, based on the record of the process of production and places it in the market by labeling the JAS mark.

e) Grading Products by the Certified Subdivider
A certified subdivider may attach the JAS mark to the subdivided products.

3-2-3 Labeling
Indication of “Organic” and indications similar to “Organic” shall be prohibited to products other than the products graded as the organic agricultural product or organic agricultural processed product (came into force in April 2001).

3-2-4 Import
Organic products could be imported through the following 2 ways.
(1) The foreign producers certified by registered certification organization or by registered foreign certification organization attach the JAS mark to their products, when they ensure the conformity of the products to the JAS standard (JAS Law Article 19-3).

(2) Only for organic products, the following way can be applied to the countries where the MAFF has recognized the equivalency of their organic standard as well as certification system with those of JAS.
   The importers certified by registered Japanese certification organization attach the organic-JAS mark on organic products with the certificate issued by the export country’s government agency that the organic foods has been certified based on the export country’s system (JAS Law Article 15-7).

Note: These countries approved by Japan are Ireland, the United States of America, Argentina, Italy, the United Kingdom, Australia, Austria, Netherlands, Greece, Switzerland, Sweden, Spain, Denmark, Germany, Finland, France, Belgium, Portugal, and Luxembourg (as of December 2006)

3-3 The Technical Standard of Production of Organic Agricultural Products
Based on the above principle, the technical standard of organic agricultural products are established on conditions of the field, manuaring practices in the field, seeds and seedlings, control of noxious animals and plants in the field, and management concerning transportation, selection, processing, cleaning, storage, packaging by the Japanese Agricultural Standard of Organic Agricultural Products (Notification No. 59 of the Ministry of Agriculture, Forestry and Fisheries of January 20, 2000), and the labeling standard is also stipulated in the same notification.

3-3-1 Conditions of Fields
A field shall be clearly divided so as to be protected from drifting fertilizers, soil improvement materials, or agricultural chemicals.
In a paddy field, necessary measures shall be taken to prevent prohibited substances from contaminating the agricultural water.

The criteria of production must be applied to the cultivation at least 3 years before the first harvesting of perennial plants (except for the pasture grass), and at least 2 years before the sowing or planting of other plants than perennial plants, and prohibited substances must not be used at least 2 years.

3-3-2 Manuring Practices in Fields
A farmland shall be preserved and promoted only by applying compost derived from remainders of the agricultural products produced in the field, and by methods effectively utilizing biological functions of the organism inhabiting and growing in the field or in the circumference.

It may utilize only the fertilizers and the soil improvement materials noted in the attached table, in cases where the productivity of the farmland cannot be preserved and promoted only by methods utilizing the biological functions of the organism inhabiting and growing in the field.

3-3-3 Seeds and Seedlings to be Sown or Planted in Fields
It shall
a) utilize seeds and seedlings with the criteria of conditions of the field, manuring practice in the field, control of noxious animals and plants, and management concerning transportation, selection, processing, cleaning, storage, packaging, and other processes. This is not applicable to cases of being hard to obtain them by ordinary means.
  b) be produced without using the recombinant DNA technology.

3-3-4 Control of Noxious Animals and Plants in Fields
It shall be executed only by
a) cultivation methods (to control noxious animals and plants by intentionally executing works generally performed as parts of the selection of crop lists and variety, the adjustment of the cropping time, and other cultivation management of the agricultural products so as to suppress the emergence of noxious animals and plants),
  b) physical methods (to control noxious animals and plants by methods using light, heat, sound, etc., or manual or mechanical methods),
  c) biological methods (to control noxious animals and plants by introducing microorganisms suppressing the proliferation of microorganisms being causes of diseases, predators of noxious animals and plants, plants repelling noxious animals and plants, or plants having effects of suppressing the emergence of noxious animals and plants, or by improving the environment suited for growing them),
  d) an appropriate combination of these methods, or
  e) use of the agricultural chemicals noted in the attached table, in cases of being critical or seriously risky for the agricultural products and being impossible of effectively
controlling noxious animals and plants in the field, etc., only by an appropriate combination of these methods.

3-3-5 Management Concerning Transportation, Selection, Processing, Cleaning, Storage, Packaging and Other Processes
a) In transportation, selection, processing, cleaning, storage, packaging, and other processes, it shall be controlled so as not to be mixed with other agricultural products than the organic agricultural products.
b) In transportation, selection, processing, cleaning, storage, packaging, and other processes, only the agricultural chemicals noted in the attached table and the processing substances noted in the attached table (except for materials produced by using recombinant DNA technology) shall be used for materials used for the control of noxious animals and plants or quality preservation and improvement.
c) Ionizing radiation shall not be executed for the disease and pest control, the preservation of the foods, removal of pathogens or sanitation.
d) It shall be controlled so as not to be polluted from the agricultural chemicals, detergent, disinfectant, and other chemicals.

3-3-6 Labeling of Names of the Organic Agricultural Products
The names of the organic agricultural products shall be labeled by the methods prescribed as follows.

The Labeling shall be made according to any of the examples in Japanese language which mean as follows.
- Organic Agricultural Product
- Organically Grown Agricultural Product
- Organic Agricultural Product
- Organic Farming
- Organic

3-4 Technical Standard of Organic Agricultural Processed Foods
Based on the above principle, criteria of raw materials including processing aid, utilization of raw materials, management concerning manufacturing, processing, packaging and other processes are defined by the ministerial notification of Japanese Agricultural Standard of Organic Agricultural Products Processed Foods (Notification No. 60 of the Ministry of Agriculture, Forestry and Fisheries of January 20, 2000). And the labeling standard is also stipulated in the same notification.

3-5 Production and Consumption of Organic Products in Recent 5 Years
In Japan, production of organic products has less increased than expected since the establishment of the System. The quantity of certified and graded products in 2003 was 46,000 tonnes, while it was 34,000 tonnes in 2001. On the other hand, the volume of organic products certified and graded in foreign countries was 298,000 tonnes in 2003,
while it was 94,000 tonnes in 2001.

Organic products certified and graded in foreign countries are mainly used for the production of organic processed food in Japan. For example, vegetables and fruits are used for juice, soybeans are used for soy sauce, soybean paste and soybean curd. It should be noted that 298,000 tonnes in 2003 of organic products certified and graded in foreign countries includes 150,000 tonnes of sugar cane in Brazil whose sugar is an ingredient of organic processed food in Japan. If this quantity is taken out, the increase of organic products certified and graded in overseas is not so remarkable. However, the share of organic products of overseas in the total supply is well over that of organic products produced in Japan.

As of 2004, 44,000 farmers are engaged in production of organic products. The size of the market is expected to be 110 billion yen (approximately 1 billion dollars). The share of organic agricultural products is only 0.15% of the total production in terms of quantity (IFAOM Japan).

Such a stagnant situation of organic products in Japan is analyzed in the report of a study conducted by IFAOM Japan at the request of FAO and World Bank. Its view on causes of the stagnation is as follows.

a) Consumers refrained from increase of purchase of organic products whose prices were comparatively high in the economic mal-performance since the collapse of the economic bubble in early 1990s.

b) Organic products could not well response to requirements by the mainstream of the distribution system through the market, such as stable supply through the whole year, precise quality grading, etc.

c) The costs of collection and transport of organic products were comparatively high, due to the small quantity in the distribution.

d) Consumers have not well understood yet the role of organic farming in the protection of environment, while organic products have been recognized gradually in the Japanese society.

By taking into account this situation of the organic farming in Japan, members of the Parliament proposed a law for the promotion of the organic farming in 2006. This Law was approved in the Parliament in December, 2006. It demands that the State shall lay the basic direction of the promotion of the organic farming, and local authorities shall establish program for the promotion of organic farming (articles 6 and 7). The Law stipulates that the State and local authorities has to take necessary measures to increase awareness of the organic farming in consumers (article 10).
### Organic agricultural products certified and graded in Japan

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<th>Vegetable</th>
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<th>Wheat</th>
<th>Soybean</th>
<th>Tea</th>
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Source: MAFF

### Organic agricultural products certified and graded in foreign countries

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Source: MAFF

### Organic processed food certified and graded

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<th>In foreign countries</th>
<th>Total</th>
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<td>2003</td>
<td>117685</td>
<td>64468</td>
<td>182153</td>
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Source: MAFF

Source:
- JAS for Organic Agricultural Products (MAFF Notification No. 59, 2000)
- JAS for Organic Agricultural Processed Foods (MAFF Notification No. 60, 2000)
- Monthly report, August 2004, Agriculture, Forestry and Fisheries Finance Corporation
- L'Agriculture biologique en Europe - Une croissance soutenue au cours de la période 1998-2000, UE Commission
- Codex guideline of organic farming
4 Production Information Disclosure JAS

4-1 Objective of the Production Information Disclosure JAS
In order to restore the reliability of food for consumers, a new JAS standard, in which a third-parity certifies the accuracy of production information of foods, was established as one of approaches to improve the transparency on production and handling operations from the tables to the farms, such as introduction of a traceability system.

JAS for disclosed production information is a certification system in which producers record, keep and publish the production information of their foods with accuracy. Consumers can confirm the production information of products with this JAS mark when they purchase it.

A standard was established for beef in 2003, and a standard for pork was established in 2004.

4-2 Scheme of Certification and Distribution of the Products

a) In receiving an application, the registered certification organization shall certify the production process manager (breeder, feeder, or slaughterer) and the sub-divider (processor, or retailer).

b) The certified production manager shall record, keep and publish the production information in conformity with the standard, and supply the product to sub-divider with attachment of JAS mark.

c) The sub-divider shall subdivide the product and publish the information on production of subdivided meat for each animal or each unit, and sell it to consumers with attachment of JAS mark.

d) Consumers can receive the production information by the label, Fax or Internet.

4-3 Standard of Production Information Disclosure JAS for Beef
Ministerial Notification of JAS for beef with the disclosed production information (Notification No. 1794 of MAFF of October 31, 2003) stipulates the standard for beef.

4-3-1 Information to be Disclosed (Article 2)
The following production information shall be disclosed.

(1) Date of birth
(2) Gender
(3) Name and address of the Manager (the owner of cattle or others to manage cattle)
and the date on which the management by the manager started

(4) Place of the facilities for raising the cattle and date on which its raising started
(5) Date of slaughter
(6) Breed of cattle
(7) Contact point of the Manager of the cattle
(8) Name and contact point of the Slaughterer, and the name and place of the abattoir where the cattle were slaughtered
(9) Name of fodder given by the Manager
(10) Drug class and name of veterinary drugs used by the Manager

The breeds of cattle shall be classified as follows:

(1) Japanese Black
(2) Japanese Brown
(3) Japanese Shorthorn
(4) Japanese Polled
(5) A breed produced by crossbreeding breeds in (1) and (2) above (including breeds produced by crossbreeding this breed with breeds in (1) or (2) above)
(6) Wagyu Crossbreed
(7) Beef Cattle
(8) Holstein
(9) Jersey
(10) Dairy Cattle
(11) Crossbreeds

The drug classes specified are classified as follows.

(1) Anesthetics
(2) Hypnotic sedatives
(3) Analgesic-antipyretic and antiinflammatory agents
(4) Antispasmodics
(5) Autonomics
(6) Cardiotonics
(7) Anti-tussive expectorants
(8) Diuretics
(9) Cardiovascular agents, agents affecting respiratory organs and agents for urinary system excepting those set forth in (6) to (8)
(10) Hormones for medical purposes
(11) Oxytocics
(12) Sulfonamide preparations
(13) Synthetic antimicrobial agents
(14) Antiprotozoan agents
(15) Antibiotic preparations
(16) Anthelmintics
(17) Anti-dermoinfectives excepting those set forth in (12) to (16)
(18) Vaccines
(19) Antisera
(20) Biological preparations for medical purposes

4-3-2 Recording and Storage of Production Information (Article 3)

The following production information shall be precisely recorded and stored.

(1) Name of fodder fed by the Manager
(2) Drug class and name of veterinary drugs used by the Manager
(3) Date of birth in case of beef from imported cattle
(4) Name and contact point of the Manager who managed cattle from birth to import, and date on which management by the Manager commenced in case of beef from imported cattle
(5) Place of the Raising Facility of cattle from birth to import, and date on which raising there started in case of beef from imported cattle
(6) Contact point of the Manager who managed cattle from birth to import in case of beef from imported cattle

4-3-3 Disclosure Method (Article 3)

The production information shall be literally disclosed for each head of cattle. However, if it is difficult to identify which animal the beef was derived from, it shall be literally disclosed for every lot of no more than twenty animals.

4-3-4 Labeling Standards (Article 4)

(1) Labeling Items
The method to disclose the production information shall be labeled. However, it can be omitted when the production information is literally indicated in a place such as an easily visible place on the container or packaging, invoice or delivery card by sellers other than retailers, and in an easily visible place on the container or packaging, a notice close to the beef or any other easily visible location by retail sellers.

