Chapter 1 Introduction

1.1 What is Food Safety and Security?

Is the food we eat every day safe? Food safety is defined by CODEX Alimentarius Commission, a Joint FAO/WHO Food Standards Program (details will be described later) as “to guarantee that the food is produced in an anticipated and intended way which will not harm people when the food is consumed.” In addition, it is possible that food which is considered safe when consumed in moderate amounts can become harmful when it is consumed in larger amounts. There are a number of components existing in one food item where each agent can give good or bad effects to health. Therefore, when considering food safety, it must be noted that its safety towards human health on whether the food or its substances is safe, depends on the amount consumed. The food item may not be safe in any condition or amount consumed.

Then, does safe food mean the food is secure? Safety and security are two different concepts. Safety is an objective issue that is determined with scientific assessments but security is a subjective and psychological issue. Therefore, there are times when it is not secure even though the food is said to be safe or, on the other hand, we can feel secure and enjoy eating the food even though that food item has not been proved to be safe.

The government, producers and manufacturers, and distributors must endeavor to equate safety and security. However, primarily they would need to ensure consumer confidence. No matter how much the said food item is recommended to be safe, if the public cannot trust the advocate, no one will believe in what is being said or can feel reassured. To secure consumer confidence, the government, producers and manufacturers, and distributors must ensure safety as well as strive to make efforts such as disclose other information, attach the correct notification and so forth.

1.2 Complete Elimination of Hazards is Impossible

The current international trend in food safety is generally conceived to be impossible to completely eliminate hazardous factors in food that have adverse effects to our health and all foods should be controlled under the premise of having risk factors. In addition some foods, which were thought to be safe, are now found to contain risk factors as detailed flaws that were never discovered before can now be detected in detail with the improvement in analyzing abilities of analysis instruments.

Adverse effects and profits are two sides to a coin. Neither can be removed without the other and both depend on the extent of each effect and profit. For example, food and supplements can be harmful if taken in excess. There are bacteria that cause food poisoning that strive in human skin, or human and animal intestines which are difficult to eradicate.

With the pursuit in convenience, the risks in food are more diverse and complex as food is being distributed worldwide with the globalization of food and the development of new pesticides and additives.

At times there are unknown and scientifically unpredictable hazards. Verotoxin in Escherichia coli 0157:H7 and an abnormal prion that are said to be the cause of variant Creutxfeld-Jakob Disease (hereinafter referred to as vCJD) in humans are thought to be a variant of our genes that was triggered by some cause. The discovery of the peril and eradication is restricted to the precision of the test technologies as seen in the progress in the surveillance in BSE or conversely, in the slip of discovering HIV during blood donations. Above all, even if a highly sophisticated monitoring system is set up, there is always the possibility of human error.

Furthermore, controlling food provision is not as systematic as controlling industrial products. Agricultural and food products are organic and their properties are affected by inner and outer conditions such as temperature. The food provision system is called a food chain where each stage from producing the basic ingredients, processing, and distribution is complex and each stage bears the possibility to cause threats. It will be necessary to grasp the characteristics of the changing risks within the whole food chain and find ways to control it.

Chapter 2 Philosophy in Food Risk Analysis

2.1 Philosophy in Food Originating Risks and Confidence in Food Safety

When it is recognized that a complete elimination of all food hazards is impossible, the importance in a tighter control of food control which is neither absolute nor inaccurate emerged. Also people began to control the situation as much as possible under speculation.

This new philosophy in securing food safety is to implement measures prior to its outbreak by introducing the concept of risk and make scientific predictions that may occur in future loss of food.

The risks originating in food are defined by CODEX Alimentarius Commission in 2003 as “the probability of adverse effects to our health that is brought about by risks in foods and its severity function.” At times the term “risk” and “hazard” are mixed together but there is a distinct usage of the terms in the food industry. Food hazard is “ingredients in food or a state of food that trigger biological, chemical, or physical effects that may induce adverse effects to our health.” (CODEX Alimentarius Commission 2003).

If it is infeasible to eliminate hazards completely means that risk always exist. Zero risk is impossible. The objective of risk control is to control risks that are permissible in society. The safety of food has yet to be defined but if it did exist, it can be defined as “when the risk can be controlled at a level that is permissible in society.”