(2) Labeling Method
The items set forth in Article 3, Paragraph 1, (1) of the Quality Labeling Standard for Perishable Foods and the method to disclose the production information shall be indicated as follows:
a) Title
   “Beef with disclosed production information” shall be indicated, following the general name of the content.
b) Method to Disclose the Production Information
The contact point to obtain the production information, such as a fax number or website address, shall be indicated in an easily visible place on the container or packaging, invoice or delivery card by sellers other than retailers, and in an easily visible place on the container or packaging, a notice close to the beef or any other easily visible place by retail sellers.

Source:

Japanese Agricultural Standard for beef with the disclosed production information
(Notification No. 1794 of the Ministry of Agriculture, Forestry and Fisheries of October 31, 2003)
VI Labeling Standards for Food Quality under the JAS Law

1 Labeling Standards for Food Quality under the JAS Law
Under the JAS Law the general quality labeling standards are established for perishable food, processed food, fishery products and genetically modified food. They are as follows

- Quality labeling standard for perishable foods
- Quality labeling standard for processed foods
- Quality labeling standard for genetically modified foods

Secondly, quality labeling standards for individual perishable food are adopted as follows.
- Quality labeling standard for brown rice and polished rice
- Quality labeling standard for fishery products
- Quality labeling standard for Chinese mushroom

In addition to the above mentioned standards, 51 quality labeling standards for specified processed foods are adopted.

Processed food to which a quality labeling standard is applied

- **Canned and bottled products**
  1) Canned and bottled agricultural products, 2) Canned and bottled livestock products, 3) Canned and bottled prepared food
- **Beverages**
  4) Fruit juice, 5) Carbonated soft drinks, 6) Soy milk, 7) Carrot juice and carrot mixed juice,
- **Meat products and Fish paste products**
- **Processed cereal products**
  19) Dried noodles, 20) Instant noodles, 21) Raw type instant noodles, 22) Macaronis, 23) Frozen soy bean curd, 24) Bread
- **Processed agricultural and forestry products**
- **Processed marine products**
- **Seasoning**
  36) Dressings, 37) Edible vinegar, 38) Flavoring seasonings, 39) Dehydrated soups,
(40) Worcester sauces, (41) Soy sauce, (42) “Miso” (soy bean paste), (43) “Tsuyu” (dipping soup) for noodles,

**Fats**
(44) Edible vegetable oils and fats, (45) Refined lard, (46) Margarines, (47) Shortening,

**Others**
(48) Retort-pouch food, (49) Frozen vegetables, (50) Chilled “gyoza”, (51) Frozen prepared food,

Source: MAFF

**Article of the JAS Law related to the Quality Labeling**

**(Labeling Standard to be Complied with by Manufacturers, etc.)**

**Article 19-8** For the purposes of achieving proper quality labeling of beverages and foods and helping general consumers choice, the Minister of Agriculture, Forestry and Fisheries must provide the standard to be observed by the manufacturers or sellers concerning necessary ones of the matters mentioned in the following, as to the respective classes to be provided by a Ministerial Ordinance of the Ministry of Agriculture, Forestry and Fisheries, as regards the quality labeling of beverages and foods out of agricultural and forestry products (except those which are judged to be characteristic in the production method thereof and thereby expected to enhance the value thereof):
(1) Name, ingredients, storage method, place of origin and any other matters to be indicated; and
(2) Method of labeling and any other matter to be complied with by manufacturers or sellers in labeling the matters mentioned in the preceding Item.

Translated by MAFF

**2 Quality Labelling Standard for Perishable Foods**
This standard is established by Quality Labelling Standard for Perishable Foods (Notification No. 514 of the Ministry of Agriculture, Forestry and Fisheries of March 31, 2000)

**2-1 Definitions (Article 2)**
The article 2 of the Notification defines the perishable food as described in the table attached. According to this article the perishable foods for institutional use are those which are used as ingredients for processed foods.

**2-2 Matters to be Labeled (Article 3)**
The matters to be labeled by distributors (and packers) for perishable foods other than those for institutional use shall be as described below. Where distributors produce, collect or catch fresh foods and directly sell them to general consumers or offer them for eating and
drinking at facilities, those perishable foods need not be labeled.

(1) Name of the food
(2) Place of origin

2. With regard to the specified products listed under Article 5 of the Cabinet Order for the Measurement Concerning Sale of Specified Commodities (Cabinet Order No. 249 of 1993) and filled in containers or packed, the matters to be labeled on the containers or packages by distributors shall be net content and name or trade name and addresses of the distributors in addition to those cited above.

2-3 Method of Labeling (Article 4)
Distributors shall comply with the following provisions:

(1) Name of the food
   The name shall be declared with a generic name expressing its content.

(2) Place of origin
   The place of origin shall be declared as provided below based on the facts, provided, however, that, in the case that the perishable foods of the same kind and of multiple origins are mixed, the place of origin of each of the said perishable foods shall be declared in descending order of weight percentage in the total, and, in the case that the perishable foods of different kinds and of multiple origins are assorted, the place of origin of each of the said ones shall be declared in addition to the corresponding names of them.

a. Agricultural products
   A domestic product shall indicate the name of a prefecture, and an imported product shall indicate the country of origin. However, any domestic product may indicate the name of city, town, village or another generally known name of place, and any imported product may indicate the generally known name of place as its place of origin. In this case, the indication of a prefecture or a country of origin may be omitted.

b. Livestock products
   (a) A domestic product (excluding products from livestock which has been raised in Japan shorter than in foreign countries (in the case that the livestock has been raised in two or more foreign countries, each period in countries should be compared to that in Japan) shall indicate that it is domestic, and an imported product (including products from livestock which has been raised in Japan shorter than in foreign countries and slaughtered in Japan) shall indicate its country of origin (in the case that the livestock has been raised in two or more foreign countries, the name of country that the livestock has been raised longer shall be indicated). However, any domestic product may indicate the name of prefecture, city, town, village or another
generally known name of its main raising place as its place of origin. In this case, the indication of “domestic” may be omitted.

(b) In the case of indicating any name of place other than the name of its main raising place, the product shall indicate the name of prefecture, city, town, village or another generally know name of its main raising place as its place of origin, in addition to the name of place.

c. Marine products
(a) A domestic product shall indicate the name of a water area where the product has been produced or the name of district (meaning the name of the prefecture to which the main fish farm belongs), and an imported product shall indicate the country of origin. However, if it is difficult to indicate the name of water area, it may be replaced by the name of the port where the marine product has been landed or the name of the prefecture to which such port belongs.

(b) Notwithstanding the provisions of (a) above, any domestic product may indicate the name of the port where the marine product has been landed or the name of the prefecture to which such port belongs in addition to the name of the water area, and any imported product may indicate the name of the water area in addition to its country of origin.

(3) Net contents
Net contents shall be declared in accordance with the examples under the Measurement Law (Law No. 51 of 1992).

The labeling of the name of food is required at a conspicuous place of the container or package, in the invoices or in the statement of delivery by distributors other than retailers, and also at a conspicuous place of the container or package or at a signboard in close proximity to the product or other conspicuous place by retailers.

The labeling of the place of origin is required at a conspicuous place of the container or package.

The letters used for the labeling on the containers or packages shall be in the uniform-sized printing type and the size equivalent to or larger than 8 point as provided in the Japanese Industrial Standards (JIS) Z8305 (1962).

2-4 Method of labeling of perishable foods for institutional use (Article 4-2)
Distributors shall label the name of the food and the place of origin for perishable foods for institutional use. Where perishable foods are used for ingredients for processed foods which are manufactured or processed and sold to general consumers at the spot by distributors or which are offered for eating or drinking at facilities, those perishable foods need not be labeled.
However, labeling of place of origin may be omitted for those other than those used as main ingredients of processed foods.

2-5 Other Matters to be Labeled and Method of Labeling (Article 5)
The product which has been treated with ionizing radiation (limited to those kept in container or package) shall carry a written statement to that effect at a conspicuous place of the containers or packages.

2-6 Matters Prohibited from Labeling (Article 6)
The following matters are prohibited from labeling:
(1) Any wordings which may mislead consumers into believing as if a product were by far more excellent or advantageous than it is;
(2) Any wordings which are in conflict with those expressed in accordance with the provisions of Article 3; and
(3) Any letters, pictures, photographs or other labeling which may mislead consumers about the quality of the product.

Attached Table (Definition of Perishable Food)

1. Agricultural products, including mushrooms, wild vegetables and bamboo shoots
   (1) Rice (including those obtained through preparation, sorting and washing after harvesting, and merely cut, and mixed with polished barley and miscellaneous cereals)
       Brown rice and polished rice
   (2) Wheat and barleys (including those obtained through preparation, sorting and washing after harvesting and merely cut)
       Barley, naked barley, wheat, rye, oat
   (3) Other cereals (including those obtained through preparation, sorting and washing after harvesting, and merely cut)
       Corn, foxtail millet, barnyard millet, buck wheat, proso millet, grain sorghum, job’stear, and other miscellaneous cereals
   (4) Pulses (including those obtained through preparation, sorting and washing after harvesting, and merely cut, and excluding immature ones)
       Soybeans, red beans, kidney beans, peas, cowpeas, broad beans, mung beans, peanuts and other pulses
   (5) Vegetables (including those obtained through preparation, sorting and washing after harvesting, merely cut and frozen only)
       Root vegetables, leaf and stem vegetables, fruit vegetables, savory herbs and garnishes, mushrooms, “sansai” group (wild vegetables), fruity vegetables and other vegetables
   (6) Fruits (including those obtained through preparation, sorting and washing after harvesting, and cut only, and frozen only)
       Citrus fruits, kernel fruits, stone fruits, berries, edible nuts, tropical and sub-tropical fruits, and other fruits
   (7) Other crops
       Sugar crops, alimentary konjac roots, unprocessed crops for drinks, ingredients for spices,
other fresh crops

2. Livestock products

(1) Meats (including those cut and sliced only, and chilled and frozen only)
Beef and veal, pork and boar meat, horse meat, mutton and lamb, goat and kid meat, rabbit
meat, poultry meat and other meats

(2) Milk
Raw cow milk, raw goat milk, other milks

(3) Market poultry eggs (limited to those with shells)
Chicken eggs, duck eggs, quail eggs and other market poultry eggs

(4) Other fresh livestock products

3. Marine products (including those which are round, semi-dressed, dressed, fillet, cut,
slices of raw fish (excluding those assorted), shuckled shellfishes, and frozen and defrosted
only, and live products)

(1) Fishes
Freshwater fishes, salmons and trouts (anadromous type), herrings and sardines, skipjacks,
tunas and mackerels, jacks, yellow tails and dolphin fishes, cods, teleosteam flat fishes, sea
basses, sea breams and croakers and other fishes

(2) Shelled molluscas
Fresh water clams and flesh water snails, oysters, scallops, ark shells, hard clams and little
neck clams, surf or hen clams, abalones, top shells and other shelled molluscas

(3) Aquatic animals
Cuttle fishes, octopus, shrimps and prawns, lobsters, horse-shoe crubs and cray-fishes,
crabs other crustaceas, sea urchins and sea cucumbers, turtles and other aquatic animals

(4) Marine mammals
Whales, porpoise and other marine mammals

(5) Seaweeds
Tangles, "wakame,” lavers, perforated sea lettuces, seaweeds of a kind used for
manufacturing agar-agar and other sea weeds

Translated by MAFF

Source:

- *Quality Labelling Standard for Perishable Foods*
  *(Notification No. 514 of the Ministry of Agriculture, Forestry and Fisheries
  of March 31, 2000, Revised: 14 September 2004)*
3 Quality Labeling Standard for Processed Foods

This standard is established by Notification No. 513 of the Ministry of Agriculture, Forestry and Fisheries of 31 March 2000.

3-1 Definitions (Article 2)
Article 2 of the Notification defines the processed food as described in the attached Table 1, and according to this article, the processed foods for institutional use is the processed foods other than those sold to general consumers.

3-2 Matters to be Labeled (Article 3)
(1) Manufacturers (including processors/packers, importers or distributors) shall label the following items on containers or packages of processed foods other than those for institutional use. Where manufacturers manufacture or process foods and sell them directly to general consumers or offer them for drinking and eating at facilities, those processed foods need not be labeled.

① Name
② Names of ingredients
③ Net contents
④ Best-before
⑤ Instruction for storage
⑥ Name or trade name and address of manufacturer, etc.

Note: Best-before
The date which signifies the end of the period under any stated storage conditions during which the product will retain any specific qualities. However, beyond the date the food may still be satisfactory.

(2) With regard to the products where liquid packing media are added to solid products and then the final products are sealed in cans or bottles, the drained weight and the total quantity of contents shall be labeled.

(3) With regard to the products that should be consumed promptly after manufactured due to its quickly changeable quality, the use-by date shall be labeled in place of the best-before

Note: Use-by date
The date which signifies the end of the estimated period under any stated storage conditions during which there will be no danger of health risks due to decomposition.
(4) With regard to the products other than imported products listed in Table 2, a name of place of ingredient origin shall be labeled.

(5) With regard to imported products, a name of country of origin shall be labeled.

(6) With regard to those products falling under the division given in the left column of the following table, the labeling items in the right column may be omitted.

<table>
<thead>
<tr>
<th>The area of the container or package of the product is not more than 30cm$^2$.</th>
<th>Name of ingredients, best-before or use-by date, instructions for storage, and name of place of ingredient origin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Those containing a kind of ingredient only (except canned foods and meat products)</td>
<td>Name of ingredients</td>
</tr>
<tr>
<td>Those of which net contents can be easily identified (except the specified commodities listed under Article 5 of the Government Ordinance for the Measurement Concerning Sale of Specified Commodities (Government Ordinance No. 249 of 1993))</td>
<td>Net contents</td>
</tr>
<tr>
<td>Those listed in the Attached Table 3 as the products that undergo very slight change of quality</td>
<td>Best-before ; and storage instruction</td>
</tr>
<tr>
<td>Those for which there is no particular instruction for storage other than the storage at an ordinary temperature</td>
<td>Instructions for storage</td>
</tr>
</tbody>
</table>

3-3 Method of Labeling (Article 4)

(1) Name
Name shall be declared with a generic name expressing the content of the product. However, the established Quality Labeling Standards of processed food regulate the name(s) to be labeled. Products other than the categories of the products in the Quality Labeling Standards are prohibited to use the names designated in the Quality Labeling Standards (Refer to Table 4).
(2) **Names of ingredients**

a. Names of ingredients other than food additives shall be indicated with the most generic names in descending order of weight percentage in the total ingredients.

b. Names of food additives shall be indicated in the descending order of weight percent in the total ingredients pursuant to the provisions of Article 5, Paragraphs 11 and 12 of the Enforcement Regulations of the Food Sanitation Law (Ministerial Ordinance No. 23 of the Ministry of Health and Welfare of 1948).

c. Regardless the provisions of a., those products in the left column of the following table may be labeled with the names in the right column.

<table>
<thead>
<tr>
<th>Division</th>
<th>Names</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edible oils and fats</td>
<td>“Vegetable oil”, “Vegetable fat” or “Vegetable oil and fat”; “Animal oil”, “Animal fat” or “Animal oil and fat”; or, “Processed oil”, “Processed fat” or “Processed oil and fat”</td>
</tr>
<tr>
<td>Starch</td>
<td>“Starch”</td>
</tr>
<tr>
<td>Fishes and fish meat, where a name of a specific kind of fish is not labeled</td>
<td>“Fish” or “Fish meat”</td>
</tr>
<tr>
<td>Poultry meat, where a name of a specific kind of poultry is not labeled. Meat products excluded</td>
<td>“Poultry meat”</td>
</tr>
<tr>
<td>Dextrose anhydrous, dextrose monohydrate and total sugar glucose</td>
<td>“Glucose”</td>
</tr>
<tr>
<td>Glucose and fructose corn syrup, fructose and glucose corn syrup, and high fructose corn syrup (90%)</td>
<td>“Isomerized corn syrup”</td>
</tr>
<tr>
<td>Sugar added; glucose and fructose syrup, sugar added corn syrup, and high fructose corn syrup</td>
<td>“Sugar added isomerized corn syrup” or “Sugar/isomerized corn Syrup”</td>
</tr>
<tr>
<td>Description</td>
<td>Label</td>
</tr>
<tr>
<td>-----------------------------------------------------------------------------</td>
<td>------------------------------</td>
</tr>
<tr>
<td>Spices and spice extract other than listed on the “List of the Existing Food Additives” (Notification No. 120 of the Ministry of Health and Welfare of 1996), of which weight is no more than 2% in total ingredients</td>
<td>“Spice” or “Mixed spice”</td>
</tr>
<tr>
<td>Savory herbs and garnishes and their processed products of which weight is no more than 2% in total ingredients</td>
<td>“Herb” or “Mixed herb”</td>
</tr>
<tr>
<td>Fruits penetrated with syrup, of which weight is no more than 10% in total ingredients</td>
<td>“Candied fruit”</td>
</tr>
<tr>
<td>Side dishes in lunch box, of which ingredients are identifiable by their appearance</td>
<td>“Okazu”</td>
</tr>
</tbody>
</table>

d. In the case that organic agricultural products or organic agricultural product processed foods are used as an ingredient, such product may carry the statement to the effect that the ingredient is an organic agricultural product or an organic agricultural product processed foods.

(3) **Net contents**
Net contents of the specified commodities listed under Article 5 of the Government Ordinance for the Measurement Concerning Sale of Specified Commodities shall be indicated under the provisions of the Measurement Law (Law No. 51 of 1992), and those of the other products shall be indicated by weight of contents, volume of contents or number of contents, and the weight of contents shall be mentioned in grams or kilograms, the volume of contents in milliliters or liters, and the number of contents in number, clearly stating the unit used respectively.

(4) **Drained weight**
Drained weight shall be mentioned in grams or kilograms clearly stating the unit used.

(5) **Total quantity of contents**
Total quantity of contents shall be mentioned in grams or kilograms clearly stating the unit used.
(6) **Use-by date or Best-before**

Use-by date or *best-before* shall be indicated as provided below:

a. With regard to a product whose period from manufacture to use-by date or *best-before* does not exceed three months, it shall be mentioned by any of the following samples. However, if it is difficult to print “.” in the case of (b), (c) or (d), “.” may be omitted. In this case, if the month or the date is one digit, its second digit shall be represented by 0.

   (a) Heisei 12, April 1  
   (b) 12.4.1  
   (c) 2000.4.1  
   (d) 00.4.1  

b. With regard to a product whose period from manufacture to use-by date or *best-before* exceeds three months, it shall be mentioned as provided below:

   (i) Heisei 12, April  
   (ii) 12.4  
   (iii) 2000.4  
   (iv) 00.4  

(7) **Instructions for storage**

Instructions for storage shall be declared as “Avoid the direct sunshine and store at the normal temperature”, “Store below 10°C”, etc. according to the properties of the product.

(8) **Place of origin of ingredient**

Place of origin of a main ingredient shall be labeled for processed foods as provided below. The main ingredient is a perishable food which has the largest percent by weight and of which weight is no less than 50% in total ingredients.

a). “Domestically produced” shall be labeled on domestic products, while “country of origin” shall be labeled on imports. The following names of places may be substituted for
labeling as “domestic”:

i) Agricultural products
Name of prefecture or other generally known name of place;

ii) Livestock products
Name of prefecture or other generally known name of its main growing location; and

iii) Marine products
Name of water area where the product has been produced, collected or caught; name of port where the product has been landed; or name of prefecture or other generally known name which the port or main fish farm belongs to.

b). Imported marine products may be labeled with the name of water area in addition to the country of origin.

c). Where the main ingredient has no less than two places of origins, the names of places shall be labeled in the descending order by weight in the total ingredients.

d). Where the main ingredient has no less than three places of origins, the names of no less than two places shall be labeled in the descending order by weight in the total ingredients, and the names of other places may be categorized as “others”.

e). Where there are specific reasons, the roughly identified place shall be labeled in accordance with the provisions of a to d above. In this case, that effect shall be labeled so that consumers are able to recognize the fact.

2. All the matters shall be labeled at a conspicuous place of the container or package according to the attached form. However, if the container or package is packed by wrapping paper or paper box, etc., necessary matters shall be labeled on the wrapping paper or paper box, etc.; the wrapping paper or paper box, etc. shall be made so that the labeling on the container or package can be looked through; or the labeling on the container or package shall not be covered by the wrapping paper or paper box, etc.
3. The place of origin of other ingredients for the products listed in Table 2, and the place of origin of ingredients for other products may be labeled according to the provision of (8) a. to e. In this provision, the term of “main ingredient” is to be turned to the term of “ingredient”.

4. The provision of 2. shall apply to labeling of the origin of ingredient. In this case, the term of “Name of place of origin of main ingredient” in the attached form is to be turned to “Name of place of origin of ingredient”.

3-4 Method of labeling of processed foods for institutional use (Article 4-2)
Manufacturers shall label the items as provided below for processed foods for institutional use on containers, packages, invoices, delivery statements attached to products or specifications. Where processed foods for institutional use are used for ingredients for the processed foods: which are sold to general consumers at the place of manufacture or production; or which are offered for eating or drinking at facilities, those processed foods need not be labeled.
(1) Name;
(2) Names of ingredients; and
(3) Name or trade name and address of manufacturer, etc.

The definition of “processed foods for institutional use subject to labeling” is those used for processed foods under the coverage other than those used for processed foods which are sold to general consumers at the place of manufacture or production; and for drinking or eating at facilities. Manufacturers shall label place of origin of ingredient on containers, packages, invoices, delivery statements or specifications for processed foods for institutional use subject to labeling which contain the main ingredient of the processed foods under the coverage.

3-5 Labeling of Characteristic Ingredients (Article 5)
Cases where a product has a label that ingredients are of certain origins, organic plants, organic livestock products, organic processed foods and other characterizing
ingredients or where a name of a product shows that characterizing ingredients are used, any
of the percent listed below shall be labeled in a close proximity to the mentioned label. If the percent is 100%, labeling of the percent may be omitted:

(1) The percent by weight of the characterizing ingredient in the total ingredients; or
(2) The percent by weight of the characterizing ingredient in the ingredients of the same category.

3-6 Matters Prohibited from Labeling (Article 6)
(1) Any wordings which conflict with those expressed in accordance with the provisions of article 3 or article 4-2;
(2) Name of place which may mislead the place of origin;
(3) Any letters, pictures, photographs or other labeling which may give a wrong impression on the contents; and
(4) Making a cutting mark on the top of the roof-shaped paper package.

Table 1 (Definition of Processed Food)

1. Wheat and Barleys
   Processed barley
2. Flour
   Rice flour, Wheat flour, Cereal flour, Pulse flour, Sweet potato flour, Prepared flour and other flour
3. Starch
   Wheat starch, Cornstarch, Sweet potato starch, White potato starch, Tapioca starch, Sago starch and other starch
4. Processed vegetables
   Canned or bottled vegetables, Processed tomatoes, Processed mushrooms group, Salt storage vegetables (except pickles), Vegetable pickles, Frozen vegetables, Dehydrated vegetables, Vegetables “tsukudani” (Preserved vegetables boiled in soy sauce) and other processed vegetables
5. Processed fruits
   Canned or bottled fruits, Jams, marmalades, fruit butter, Fruit pickles, Dried fruits, Frozen fruits and other processed fruits
6. Teas, coffee and cocoa
Tea, Coffee products and Cocoa products

7. Spices
   Black pepper, White pepper, Red pepper, Cinnamon, Clove, Nutmeg, Saffron, Bay leave, Paprika, All spices, Japanese pepper, Curry powder, Mustard powder, “Wasabi” powder, Ginger and other spices

8. Noodles, bread and similar preparations
   Vermicelli, macaroni and similar preparations and Bread and bun

9. Cereal processed goods
   Alpha cereal, Processed rice, Oat meal, Bread crump powder, Wheat gluten bread, Barley tea and other cereal processed goods

10. “Kashi” (cake and confectioneries)
    Biscuits, Baked cakes, Rice crackers, Fried candies, Japanese cakes, Foreign cakes, Half pastries, Japanese dry confectioneries, Candies, Chocolates, Chewing-gum and bubble gum, Coating sugar confectioneries, Snack confectioneries, Ice confectioneries and other confectioneries

11. Prepared pulses
    Bean jam; Boiled pulses; Soybean curd and fried soy bean curds; “Yuba”; Dehydrofreezed bean curds; “Natto”; “Kinako”, roasted and ground; Peanut products; Roasted beans and prepared beans

12. Sugars
    Sugar, Molasses and sugars

13. Other processed agricultural foods
    “Kon’nyaku” and other processed agricultural foods not covered by items 1 through 12 above

14. Meat, prepared
    Processed meat, Canned or bottled meat, Frozen meat, and other prepared meat

15. Dairy products
    Fluid milk, Processed milk, Milk drinks, Condensed and evaporated milk, Powdered milk, Fermented milk and lactic fermented milk drinks, Butter, Cheese, Ice cream and other dairy products

16. Processed poultry eggs
    Processed chicken eggs and other processed eggs

17. Other processed animal foods
    Honey and other processed animal foods not covered by items 14 through 16 above

18. Fish and shellfish
Unsalted and dried fish and shellfish, Salted and dried fish and shellfish, Cooked and dried fish and shellfish, Salted fish and shellfish, Canned fish and shellfish, Processed frozen prepared aquatic products, Fish paste products and other fish and shellfish, prepared of preserved

19. Seaweeds, prepared or preserved
   Dried tangle, Processed tangle, Dried laver, Processed laver, Dried undaria, “Hoshi-hijiki”, “Hoshi-arame”, Agar-agar and other seaweeds, processed or preserved

20. Other processed seafoods
   Other processed seafoods not covered by items 18 and 19

21. Seasonings and soups
   Salt, “Miso”, Soysauces, Sauces, Vinegar, “Umami” seasonings, Related products of seasoning, Soups and other seasonings and soups

22. Edible oils and fats
   Edible vegetable oils and fats, Edible animal oils and fats and Edible processed oils and fats