【Codex Alimentarius Commission】

Codex Alimentarius Commission (hereinafter referred to as CODEX) is an international intergovernmental authority that was set up by FAO and WHO in 1962 to protect consumer health and to secure fair trade in food. They are the organization that designs the international food standard called CODEX Standard. (Japan participated in this standard from 1966.) There are a total of 173 countries participating and the head office is in the FAO headquarters in Rome. Japan is examining the reference value of harmful substances that have been examined and decided by CODEX.

2.2 Risk Analysis of Food

Risk analysis is the total process of preventing (restraining) the occurrence of the possibility of harmful effects to public health by consuming food. It consists of three elements, namely, risk assessment, risk management, and risk communication. Better results in risk analysis arises when these three element function mutually together. The basic idea of risk analysis is “to minimize the risk when the people may be exposed to hazard not by clearing up the mess after the incident occurs but by preventing the harm beforehand as much as possible.”

Since there never can be a zero risk in food, under this assumption, the Agence Francaise de Securite Santaire des Aliments (AFSSA) in 1999, the European Food Safety Authority (EFSA) in 2002, and the German Federal Agency for Risk Assessment (BfR) in 2002 were established as agencies for risk assessment where their main job will be to scientifically assess and reduce the risk, which is the basic idea of risk analysis.

A Food Safety Commission was established in 2003 even in Japan under this world trend.

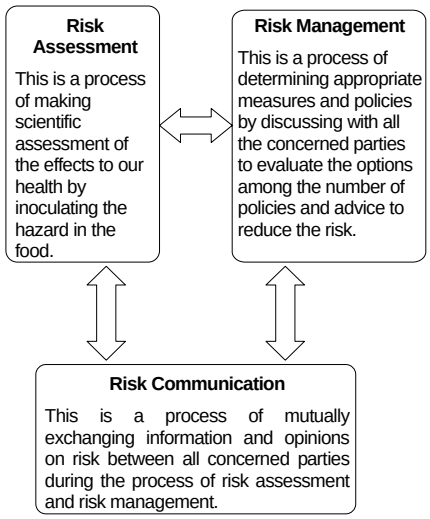
2.2.1 Risk Evaluation

Risk evaluation is a process that is based on the following scientific steps: hazard identification, hazard characterization, exposure assessment, and risk assessment. According to the Joint FAO/WHO Meeting in 1995, it is defined as “a process to evaluate scientifically the probability of adverse effects formed to our health by consuming hazards in food.”

Hazard identification is an identification of biological, chemical, physical substances and factors that may exist in specific food or food categories which may cause adverse effects to our health.

Hazard characterization is a qualitative and/or quantitative evaluation of properties that have adverse effects to our health that derive from biological, chemical, and physical substances and factors that may exist in food.

Figure 2 Three Elements in Risk Analysis



* Hazard

Food safety hazards are biological, chemical, or physical substances in food or its state that may be harmful to our health.

Exposure evaluation is to predict the qualitative and quantitative realistic dosage from the biological, chemical, and physiological substances and factors and other causes.

Risk assessment is to predict the qualitative and/or quantitative percentage of potential adverse effects or the amount of adverse effects known in a collective group that will occur to our health and the extent of adverse effects that is based on the hazard identification, hazard characterization, and exposure assessment.

2.2.2 Risk Management

Risk management is when government authorities and concerned parties cooperate to decide and implement measures, based on the risk assessments, which will suppress the occurrence of risks that may generate major hazards to public health under the consideration of the conditions of dietary habits of the people. In Japan, the risk management authorities are the Ministry of Agriculture, Forestry, and Fisheries and the Ministry of Health, Labor, and Welfare.

The most important factor in risk management is “health protection.” However, it is necessary to consider the balance between consumer protection, and protection of small-sized producers and industries by the food safety administration.

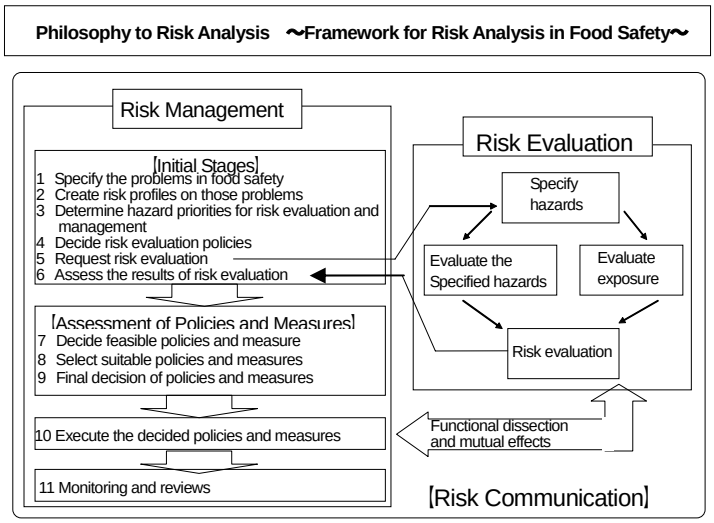
Risk management is a continuing process and the necessity of reevaluation must not be forgotten. Furthermore, considering scientific uncertainties, there is an international agreement to apply preventive measures when the probable uncertainty is high.