23. Prepared foods
   Prepared frozen foods, Chilled foods, Retort-pouched foods, Box lunch, Prepared dishes and other prepared foods

24. Other processed foods
   Yeast and baking powder; Vegetable protein and seasoned vegetable protein; Malt, malt extract and malt syrup; Instant powder juice and other processed foods not covered by items 21 through 23

25. Beverages
   Drinking water, Soft drinks, Ice and other beverages

**Attached Table 2 (Place of origin should be labeled)**

1. Dried mushrooms, vegetables and fruits (excluding those flaked or powdered)
2. Salted mushrooms, vegetables and fruits (excluding agricultural pickles those provided under Article 2 of the Quality Labelling Standard for Agricultural Pickles (Notification No. 1747 of the Ministry of Agriculture, Forestry and Fisheries of 28 December 2000))
3. Boiled or steamed mushrooms, vegetables and pulses, and Beans Jam (excluding those canned, bottled or retort-pouched)
4. Mixed vegetables, Mixed fruits, Other mixtures of vegetables, fruits and...
mushrooms (excluding those mixed without cut)
5. Green tea, and packaged or bottled green tea beverage
6. Rice cake
7. Roasted in shell peanuts, roasted shelled peanuts, fried peanuts and roasted pulses
8. Kon’nyaku
9. Seasoned meat (excluding those processed with heat, or those frozen after processed)
10. Boiled or steamed meat and eggs (excluding those canned, bottled or retort-pouched)
11. Slightly grilled meat
12. Coated meat prepared for deep-frying (excluding those processed with heat, or those frozen after processed)
13. Ground meats and other mixed meats (including ground meats or meats formed in case)
14. Unsalted and dried fish and shellfishes, salted and dried fish and shellfishes, boiled and dried fish and shellfish, tangle, dried laver, roasted laver and other dried seaweeds (excluding those chopped, minced powdered)
15. Salted fish and shellfishes, Salted seaweeds
16. Seasoned fish and shellfishes (excluding those processed with heat, those frozen after processed or those canned, bottled or retort-pouched)
17. Boiled or steamed fish, shellfishes and seaweeds (excluding those canned bottled or retort-pouched)
18. Slightly grilled fish and shellfishes
19. Coated fish and shellfishes prepared for deep-fry (excluding those processed with heat, or those frozen after processed)
20. Mixtures of fresh foods other than those described in 4 and 13 (excluding those mixed without cut)

Note: In addition to the above 20 products, pickles of vegetables, frozen vegetables, “Katsuobushi” and broiled eel should indicate the place of origin on the label. The quality labeling standards for these products stipulate the regulation related to compulsory labeling of place of origin of the main ingredient

Attached Table 3 (Products which is not necessary to label the best-before date)
1. Starch
2. Chewing gum and bubble gum and Ice
3. Sugar
4. Ice creams
5. Salt and “Umami” seasonings
6. Drinking water and Soft drinks [limited to those packed in glass bottles (excluding those sealed with paper caps) or polyethylene containers] and ice

Attached Table 4 (Products whose Quality Labelling Standards are established)

(1) Processed tomatoes,
(2) Dehydrated “shiitake”
(3) Carrot juice and carrot mixed juice
(4) Instant noodles
(5) Raw-type instant noodles
(6) Macaronis
(7) Hams
(8) Pressed hams
(9) Mixed pressed hams
(11) Sausages
(12) Mixed sausages
(13) Bacons
(14) Special-packaged “kamaboko” (steamed fish paste)
(15) Fish hams and fish sausages
(16) Shaved “kezuribushi” (shaved dried fish)
(17) Processed sea urchin
(18) “Uni-aemono” (mixture of sea urchin’s eggs and other marine products)
(19) Dried “wakame” (undaria)
(20) Salted “wakame”
(21) “Miso” (soy bean paste)
(22) Soy sauce
(23) Worcester sauces
(24) Dressing and dressing type seasoning
(25) Vinegar
(26) Stock soup for noodles
(27) Dehydrated soups
(28) Edible vegetable oils and fats
(29) Refined lard, (30) Shortening
(31) Margarines
(32) Chilled hamburg steak
(33) Chilled meatballs
(34) Chilled “gyoza” (potsticker)
(35) Soy milk
(36) Prepared soy milk and soy drinks

Attached Form (regarding to Article 4)

<table>
<thead>
<tr>
<th>Name</th>
<th>Names of ingredients</th>
<th>Name of place of origin of main ingredient</th>
<th>Net contents</th>
<th>Drained weight</th>
<th>Total quantity of contents</th>
<th>Best before</th>
<th>Storage instructions</th>
<th>Country of origin</th>
<th>Manufacturer</th>
</tr>
</thead>
</table>

Source: Quality Labelling Standard for Processed Foods (Notification No. 513 of the Ministry of Agriculture, Forestry and Fisheries of 31 March 31 2000), as of 2004
4 Quality labeling standards for GM food
Refer to

5 Labeling of the Place of Origin

5-1 Mandatory Labeling of the Place of Origin for Perishable Food
(1) Japanese vegetable producers were concerned about the increase of imported vegetables from Asia and the USA, as the import of vegetables has been growing in 1990s. Lower prices of imported vegetables were a threat to certain vegetable producers in Japan.

On the other side, consumers were also concerned about the safety of imported food, in particular imported vegetables from China, where it was reported that prohibited pesticides were used. From time to time residues of pesticides were detected as to be over the limit level of standard. Receiving the growing requests from producers which were supported by consumers, the government introduced in 1996, the obligation of indication of the country of origin for ginger, garlic, Japanese taro, broccoli and Chinese mushroom.

Taking into account of a good performance of the system on the mandatory labeling of the place of origin for certain perishable products as mentioned above, the government extended items to be applied to the indication of the place of origin in 1998. These items were burdock, asparagus, edible podded pea and onion.

(2) Consumers have been much interested in food quality concerning safety, health and taste. Many consumers were concerned about the food safety of imported food, since they had some doubt on how such a large amount of imported food could be efficiently inspected at the border of import. Therefore, they considered that the labeling of the place of origin is one of useful information for the selection of products with consumers. By the establishment of the quality labeling standard for perishable food in 2000, the labeling of the place of origin has been compulsory for all perishable foods in both imported food and domestically produced food. The imported perishable foods shall indicate the name of country of origin and the domestically produced perishable foods shall in principle indicate the name of prefecture where they have been produced.

The method of labeling of the place of origin is as follows, according to the notification
of the quality labeling standard for perishable food in the framework of the JAS Law.

**a. Agricultural Products**

<table>
<thead>
<tr>
<th>Domestic products</th>
<th>Imported products</th>
</tr>
</thead>
<tbody>
<tr>
<td>shall indicate the name of prefecture; may indicate the name of city, town, village or other generally known name of place.</td>
<td>shall indicate the country of origin; may indicate the generally known name of place as its place of origin.</td>
</tr>
</tbody>
</table>

**b. Livestock Products**

<table>
<thead>
<tr>
<th>Domestic products</th>
<th>Imported products</th>
</tr>
</thead>
<tbody>
<tr>
<td>shall indicate that it is domestic; may indicate the name of prefecture, city, town, village or other generally known name of its main raising place.</td>
<td>shall indicate its country of origin.</td>
</tr>
</tbody>
</table>

**c. Marine Products**

<table>
<thead>
<tr>
<th>Domestic products</th>
<th>Imported products</th>
</tr>
</thead>
<tbody>
<tr>
<td>shall indicate the name of water area where the product has been produced or the name of district. - if it is difficult to indicate the name of water area, it may be replaced by the name of the port where the marine product has been landed or the name of the prefecture to which such a port belongs. - may indicate the name of the port where the marine product has been landed or the name of the prefecture to which such a port belongs in addition to the name of the water area.</td>
<td>shall indicate the country of origin; may indicate the name of the water area in addition to its country of origin.</td>
</tr>
</tbody>
</table>

**5-2 Labeling of the Place of Origin for Ingredient(s) of Processed Food**

(1) Regarding processed food, quality labeling standard for processed food of 2001 introduced the obligation of labeling the name of the country of origin for all imported processed food.

However, producers of agricultural products in Japan claimed that certain processed foods, which are produced in Japan but whose ingredients are imported ones, were giving adverse effects against the sound development of agriculture in Japan. In addition, consumers were very concerned about safety and quality of imported agricultural products including imported ingredients for domestically produced
processed foods. Consumers argued that many types of claims concerning the place of origin were observed for processed food, however, there are many cases that might mislead consumers, such as claims which are not clear whether it indicates the place of origin of ingredient(s) or the place of processing.

As the result of the examination, the MAFF decided, in 2002, to establish a compulsory labeling system of the place of origin of ingredients for certain processed foods, instead of introducing the obligation of labeling of origin of ingredients for all processed foods. This obligation was applied to dried prune, "ume" and "rakkyo" pickles in 2001, to other pickles in 2002, to salted mackerel, dried and salted mackerel and "aji", grilled eel and dried and salted “wakame”, “kuwai” in 2002, and to frozen vegetables in 2003. The indication of the place of origin of these products are regulated by 6 quality labeling standards, respectively.

(2) The issue of labeling of the place of origin of ingredients of processed food was further examined in the joint labeling committee of the MAFF and the MHLW during 2003. Based on the result of the joint committee, the quality labeling standard for processed food was revised in April 2004. By the amendment of the standard, the description which could not be clearly understood whether the place of origin of ingredient(s) or the place of manufacturing of the food shall be prohibited. Also 20 categories of processed foods shall indicate the place of origin for their main ingredient. The government adopted the following criteria for processed foods in applying the obligation of labeling of the place of origin for the ingredients.

① The quality of the processed food largely depends on the origin of its ingredient. In another word, the processed level of the processed food is not so high.
② The share in weight of the main ingredient of the total ingredients is more than 50%.

Accordingly, the ingredient of imported food of 20 categories shall indicate the name of the country of origin, and the domestically produced ingredient of 20 categories shall indicate “domestically produced” and may indicate the name of prefecture, city or village.

The obligation of indication of the place of origin of the main ingredient of these
products are stipulated in the Quality Labelling Standard of Processed Food.

The processed foods other than 20 categories as above, which were requested to apply the labeling obligation, are, for example, green tea beverage, fruit juice, vegetable juice, soybean curd, fermented soybeans (“natto”), roll of sea weed, and rice cake, are to be further examined.

(3) The place of origin of the main ingredient whose weight percentage is the most in all ingredients and more than 50% shall be indicated as follows.

a. Domestic products shall indicate that it is domestically produced, and imported products shall indicate the name of the country of origin. However, any domestic product may indicate the following name of place instead of “domestic” statement.
   (a) Agricultural products: the name of a prefecture, city, town, village or other generally known name
   (b) Livestock products: the name of prefecture, city, town, village or other generally known name of its main raising place
   (c) Marine products: the name of a water area where the product has been produced, collected or caught, the name of a port where the product has been landed, or the name of prefecture, city, town, village or other generally known name to which a port or a main fish farm belongs.

b. An imported marine product may indicate the name of water area in addition to the country of origin.

c. In the case that the main ingredient has more than two places of origin, the names of place shall be indicated in descending order of weight percentage in the total ingredients.

d. In the case that the main ingredient has more than three places of origin, the names of more than 2 places shall be indicated in descending order or weight percentage in the total ingredients, and the names of other places may be turned to “Others”.

5-3 Study on the Introduction of the Labeling Obligation of the Origin of the Ingredient in the Green Tea Beverage
In the middle of 2005, tea producers in Japan requested the government to introduce the obligation of labeling the place of origin of the ingredients of green tea beverages, for the reason that the appropriate labeling should be assured in the situation of growing import of green tea from China in recent years.

On receipt of this request and others from consumers, the MAFF started a study on the further extension of processed foods to be applied the mandatory indication of the origin of their ingredient. In April 2006, an interim report was adopted in the joint committee on labeling on food by the MAFF and the MHLW. According to the report, several processed foods which remained not being applied the labeling obligation in the previous examination would be examined, after receiving the public comments. The criteria for the obligation would be the same, in principle, as the previous study. The examination reached to the conclusion in December 2006 that the labeling obligation of the place of origin of the main ingredient would be applied to the green tea beverage and the fried peanuts.

5-4 Fair Trade Commission’s Control of the Indication of the Place of Origin
In addition to the mandatory labeling of the place of origin of foods, the indication of the place of origin for many types of products other than foods has been popular in order to attract the consumers’ interest. The Fair Trade Commission notified in 1973 that presentations which make consumers misunderstand the country of origin of the product is an unfair action to be prohibited under the Act against Unjustifiable Premiums and Misleading Representations.

5-5 Indication of the Place of Origin: One of Important Elements for the Labeling System in Japan
As mentioned above, the indication of the place of origin has been regarded as one of the most important factors to be labeled on foods, although it is originated from protection of domestic products against increased import of the same kinds of products from overseas. The objective of the labeling of the place of origin is not so clear in terms of food safety and quality. However, it is now serving for consumers in selecting products, and is widely accepted in the society. It may be considered as a type of traceability. This wide acceptance in the society could be based on the Japanese traditional culture that the place of origin is one of the important elements to judge persons or things under the limited information available. Accordingly, in 2005, the
MAFF started a study in view of introducing a guideline for labeling of the place of origin of ingredients of dishes to be served in restaurants.

Such a compulsory labeling system of the place of origin in Japan is very peculiar in the world. It seems that there is no such obligation of labeling of the place of origin to be applied to so many products in other countries.

5-6 Regulations of Labeling of the Place of Origin in the EU Countries
The directive concerning labeling of food of EU only states that particulars of the place of origin or provenance on the labeling shall be compulsory, where a failure to give such particulars might mislead consumers to a material degree as to the true origin or provenance (Article 3 of the directive 2000/13/EC of the European parliament and of the council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs).

The Codex standard provides very simple clauses on this matter. The general standard of Codex stipulates that the country of origin of the food shall be declared, if its omission would mislead or deceive consumers. Further discussions were suspended for establishment of standard of the labeling of the place of origin in the framework of Codex.

Note:

Codex General Standard for the Labelling of Prepackaged Foods
(CODEX STAN 1-1985 (Rev. 1-1991))

Mandatory labelling of prepackaged foods
Country of origin
The country of origin of the food shall be declared if its omission would mislead or deceive the consumer.

When a food undergoes processing in a second country which changes its nature, the country in which the processing is performed shall be considered to be the country of origin for the purposes of labelling.
VII Geographical Indications

1 Legal System of Geographical Indications in European Countries and the EU

Since older times, many products, in particular agricultural products have been identified by the names of region where the products are made in European countries, Japan and other countries. The first juridical system of geographical indications was created in 1919 in France. It was the law of *appellation d’origine* which protects the names of regions of the products, when the quality and characteristics of the products are essentially attributed to the natural and human factors of the regions. This system has been formulated in some Latin countries in Europe. In addition, France introduced a system of *Label Agricole* in the *Loi d’Orientation Agricole* of 1960, in view of maintaining traditional or regional high-quality foods against the rationalization of agriculture intensively pursued after the Second World War.

[Definition of Appellation d’Origine]

*Article A de la loi du 6 mai 1919 par la loi 66-482 du 6 juillet 1966*

Constitue une appellation d’origine la denomination d’un pays, d’une region ou d’une localite servant a designer un produit qui en est originaire, et dont la qualite ou les characteres sont dus au milieu geographique, emprenant des facteurs naturels et des facteurs humains.

Cette definition a ete definie par l’Arrangement de Risbonne de 31 octobre 1958.

As these systems have been well elaborated, it appeared that these systems were an effective tool which creates an additional value of products by providing variety of high-quality, regional or traditional foods. In addition, these systems contributed to maintain the economy in regions with unfavorable conditions. In 1992, just before the establishment of the single market of the EC, the EC introduced a legal system for protection of geographical indications and designations of origin.

2. For the purposes of this Regulation:
(a) designation of origin: means the name of a region, a specific place or, in exceptional cases, a country, used to describe an agricultural product or a foodstuff:
- originating in that region, specific place or country, and
- the quality or characteristics of which are essentially or exclusively due to a particular geographical environment with its inherent natural and human factors, and the production, processing and preparation of which take place in the defined geographical area;
(b) geographical indication: means the name of a region, a specific place or, in exceptional cases, a country, used to describe an agricultural product or a foodstuff:
- originating in that region, specific place or country, and
- which possesses a specific quality, reputation or other characteristics attributable to that geographical origin and the production and/or processing and/or preparation of which take place in the defined geographical area.

2 Establishment of Legal System for Geographical Indications in Japan

The Agriculture Basic Law was promulgated in Japan in 1961, following careful examination on Loi d’Orientation Agricole in France of 1960. Basic policies of the Japanese law were composed of a policy for increase of farmers’ income through the intensification of agriculture and supported prices, and a policy for the expansion of products whose consumption was expected to increase, such as vegetables and livestock products (Selected Expansion Policy). However, the food quality policy was not taken in the Agriculture Basic Law.

Consumers’ requirements on food have been gradually shifted from quantity to quality as the income of households has grown, along with the development of the economy. Consumers began to place much importance on safety, health and quality of food. Regarding the food quality, consumers have been interested in organic products, regional special food and traditional food which are characterized by their production processes.

To meet these requirements of consumers, a new category of JAS standards, which is called as Specified JAS, was introduced by the amendment of the JAS Law in 1993. The quality or characteristics of the Specified JAS products are defined by the process or method of production. The organic product is one of Specified JAS. However, the legal system for geographical indications was not created in Japan.

In 1994, the TRIPS Agreement was established under the WTO, which provides the protection of geographical indications as one of the intellectual property rights. In December 1994, a legal arrangement was made for the TRIPS agreement by the notification of the National Tax Agency.
concerning wine and spirits. This notification (Notification of the National Tax Agency No. 4, December 28 1994) prohibits Japanese producers and distributors to use geographical indications of wine and spirits which are prohibited by member countries’ laws to be used for other products than those that are originated in the regions. The notification also designated 3 Japanese spirits (Iki Syochu, Kuma Syochu and Ryukyu Syochu) as geographical indications to be protected.

Note:

*Syochu*: Distilled alcohol made of fermented rice, sweet potato and other grains  
*Iki*: one of the regions of Nagasaki Prefecture,  
*Kuma*: one of the regions of Kumamoto Prefecture  
*Ryukyu*: is the ancient name of Okinawa

As discussions on the geographical indications have been intensified in the world, the government of Japan felt that new legal system would be needed. In 2004, the MAFF tried to establish a special law which is similar to the EU’s regulation of geographical indications. On the other hand, the Ministry of Economy, Trade and Industry claimed that the new system should be arranged under the Trademark Law. After discussions between 2 ministries, the government decided that the new system for the geographical indications should be arranged by the amendment of the Trademark Law. Then, the amendment of the Trademark Law was passed in the parliament in 2005 and was enacted in early 2006.

3 Regional Collective Mark under the Amended Trademark Law

The existing Trademark Law prohibited in principle the trademark with a name of a region. However, the new system allows to use geographical indications for products whose reputation is recognized in only a few prefectures. This arrangement is intended to promote efforts taken in the region for formulate nation-wide reputation of the products. These efforts would contribute to the revitalization of the regional economy. This new system is called “Regional collective mark” which allows only cooperatives and similar legal persons to apply for a mark.
The regional collective mark does not certify the quality or characteristics of products, while it identifies the products.

The outline of the regional collective mark is as follows.

a) Business cooperatives and agricultural cooperatives or corresponding foreign juridical persons may obtain a registered regional collective mark, when the mark is to be used by members of the cooperative, and is widely recognized by people as an indication referred to the good or service provided by the members.

The modality of indication of the collective regional mark is composed of letters indicating the name of the region and the name of good or service provided by the members (Article 7 of the Trademark Law).

b) The person who has used a mark which is the same as or similar to the regional collective mark, before the application to the registration of the regional collective mark is made, has a right to continue to use the mark. The cooperative using the regional collective mark may request this person to make an arrangement in view of avoiding confusion of indications (Article 32-2).

c) The right of the regional collective mark is not transferable (negotiable) (Article 24-2).

d) The regional collective mark is cancelled through a trial, when the mark is not any more recognized by people as the indication referred to good or service provided by members of the cooperative, or the mark has lost the relation with the region (Article 53).
Source:

- Trademark Law of 1959
- Notification by the National Tax Agency No. 4, 28 December 1994
- Agriculture Basic Law of 1961
- Loi du 6 mai 1919 relative à la protection des appellations d’origine
- Reconnaissance des Appellation d’Origine Contrôlée
  - Décret-loi du 30 juillet 1935
- Loi d’Orientation Agricole 1999, 1960
- Agreement on Trade-related Aspects of Intellectual Property Rights of 1994
VIII System for the Social Quality of Food

1 Formation of the GAP Concept
In recent years, consumers have been more conscious about food safety and food quality. In terms of food quality, consumers’ interest has been shifted from the negative quality to the positive quality. In other word, consumers are more interested in the food qualities related to the conservation of environment, the animal welfare, biodiversity, agricultural workers’ welfare, which could be called “food social quality”. In the course of the development of the integrated agriculture, for the sustainable agriculture, the notion of the GAP (good agricultural practices) has been formulated. In recent years, not only the public sector but also the private sector, including NGOs, has been involved in elaborating the GAP. This evolution is characterized by the active participation of large retailers, food processing companies and NGOs in Europe.

FAO outlined the definition of the GAP approach in its conference held in 2003 as follows.

“GAP approach applies recommendations and available knowledge to addressing environmental, economic and social sustainability for on-farm production and post-production processes resulting in safe and healthy food and non-food agricultural products. A GAP approach can provide a means for farmers to respond to existing standards, norms, and certification efforts. It offers management options for sustainable agriculture practice, taking into account universal criteria associated with environmental, economic and social dimensions.”

2 Various Types of GAP and Evolution of GAP in Europe
In the early stage, the GAP was a concept referring to codes of practices in the international standards. The Codex guideline of the use of pesticides aiming at minimizing and preventing the risk associated with the use of pesticides was one of the GAPs.

In 1990s, when the contamination of dioxin in Europe as well as the food poisoning by O-157 and by salmonella in the USA broke out, the GAP approach has been formulated as one of the approaches for ensuring food safety by introducing the management of the
production process, like the HACCP to be applied to the food processing industry.

In the United-States, the FDA and the USDA established a GAP in 1998 to reduce microbial risks to fresh fruits and vegetables at the farm level which is applied on the voluntary basis, and are now promoting the dissemination of the GAP in collaboration with several states and an university. In the Great Britain, the DEFRA (Department for Environment, Food and Rural Affairs) created a GAP guidelines to prevent the contamination by the agricultural practices to the land, the water and the air.

In later years, to meet the consumers’ various demands for food quality, such as qualities related to the protection of environment, animal welfare and biological diversity, numerous GAP approaches, including voluntary standards or certifications have been sought by the private sector, the civil society and the governments.

Under the EU’s reformed agricultural policy, including the allocation of agricultural subsidies, which was based on the Agenda 2000 emphasizing the protection of environment and the sustainable agriculture, the EU Commission requested its member countries to establish the clear GAP standards (Good farming practices in EU’s terminology). The EU allocates the subsidies to agricultural activities beyond the minimum level of activities based on the GAP in each member country.

In recent years, the GAPs have been elaborated in the EU countries in order to achieve the sustainable agriculture for ensuring not only the food security but also the protection of environment, high quality of food, animal welfare and workers’ welfare. One of these GAPs is the integrated farming or the agriculture raisonné which originated in 1906 in Switzerland. In 2002 in France, it was legalized as “the agriculture raisonné (integrated agriculture)”, in which the certification system is incorporated. In Switzerland and in Austria, the integrated farming is also a legal GAP.

However, in recent years, the GAPs have been further developed by the initiative of the private sector and the civil societies, in particular, in countries which have not developed the official certification system of food quality. Non-governmental organizations such as the EurepGAP, the SAI (Sustainable Agriculture Initiative), the EISA (European Initiative for Sustainable Development of Agriculture), COLEACP (Europe-Africa-Caribbean-Pacific Liaison Committee), the Fair-Trade and the Greener Field are the major promoters which are actively involved in supporting the
sustainable agriculture though the GAP approach.

3 EurepGAP (Global GAP)

The EurepGAP was created in 1997 as an initiative by large retailers. British retailers in collaboration with supermarkets in continental Europe were the driving forces. Facing the growing concerns of consumers on food safety after the incidence of BSE and their increasing interest to other qualities-related to the protection of environment, animal welfare, the retailers considered that a system for restoring the consumers’ confidence on food should be provided by themselves by a common certification standard. Except the organic farming, the official quality certification system has not been well established in Anglo-Saxon countries in Europe. In this context, they started to work on harmonized standards using the new GAP concept which has been developed in Europe.

The EurepGAP is a private sector body composed of members of retailers and producers. Its main activity is to certify the products which are produced in line with the standards set by the EurepGAP, which are primarily designed to maintain consumers’ confidence in securing food safety and in taking care of the environmental protection, the occupational health, safety, welfare and animal welfare.

Note: The title of EurepGAP has been changed to Global GAP in 2007

Its activities are focused on fruits and vegetables, flowers and ornamentals and green coffee by establishing the corresponding committees. Each committee defines the standards for the productions with consultation between retailers and producers, and the producers to produce their products based on the standards under the contract will be certified by a third party certification body. The EurepGAP is open to foreign countries other than European countries, and adopts the benchmarking method which recognizes the equivalence of local GAPs to the standards of the EurepGAP. In recent years, exporting countries have become more involved in the EurepGAP, since the large European retailers tend to prefer to sell imported products certified under the EurepGAP.

China started the process to develop ChinaGAP on the basis of EurepGAP, and signed a memorandum of understanding with the EurepGAP in 2006. This agreement will initiate the formal benchmarking procedure and cover the rules on the surveillance of ChinaGAP after achieving full recognition. In April 2006, the Japan Good Agricultural
Initiative (JGAI) also announced the start of its task towards global harmonization of the GAP. In this relation, the chairman of the JGAI and the Secretary of the EurepGAP signed an agreement, which lays the foundation of the benchmarking process for the JGAP to the EurepGAP.

Since the creation of the EurepGAP, its activities have been rapidly expanding. As for the committee of fruits and vegetables, 27 European retailers and a Japanese one sit on it. However, any French and Italian retailer does not participate in the EurepGAP. Approximately 30,000 farmers and groups of farmers participate in the EurepGAP from over 60 countries including Japan. The area of agricultural lands covered by these members accounts to 3 million ha as of 2005. In the UK and the Netherlands, almost 100% of fruits and vegetables in the market are covered by the EurepGAP members.

<table>
<thead>
<tr>
<th>Retailers</th>
<th>Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aeon Co., Ltd.</td>
<td>Japan</td>
</tr>
<tr>
<td>Ahold</td>
<td>Netherlands</td>
</tr>
<tr>
<td>Albert Heijn</td>
<td>Netherlands</td>
</tr>
<tr>
<td>ASDA Group Plc.</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>CBL</td>
<td>Netherlands</td>
</tr>
<tr>
<td>Coop Switzerland</td>
<td>Switzerland</td>
</tr>
<tr>
<td>Coop Norden</td>
<td>Norway</td>
</tr>
<tr>
<td>Delhaize</td>
<td>Belgium</td>
</tr>
<tr>
<td>DRC / Belgium Retail Association</td>
<td>Belgium</td>
</tr>
<tr>
<td>EDEKA Fruchtontor</td>
<td>Germany</td>
</tr>
<tr>
<td>Eroski</td>
<td>Spain</td>
</tr>
<tr>
<td>Globus SB Warenhaus Holding</td>
<td>Germany</td>
</tr>
<tr>
<td>Kesko</td>
<td>Finland</td>
</tr>
<tr>
<td>Laurus</td>
<td>Netherlands</td>
</tr>
<tr>
<td>Lidl Stiftung &amp; Co. KG</td>
<td>Germany</td>
</tr>
<tr>
<td>Marks and Spencers</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>McDonald ´s Europe</td>
<td>Germany</td>
</tr>
<tr>
<td>Metro Group</td>
<td>Germany</td>
</tr>
<tr>
<td>Migros</td>
<td>Switzerland</td>
</tr>
<tr>
<td>Musgraves Supervalu Centra</td>
<td>Ireland</td>
</tr>
</tbody>
</table>
4 SAI (Sustainable Agriculture Initiative)

The SAI Platform is an international organization created by the food industry to actively support the development of sustainable agriculture involving various stakeholders of the chain of food industry. The SAI Platform supports sustainable agricultural practices based on the principles for providing the base for ensured food safety, for securing adequate food supply, for protecting and improving the natural environment and resources and for supporting economically viable and responsible farming systems.

Founding members are Danone, Nestle and Unilever. Other 18 food industry companies including Campina, Dole, Coca Cola, Kraft, McDonald's are members of the SAI as of July 2006.

The SAI forms several working groups on cereals, coffee, dairy, fruits, potatoes and vegetables, and their current activities are focused on the exchange of views of stakeholders in the chain of food industry, the establishment of principles and practices based on the exchange of views and the execution of pilot projects, and the dissemination of the sustainable agriculture.

5 Agriculture Raisonnée/ Integrated Agriculture

The OILB (Organisation Internationale de Lutte Biologique), founded in 1956 in
Switzerland, released the first message of «Towards Integrated Agricultural Production, by Integrated Approach» in 1977. The integrated production gave preference to quality, and aimed at better management of inputs to promote protection of the environment, while promoting farmer's job. It answered both fundamental requirements for the viability of agriculture, and ecology and economy.

The FARRE (Forum de l'Agriculture Raisonnée Respectueuse de l'Environnement), created in 1993 in France, announced for the first time «agriculture raisonnée», based on the notion of the integrated production of the OILB. The FARRE has a vocation to introduce the advantages of the agriculture raisonnée/ integrated agriculture and to contribute to its realization.

5-1 Agriculture Raisonnée/ Integrated Agriculture in France
In France, the qualification system of the integrated agriculture was established by decree in 2002 (Décret n° 2002-631 of April 25th, 2002). According to the decree, the structure of the system is as follows.

(1) Objective
The agriculture raisonnée/ integrated agriculture corresponds to the total steps of management of working which aim at reinforcing positive impacts of agricultural practices on environment and reducing its adverse effets. In addition, the requirements on food security for agricultural products, reasonable modes of production can make the management of health risks easier and contribute to the improvement of animal welfare. It also allows to contribute to the improvement of working conditions.

(2) Referenciel
The government will establish the frame of reference of the agriculture raisonnée/ integrated agriculture which consists of national requirements applicable to the whole territory and regional requirements in defined geographical zones. The requirements of frame of reference notably concern:
- management of agricultural inputs, effluents and waste;
- justified usage of pesticides and veterinary drugs;
- equilibrium of the fertility of cultivation;
- practices of the cultivation allowing the preservation of soil and restricting risks of pollutions;
- participation in a thrifty and balanced management of water resources;
- taking into account of regulations on food safety and hygiene;
- taking into account of the needs of animals regarding feed and animal welfare; and
- contribution to the protection of landscapes and biological diversity.

(3) Qualification
The qualification request of the farm is addressed by the leader of the farm to a certification organization agreed by the minister of agriculture (Article 5). Qualifications are allocated, for a duration of five years, by the decision of the certification organization.

(4) Use of Name and Labeling
By the decree of 2004, presentation of “agriculture raisonnée/ integrated agriculture” on labels of products, advertisings or commercial documents can be used only by the farms qualified of agriculture raisonnée/ integrated agriculture. And in the chain of the distribution of the products, every operator concerned must confirm if they are the products of agriculture raisonnée /integrated agriculture and set up a system assuring the traceability of those products, notably including an accountancy material allowing to control entries and exits of products.

6 EISA (European Initiative for Sustainable Development of Agriculture)

The EISA is an alliance of national organizations in seven European countries established in 2001 with the common aim of developing and promoting sustainable farming systems, which is an essential element of sustainable development. Seven countries are France, Germany, Italy, Luxembourg, Sweden, United Kingdom, Austria and Hungary.

The EISA established the common codex in line with “the EISA Charter – Integrated farming system – the basis for sustainable agriculture”. The principles of the common codex are constituted for producing sufficient high-quality food, meeting the demands of society, maintaining a viable farming business, caring for the environment, and sustaining natural resources.

The EISA members are strongly committed to disseminate the common codex for the sustainable agriculture. The EISA continues to work in partnership with all stakeholders to achieve the goal of sustainable agriculture through promotion and further
development of integrated farming.

Note: Main members of the EISA
FNL in Germany, LEAF in Great Britain, Odling i Balans in Sweden, FARRE in France, and FILL in Luxembourg

7 GAP in Japan

7-1 GAP Elaborated by the Government
Just after the establishment of the Food Safety Fundamental Law, people concerned were preoccupied with traceability. However, the introduction of the GAP approach has been considered to be necessary as one of the measures for food security at the stage of production in the chain of food industry.

In the master plan for food, agriculture and rural communities adopted in 2003, it was declared that the government shall establish a prototype of GAP by 2005, which would encourage farmers and farmers’ groups to formulate GAPs suitable to the conditions and characteristics of their regions and to promote their voluntary involvement in the risk management for food safety.

Following the master plan, the prototypes of GAP have been established for vegetables, fruits, cereals and mushrooms by the end of 2005. Then pamphlets and manuals for the dissemination were published in the same year. In addition, the government provided subsidies to pilot projects of GAP in the framework of subsidies for food safety and food reliability. The number of regions adopting pilot projects has increased year by year. In 2007 the number reached 113.

Examples of GAP pilot project sites which receive the subsidies from the government  

<table>
<thead>
<tr>
<th>No.</th>
<th>Sites</th>
<th>Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>JA Towada City</td>
<td>Taro, garlic, leek</td>
</tr>
<tr>
<td>2</td>
<td>Iwate prefecture (2 pilot sites)</td>
<td>Spinach</td>
</tr>
<tr>
<td>3</td>
<td>JA Ashikaga</td>
<td>Tomato</td>
</tr>
<tr>
<td>5</td>
<td>Totigi agricultural cooperative</td>
<td>Spinach</td>
</tr>
</tbody>
</table>
6. JA sunflower and strawberry committee (pilot site in Toyokawa)

7. Kyoto city

8. Kaisi town

9. JA Unnan

10. JA Kagawa strawberry committee in Miki town (pilot site)

11. JA fukuren

12. JA Simabara unzen

13. Production cooperative in the south Nagasaki

14. JA Oita mitsuba committee (pilot site)

15. Oita Beppinnegi committee (pilot site)

The target of the GAP in Japan is limited to securing food safety at the farm level in the chain of food industry. Stakeholders of the distribution do not participate in the system. Either the certification is not linked to the GAP. Therefore, the GAP elaborated by the government of Japan is a simple guideline without an enforcement mechanism. However, the GAP would be appreciated by retailers, food processing industry and food service industry from the point of addressing the newly adopted positive list system of pesticide residue, since the good practices and the registration of the history of using pesticides provided by the GAP would facilitate to determine the pesticides to be checked in the distribution and processing process, and to exactly identify the products to be withdrawn from the market in the case of an accident related to pesticides. Thus, the GAP approach would be widely accepted when a large part of stakeholders in the chain of food industry after harvest tend to request producers to supply their products under the GAP approach, aiming at alleviating their food safety risks.

7-2 Japan Good Agricultural Initiative

Besides the GAP, which is promoted at the government initiative, the Japan Good Agricultural Initiative (JGAI) was created at the initiative of the private sector in Japan.

The objective of the JGAI is to encourage safe and sustainable agriculture in Japan by establishing and disseminating the Japan Good Agricultural Practices (JGAP), taking into account of the GAP elaborated by the government and to harmonize the GAP
standards in Japan in collaboration with the EurepGAP. In April 2006, the second manual for the management of farm referring to farm management, water control, use of pesticides and fertilizers, harvest, post harvest, safety and welfare of workers, and waste management and recycling was issued.

In April 2006, the JGAI announced the start of its task towards global harmonization of GAP. In this relation, the chairman of the JGAI and the Secretary of the EurepGAP signed an agreement, which provides the foundation for the benchmarking process of JGAP to EurepGAP.

At the moment, the activities of the JGAI remains in a very preliminary stage. The JGAI is composed of 57 farmers, 19 farmers’ group, 14 associate members of private companies (as of March 2006).

However, AEON, one of the top three retailers in Japan, has joined the JGAI and the EurepGAP as a retail member in 2006. Since 2002, AEON has been operating its own company standard which is based on the GAP approach. AEON intends not only to shift their demand to include EurepGAP certified products, but also to participate actively in the EurepGAP committees to exchange their knowledge for standard.

8 Observation
The GAP including the EurepGAP, in which stakeholders in the distribution or processing participate, is one of the methods for performing social responsibility of the private sector in assisting sustainable agriculture and in providing safety and quality food. It would also contribute to narrow the gap between agriculture and consumption. In addition, the safety of imported food could be secured to some extent through the GAP system. Some additional costs for the protection of environment, animal welfare and other social objectives related to food could be born by the chain of food industry in the framework of the GAP system, not relying on the government expenditures.

However, a product of the GAP is regarded at the moment as a product which is produced under the producer’s minimum obligation, like HACCP or hygiene standards, rather than a value-added product. In this regard, the logo-mark of the EurepGAP is prohibited to be labeled on products in the retail stage.

Consumers could not in principle distinguish the products under the GAP approach
from ordinary products. Therefore, it is very difficult to expect higher prices. In this situation, an important problem of who should bear the additional costs remains in applying the GAP standards. Retailers, in particular European retailers and also Japanese retailers with a large share in the market, who have the strong bargaining power, are in a position of transferring the additional costs to producers, and possibly to exporters or producers in foreign countries.

To address the situation of the constant increase of various food quality assurance and certification schemes involving governments, the private sector and the civil society as mentioned above, the European Parliament has requested the European Commission to analyze the opportunity to implement a community legal framework for the protection of such schemes in the chain of food industry.
Source

- Summary Analysis of Relevant Codes, Guidelines, and Standards Related to Good Agricultural Practices (GAPs), FAO, 5 November 2003
- Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, FDA, October 26, 1998
- Codes of Good Agricultural Practices for air, soil and water, Defra (Department for Environment, Food and Rural Affairs in UK).
- A report for the European Environmental Bureau, G. van der Bijl Centre for Agriculture and Environment Utrecht, October 1999
- Common Codex for Integrated Farming, EISA
- Décret n° 2004-293 du 26 mars 2004 relatif aux conditions d'utilisation du qualificatif « agriculture raisonnée »
- Décret n° 2002-631 du 25 avril 2002 relatif à la qualification des exploitations agricoles au titre de l'agriculture raisonnée
- Rapport au Ministère de l’Agriculture et de la Pêche “L’agriculture Raisonnée” par Guy Pailotin
- Rapport de INRA juin 2001, sur Aide à la définition d’un référentiel de l’agriculture raisonnée et étude comparée des politiques et des pratiques des états membres de l’union européenne relatives a l’agriculture raisonnée
- Arrêté du 30 avril 2002 relatif au référentiel de l’agriculture raisonnée
ANNEXE I

The Food Safety Basic Law
(Tentative Translation by the Food Safety Commission)
Law No. 48, May 23, 2003/12/15
Last Amendment: No. 74. June 11, 2003

Chapter I General Provisions

(Purpose)
Article 1
In consideration of the vital importance of precise responses to the development of science and technology, and to the progress of internationalization and other changes in the environment surrounding Japan’s dietary habits, the purpose of this Law is to comprehensively promote policies to ensure food safety by establishing basic principles, by clarifying the responsibilities of the state, local governments, and food-related business operators and the roles of consumers, and establishing a basic direction for policy formulation, in order to ensure food safety.

(Definition)
Article 2
“Food” as used in this Law shall mean all food and drink (excluding drugs and quasi-drugs provided by the Pharmaceutical Affairs Law (Law No. 145 of 1960)).

(Basic recognition in taking measures for ensuring food safety)
Article 3
Food safety shall be ensured by taking the necessary measures based on the simple recognition that the protection of the health of our citizens is a top priority.

(Appropriate measures at each stage of the food supply process)
Article 4
Food safety may be affected by every element in a series of internal and external food supply processes, from the production of agricultural, forestry, and fishery products to food sales (hereinafter referred to as “food supply process”); it thus shall be ensured by taking the necessary measures appropriately at each stage of
the food supply process.

**Prevention of adverse effects on the health of citizens**

**Article 5**

Food safety shall be ensured by taking the necessary measures on the basis of scientific knowledge and in sufficient consideration of international trends and the opinions of citizens with respect to ensuring food safety, for the purpose of preventing adverse effects on the health of citizens due caused by food.

**Responsibilities of the state**

**Article 6**

The state shall be responsible for comprehensively formulating and implementing policies to ensure food safety on the code of basic principles for ensuring food safety, provided in the preceding three articles (hereinafter referred to as the “basic principles”).

**Responsibilities of the local governments**

**Article 7**

Local governments shall be responsible for formulating and implementing policies to ensure food safety that corresponds to the natural, economic, and social conditions of the area under their jurisdiction, on the code of the basic principles and on the basis of an appropriate sharing of roles with the state.

**Responsibility of food-related business operators**

**Article 8**

Business operators that produce, import, sell, or conduct other business for fertilizers, agricultural chemicals, feed, feed additives, veterinary medicines and other production materials for agriculture, forestry, or fishery that may have an effect on food safety, food (including agricultural, forestry, and fishery products used as raw materials or materials), additives (those provided in Article 2, paragraph 2 of the Food Sanitation Law (Law No. 233 of 1947)), apparatuses (those provided in Article 2, paragraph 4 of the said Law) or containers and packages (those provided in Article 2, paragraph 5 of the said Law) (hereinafter referred to as “food-related business operators”) shall be responsible for appropriately taking the necessary measures to ensure food safety at each stage of the food supply process. This will be done according to the code of the basic principles and on the basis of the recognition that they bear the primary
responsibility for ensuring food safety when conducting their business activities.
2. In addition to the provisions of the preceding paragraph, food-related business operators shall, in conducting their business activities, make efforts to provide accurate and appropriate information concerning food and other articles related to their own business activities on the code of the basic principles.
3. In addition to the provisions of the preceding two paragraphs, food-related business operators shall be responsible for cooperating in policies that are implemented by the state or the local governments, on the code of the basic principles, to ensure food safety.

(Roles of consumers)

Article 9
Consumers shall play an active role in ensuring food safety by endeavoring to improve their own knowledge and understanding of food safety and by making efforts to express their opinions about policies to ensure food safety.

(Legislative measures, etc.)

Article 10
The government shall take legislative or financial measures and other necessary measures to implement policies to ensure food safety.

Chapter II Basic Directions for Policy Formulation

(Implementation of assessment of the effect of food on health)

Article 11
In formulating policies to ensure food safety, assessment (hereinafter referred to as the “assessment of the effect of food on health) shall be made for each policy on the effects that potentially harmful biological, chemical, or physical agents in food or the condition of food have on human health, through the ingestion of the food, provided that this shall not apply to the following cases:
(1) where the assessment of the effect of food on health is explicitly unnecessary in consideration of the contents of the measure;
(2) where the contents and degree of adverse effects on human health are clear;
(3) where there is no time to conduct an assessment of the effects of food on health in advance in cases where the measure is urgently necessary to prevent or control an adverse effect on human health.
2. In cases as cited in (3) of the preceding paragraph, the assessment of the effect of
food on health shall be conducted subsequently and without delay.
3. The assessment of the effect of food on health provided in the preceding two paragraphs shall be conducted in an objective, neutral, and fair manner on the basis of the state-of-the-art scientific knowledge of the time.

(Formulation of policies on the basis of the results of the assessment of the effect of food on health in consideration of the conditions of nationals’ dietary habits and other circumstances)

Article 12
In formulating policies to ensure food safety, it shall be conducted for the purpose of preventing and restraining the adverse effect of food ingestion on human health, in consideration of the dietary habits of citizens and other circumstances, and on the basis of the results of the assessment of effect of food on health if conducted in accordance with the provisions of paragraph 1 or 2 of the preceding article.

(Promotion of exchanges of information and opinions)

Article 13
In formulating policies to ensure food safety, necessary measures for promoting the mutual exchange of information and opinions among persons or parties concerned, such as provision of information concerning the policies and the granting of opportunities to comment on those policies, shall be taken to reflect public opinion in the formulation of the policies and to ensure the transparency and fairness of the process.

(Establishment of a system to cope with emergency and other situations)

Article 14
In formulating policies to ensure food safety, necessary measures, such as establishment of a system to cope with or prevent emergency situations that cause or are liable to cause serious damage to human health by food ingestion, shall be taken to prevent such damage.

(Close and mutual cooperation among related administrative bodies)

Article 15
In formulating policies to ensure food safety, close and mutual cooperation among related administrative bodies shall be made to create the necessary measures for ensuring food safety to be appropriately taken at each stage of the food supply process.
(Establishment of research and other systems)
Article 16
In formulating policies to ensure food safety, necessary measures, such as establishment of research systems, promotion of research and development, dissemination of results thereof and training of researchers, shall be taken in consideration that efforts to improve scientific knowledge are important for ensuring food safety.

(Collection, arrangement, and utilization of internal and external information)
Article 17
In formulating policies to ensure food safety, necessary measures such as the collection, arrangement, and utilization of internal and external information about ensuring food safety, shall be taken to appropriately and effectively implement the necessary measures for ensuring food safety in response to changes in the environment surrounding Japanese dietary habits.

(Ensuring appropriate labeling)
Article 18
In formulating policies to ensure food safety, necessary measures for accurately conveying the information on food, such as ensuring the appropriate operation of a food labeling system, shall be taken in consideration that food labeling plays an important role in ensuring food safety.

(Education and learning regarding ensuring food safety)
Article 19
In formulating policies to ensure food safety, necessary measures for improving knowledge and understanding of ensuring food safety among citizens shall be taken by promoting education and learning and improving public relations activities on ensuring food safety.

(Consideration for effects on the environment)
Article 20
In formulating policies to ensure food safety, the effects of policies on the environment shall be considered.

(Determination and publication of Basic Matters concerning implementation of
Article 21
The government shall determine basic matters concerning implementation of measures (hereinafter referred to as “Basic Matters”) that are to be taken in accordance with the provisions of Articles 11 to 20. 2. The Prime Minister shall formulate a draft of Basic Matters after hearing the opinions of the Food Safety Commission and ask the Cabinet for its decision. 3. The Prime Minister shall promulgate the Basic Matters without delay once the Cabinet has made its decision in accordance with the provision of the preceding paragraph. 4. The provisions of the preceding two paragraphs shall apply mutatis mutandis to the changes of the Basic Matters.

Chapter III  Food Safety Commission

(Establishment)
Article 22
The Food Safety Commission (hereinafter referred to as the “Commission”) shall be established in the Cabinet Office.

(Office duties under the jurisdiction of the Commission)
Article 23
The Commission shall take charge of the following office duties:
(1) to offer opinions to the Prime Minister in accordance with the provisions of Article 21, paragraph 2;
(2) to conduct an assessment of the effects of food on health in accordance with the provisions of the following article or at its direction;
(3) to make recommendations to related ministers through the Prime Minister about policies to be implemented for ensuring food safety on the basis of the results of the assessment of the effect of food on health, which was conducted in accordance with the provisions of the preceding item;
(4) to monitor the implementation conditions of policies that are implemented on the basis of the results of the assessment of the effect of food on health, which was conducted in accordance with the provisions of item (2), and to make recommendations to related ministers through the Prime Minister if necessary;
(5) to examine and deliberate on important matters regarding policies to be implemented for ensuring food safety, and to give opinions to the heads of related
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administrative bodies if necessary;
(6) to conduct scientific research and study necessary to perform office duties cited in items (2) to (5);
(7) to plan and implement the mutual exchange of information and opinions among persons or parties concerned with respect of office duties cited in items (2) to (6); and
(8) to coordinate office duties conducted by related administrative bodies regarding the mutual exchange of information and opinions among persons or parties concerned with respect to ensuring food safety.

2. When the Commission conducts the assessment of the effect of food on health in accordance with the provisions of (2) of the preceding paragraph, it shall notify related ministers of the results of the assessment without delay.

3. When the Commission has given notification in accordance with the provisions of the preceding paragraph or made a recommendation in accordance with the provisions of (3) or (4) of paragraph 1, it shall publish the contents of the notification or the recommendation without delay.

4. Related ministers shall report to the Commission on policies that they have implemented on the basis of a recommendation in accordance with the provisions of (3) or (4) of paragraph 1.

(Hearing of the Commission’s opinions)
Article 24

(Request for submission of materials, etc.)
Article 25

(Entrustment of investigation)
Article 26

(Request in an emergency)
Article 27

The Commission may request that the research institutes of related national administrative bodies conduct an investigation, analysis, or examination necessary for the assessment of the effect of food on health if it is recognized to be necessary for coping with emergency situations that cause or are liable to cause serious damage concerning ensuring food safety.

2. If the research institutes of related national administrative bodies receive a request
from the Commission in accordance with the provisions of the preceding paragraph, they shall promptly implement the requested research, analysis, or examination.

3. The Commission may request that related ministers make a demand in accordance with the provisions of Article 12, paragraph 1 of the Incorporated Administrative Agency, National Institute of Health and Nutrition Law (Law No. 180 of 1999) or a request in accordance with the provisions of Article 12, paragraph 1 of the Incorporated Administrative Agency, Center for Food Quality, Labeling and Consumer Services Law (Law No. 183 of 1999), Article 19, Paragraph 1 of the Incorporated Administrative Agency, National Agriculture and Bio-oriented Research Organization Law (Law No. 192 of 1999), Article 12, Paragraph 1 of the Incorporated Administrative Agency, National Institute for Agro-Environmental Sciences Law (Law No. 194 of 1999), Article 12, Paragraph 1 of the Incorporated Administrative Agency, National Food Research Institute Law (Law No. 196 of 1999), or Article 14, paragraph 1 of the Incorporated Administrative Agency, Fisheries Research Agency Law (Law No. 199 of 1999), if it is recognized to be necessary for coping with emergency situations that cause or are liable to cause serious damage to the ensuring of food safety.

(Organization)
Article 28

(Appointment of Commission Members)
Article 29

(Term of the Commission Member)
Article 30

(Dismissal of the Commission Member)
Article 31

(Service of the Commission Member)
Article 32

(Allowance of the Commission Member)
Article 33

(Chairperson)
Article 34

(Meeting)
Article 35

(Expert Commission Member)
Article 36

(Secretariat)
Article 37

(Delegation to Cabinet Order)
Article 38

Chapter IV/Additional Clauses
ANNEXE I
List of Japanese words related to food safety and food quality
with corresponding English words
食品の安全と品質に関する日本語の用語とそれに対応する英語の用語

<table>
<thead>
<tr>
<th>Japanese Term</th>
<th>English Term</th>
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<tbody>
<tr>
<td>BSE</td>
<td>Bovine spongiform encephalopathy</td>
</tr>
<tr>
<td>BSE検査</td>
<td>BSE inspection</td>
</tr>
<tr>
<td>GMO</td>
<td>Genetically modified organism</td>
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<tr>
<td>HACCP承認</td>
<td>Approval of HACCP</td>
</tr>
<tr>
<td>JAS規格</td>
<td>JAS standard</td>
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<tr>
<td>病原性微生物</td>
<td>Pathogenic microorganisms</td>
</tr>
<tr>
<td>預防措置</td>
<td>Preventive measures</td>
</tr>
<tr>
<td>簡易迅速化システム</td>
<td>Simplified and expedited systems</td>
</tr>
<tr>
<td>急ぐ措置</td>
<td>Urgent measures</td>
</tr>
<tr>
<td>許可検査</td>
<td>Inspection order</td>
</tr>
<tr>
<td>BSEステータス調査</td>
<td>BSE status study</td>
</tr>
<tr>
<td>GM食品</td>
<td>GM food</td>
</tr>
<tr>
<td>HACCPの原則</td>
<td>HACCP principles</td>
</tr>
<tr>
<td>JASマーク</td>
<td>JAS mark</td>
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<tr>
<td>P B</td>
<td>Private brands</td>
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<tr>
<td>と畜場</td>
<td>Abattoir, Slaughterhouses</td>
</tr>
<tr>
<td>アミノ酸</td>
<td>Amino acid</td>
</tr>
<tr>
<td>アルコール飲料</td>
<td>Alcoholic beverages</td>
</tr>
<tr>
<td>アレルギー表示基準</td>
<td>Labelling standards</td>
</tr>
<tr>
<td>アレルギー物質</td>
<td>Allergens</td>
</tr>
<tr>
<td>カプセル</td>
<td>Capsules</td>
</tr>
<tr>
<td>キャリーオーバー</td>
<td>Carry-overs</td>
</tr>
<tr>
<td>ゼロリスク</td>
<td>Zero risk</td>
</tr>
<tr>
<td>ダイオキシン</td>
<td>Dioxin</td>
</tr>
<tr>
<td>ダエット食品</td>
<td>Diet food</td>
</tr>
<tr>
<td>トレーサビリティ</td>
<td>Traceability</td>
</tr>
<tr>
<td>バラ売りのSold loose</td>
<td></td>
</tr>
</tbody>
</table>

フードチェーン | Food chain
プロセス規定産品 | Process defined products
ポジティブ・リスト | Positive list
モニター検査 | Monitoring inspections
リスクコミュニケーション | Risk communication
リスク管理 | Risk management
リスク評価 | Risk assessment
リスク分析 | Risk analysis
悪影響 | Adverse effect
安心と安全 | "Reliability" and "Safety"
安全な食品を得る権利 | Rights to access safe food.
安全の確保 | Securing safety
意図せざる混入 | Adventitious commingling
違反産品 | Violating products
遺伝子組換え食品 | Genetically modified foods
遺伝子組換え生物 | Living Modified Organisms
一日摂取許容量 | ADI acceptable daily intake
一般名称 | Generic name
一律基準 | Uniform limit
飲料 | Beverages
栄養機能食品 | Nutrition functional food
栄養強調表示 | Nutrition claims
栄養素 | Nutrient, Nutritious elements,
栄養表示 | Nutrition labeling
栄養補助食品 Dietary supplements
永年作物 Perennial plants
衛生基準 Hygiene standards
汚染 Contamination
卸売業者 Wholesalers
加工 Processing
加工食品 Processed food
科学の原則 Scientific principles
科学的確実性 Scientific certainty
科学的証拠 Scientific evidences.
科学的証拠の不確実性 Uncertainty of scientific evidence
科学的知見 Scientific knowledge
科学的不確実性 Scientific uncertainty
過度の摂取 Excessive intake
外食産業 Food service industry,
格付け Grading
格付機関 Gading organizations
確率 Degree of probability
乾物重量 Drained weight
官報 Official gazettes,
患者 Patients
感染症（病） Infectious disease
監視 Surveillance
危害 Hazard
危害物質 Harmful substance
危害予防 Prevent hazards
危機管理 Crisis management
器具 Apparatuses
既存添加物 Existing Additives
規格基準 Specifications and standards
規格基準型特定保健用食品 Standardized FOSHU
規定する Stipulate, Declare, State, Lay down
偽装事件 Fraud cases
技術基準 Technical standards (Cahier des charges)
義務表示 Mandatory labeling
牛の識別制度 Cattle identification system
狂牛病 Mad-cow-disease
均 衡 の 原 則 Proportionate principle
緊急措置 Measures for emergency
苦情 Complaints.
景品 Premiums
計画輸入 Planned import system
欠陥 Defect
健康食品 Health food
健康被害 Hazards to human health
健康表示 Health claims
検疫所 Quarantine Station
検出 Detect
原産 Product origin
原産地 Places of origin
原産地呼称 Appellation d’origine
原産地表示 Indication of place of origin
現地検査 On-site inspection
個体識別 Individual identification
個 体 識 別 番 号 Individual identification number
交差汚染 Cross contamination
公正取引 Fair trade.
公正取引規約 Voluntary guidelines of fair trade
公聴会 Public hearing
公的品質証明制度 Official quality certification system
行政指導 Ministerial guidance
高級牛肉 High-quality beef
高度の食品安全 High level of health
protection
合理農業 Agriculture raisonnée(Integrated agriculture)
告示 Ministerial notification
国際的標準化 International harmonization
差別 Discrimination
最高残留限度 Maximum residue limits MRLs
材料 Ingredients
産業優先政策 Industry-oriented policy
暫定残留基準 Provisional residue standards
残留基準 Residue standards
指定食品添加物 Designated food additive
指令 Directive
施行 Enforcement
枝肉 Carcass
資源の多様性 Diversity of natural resources
飼料 Feed
飼料添加物 Feed additives
事業者 Business operators
事業者の責任 Responsibility of business operators
事前許可 Pre-market approval
事前届出制度 Advance notification system
持続可能農業 Sustainable agriculture
耳標 Year tags
自主検査 Self-examinations
自然循環機能 Natural recycling function
識別記号 Unique identifier
社会的品質 Social quality
主食 Staple food,
取引 Transaction
取引の記録 Record of transaction
需給調整 Supply and demand adjustment
猷医 Veterinarian
重量の多い順 Descending order of weight
熟成ハム Aged ham
出荷 Release
所管官庁 Competent minister
小売業者 Retailers
小分け業者 Subdivider
消極的品質 Negative quality
消費期限 Use-by-date
消費者の信頼の回復 Restoration of consumers’ confidence
消費者の要求 Requirements of consumers,
消費者運動 Consumer movements
消費者中心の Consumer-oriented
消費者保護 Protection of consumers
焼却する Incinerate
省令 Ministerial Ordinance
賞味期限 Best-before
情報ギャップ Information gap
情報開示 Information disclosure
条件不利地域 Regions with unfavorable conditions.
条件付特定保健用食品 Qualified FOSHU
錠剤 Tablets
食習慣 Dietary habit
食中毒 Food born illness
食肉産業 Meat industry
食品の安心 Food reliability
食品安全 Food safety
食品加工業 Food processing industry
食品健康影響評価 Assessment of the effect of food on health
食品事故、食中毒 Food poisoning,
食品摂取　Ingestion of the food、Intake of food
食品添加物　Food additives
食用油　Edible oils
新食品　Novel food
申請　Application
申請者　Petitioner
人間の健康に対する危害　Hazards to human health
水産物　Marine products
水産養殖　Aqua-culture
政府の裁量　Discretion of the government.
政府調達　Government procurement
政令　Cabinet order
清涼飲料　Soft drink
生産過程　Process of production
生産情報　Production information disclosure JAS
生鮮食品　Perishable food
生物多様性　Biodiversity,
税務当局　Tax authorities
積極的品質　Positive quality
洗剤　Detergent
選択的拡大　Selected expansion
他の正当な要素　Other factors regarded as legitimate
炭水化物　Carbohydrate
知的所有権　Intellectual property rights
地域団体商標　Regional collective mark
地理的表示　Geographical indications
中身　Contents
注意書き　Cautions
追跡　Tracing
通常国会　Ordinary diet session
提出する　Submit
適正製造基準　Good manufacturing practices
食品摂取　Ingestion of the food、Intake of food
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適正製造基準　Good manufacturing practices
農場から食卓まで　From farms to tables
農薬残留　Residue of pesticides
配給制度　Ration System.
発生　Outbreak
反芻動物　Ruminants
販売　Place on the market
比較表示　Comparative claim
肥料　Fertilizer
微生物　Microorganisms
微生物汚染　Microbial risk
漂白剤　Bleaching agent,
表示　Labeling
表示の確実性　Verifiability of labeling
表示基準　Labeling standards
品質証明産品　Quality-certified products.
品質表示基準　Quality labeling standard
普及　Dissemination
分別　Segregation
変異型クロイツヤコブ病　vCJD variant
Creutzfeldt-Jakob Disease
保管　Storing
保健所　Public health centers
保険機能食品　Food with health claims”
保存料　Preservative,
放射線照射　Ionizing radiation
法人　Juridical persons
法的義務　Legal obligation
貿易慣行　Trade practices
貿易障害　Obstacle to the international trade.
貿易制限的な　Restrictive to trade
防黴剤　Antimolding agent
未登録農薬　Non-registered pesticide
民間　Private sector
命令検査　Ordered Examination
輸入検疫　Import quarantine
輸入検査　Import inspection
輸入手続きの簡素化・迅速化
輸入通報　Import notification
輸入届出済証　Certificate of notification
有機産品　Organic products
有機農産加工品　Organic agricultural processed foods
有機農産物　Organic agricultural products
猶予期間　Grace period
予防原則　Precautionary principle
予防措置　Precautionary measures
与党　Ruling party
容器包装　Containers/packages
用法　Usage
葉酸　Folic acid
流通　Distribution.
流通 J A S　JAS standards of specially distributed products
緑茶飲料　Green tea beverage
哺乳類　Mammals

法令
食品衛生法
Food Sanitation Law (1947),
と畜場法
Abattoirs Law (1953),
Poultry Slaughtering Business control and Poultry Meat Inspection Law(1990),
健康増進法
    Health Promotion Law (2002)
農薬取締法
    Agricultural Chemicals Regulation Law (1948 )
肥料取締法
    Fertilizers Control Law (1950),
薬事法
    Pharmaceutical Affairs Law (1960 ),
家畜伝染病予防法
    Domestic Animal Infectious Disease control Law (1951)
 Provisional HACCP Promotion Law (1998)
  Provisional Law for Effective Management of Process of Manufacturing
牛の個体識別のための情報の管理、及び伝達に関する特別措置法
    Beef Traceability Law of 2003
    Law for Special Measures Concerning the Management and Relay of Information for
    Individual Identification of Cattle
消費者基本法
消費者保護基本法
    Consumer Protection Fundamental Law (1968)
公正取引法
    Unfair Competition Prevention Law (1993)
不当景品類及び不当表示防止法
    Act Against Unjustifiable Premiums and Misleading Presentations (1962)
計量法
    Measurement Law (1992)
商標法
    Trademark Law (1959)
商品安全基本法  Food Safety Basic Law (2003)
食品衛生法  Food Sanitation Law (1947)
飼料の安全性の確保及び品質の改善に関する法律  Law concerning safety Assurance and Quality Improvement of Feed (1953)
ダイオキシン類対策特別措置法  Law Concerning Special Measures against Dioxins (1999)
牛海綿状脳症対策特別措置法  Law Concerning Special Measures against Sponsiform Encephalopathy (2002)
栄養改善法  Nutrition Improvement Law (1952)
農林水産物の規格化及び品質表示の適正化に関する法律  Law Concerning Standarization and Proper Labelling of agricultural and Forestry Products (1950) (JAS Law)
有機農業振興法  Organic Agriculture Promotion Law (2006)
水道法  Waterworks Law (1957)
農用地の土壌の汚染防止等に関する法律  Agricultural Land Soil Pollution Prevention Law (Law No. 139 of 1970)
遺伝子組換え生物等の使用等の規制による生物の多様性の確保に関する法律  Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Law No. 97 of 2003)

機関名等
ヨーロッパ食品安全庁  European Food Safety Authority  公正取引委員会  Fair Trade Commission
農林水産省  MAFF  Ministry of Agriculture, Forestry and Fisheries  厚生労働省  MHLW  Ministry of Health, Labour and Welfare
コーデックス委員会  Codex Alimentarius Commission of FAO/WHO  世界貿易機関  WTO  World Food Organization
EU委員会  EU Commission  食品医薬品庁  FDA  Food and Drug Administration
アメリカ農務省  USDA  US Department of Agriculture  食品安全検査庁  FSIS  Food Safety Inspection Service
家畜改良センター  National Livestock Breeding Center  Commission on Investigation and Examination of BSE Issues
食品安全委員会  Food Safety Commission  内閣府  Cabinet Office
日本GAP協会  Japan Good Agricultural Initiative (JGAI)
国際獣疫事務局  OIE Office International des Epizooties
消費者庁  Consumer Protection Agency
国際標準化機構  International Standardization Organization
国連環境開発会議  United Nations Environment Development Conference
薬事・食品衛生審議会
IFS  International Food Safety
BRC  British Retail Consrmium,
SQF  Safe Quality Food
CIES  Comité international d’intrprises à succursales
SAI  Sustainable Agriculture Initiative,
EISA  European Initiative for Sustainable Development of Agriculture,
COLEACP  Europe-Africa-Caribbean-Pacific Liaison Committee
Fair-Trade
Greener Field
OILB  Organisation Internationale de Lutte Biologique
FARRE  Forum de l’Agriculture Raisonnée Respectueuse de l’Environnement