2.2.3 Risk Communication

Risk communication is when the concerned parties such as the consumers, producers, businessmen, and government authorities mutually exchange information and opinions to reflect them into policies. Risk communication is probably the most important element in risk analysis. However, risk communication cannot exist without risk assessment and risk management. Risk communication is not a problem solving method in itself but it assists problem solving, which are measures and policies in risk management, and has the role to have the solution be accepted into society.

Furthermore, risk communication will help establish trust and reliability among the concerned parties.

Elements that will hinder risk communication are the gap between the actual risk and the risk that the people feel, in other words, risk awareness. Normally, the difference between the actual risk and risk awareness tend to be larger when there is less accurate information. Risk derived from hazards that are thought to be controllable or hazards that are convenient and profitable are recognized to be smaller than the actual risk. There are other and various elements that create bigger gaps between the actual risk and the risk awareness. Regarding food safety, risks originating naturally have less recognition and are more acceptable than risks derived from synthetic chemicals. Whereas risks derived from unknown hazards are recognized and accepted to be greater than risks originating from known hazards. The number of preconceived ideas regarding food safety does make risk communication difficult.



2.3 Examples of Risk Analysis (Setting Criterions for Pesticide Residue)

2.3.1 Setting Acceptable Daily Intake (Risk Evaluation)

The basic philosophy on pesticide residue is to set the criterion of the daily intake of pesticides from food within a range of the accepted intake per day per person and base it on this acceptable daily intake (hereinafter ADI). ADI indicates the upper limit and unless our daily pesticide intake does

not exceed this limit, even if we continue to intake pesticides daily, it will not affect our health during our lifetime.

ADI settings are based on experiments on animals where food mixed with pesticide is given to rats throughout their lives (about two years) and to mice and dogs (for one year). This is to find out how much pesticide will generate problems in the animals. The animals are dissected to discover any minute and abnormal changes in their bodies. A so-called reproductive testing for three generations is carried out to check if any difficulties arise in each generation that takes pesticides daily. As a result, the amount that causes no problems was defined as the “no observed adverse effect level” (NOAEL). The safety coefficient was thought to be the difference between animals and humans (1/10) and differences in solids (1/10). Generally the ADI was calculated by multiplying the figures by 1/100. ADI is normally expressed as “mg/kg weight/day.” This indicates that it will be safe to take xxx mg of pesticides daily per 1kg of body weight throughout one’s lifetime.

2.3.2 Setting Pesticide Residue (Risk Management)

The criterion of pesticide residue is set so that the pesticides in food will be within 80% of the ADI.

The settings for pesticide residue is determined by finding out what kinds of food and how much of it is taken daily by the people. The settings for the standard value of the pesticide residue are based on the amount of residue in crops from the results of crops residue tests and the CODEX criterions or criterions in other overseas countries. An estimated ADI is calculated based on the criterion value of pesticide residue in four groups which not only includes the average individual but also children, expectant mothers, and the elderly with the consideration of individual differences. The pesticide residue is set so that all four groups will not exceed 80% of the ADI.

Chapter 3 Structure to Assure Food Safety and Security in Japan

3.1 System Regarding Food Safety

3.1.1 Establishing a Food Safety Commission

Recently public confidence and the sense of security toward food safety is weakening with the series of incidents threatening food safety such as the outbreak of BSE and vCJD in Japan and in other countries and the issues on pesticide residue in imported vegetables. Furthermore, the environment surrounding our dietary habits is making major transitions with the development of a wider and global food distribution, emergence of new hazardous elements, and genetically modified foods.

To deal accurately with these climatic changes and to ensure food safety, the Food Safety Basic Law was enforced in July 2003 to promote an integrated policy to secure food safety under the basic ideology that it is most important to protect public heath by clarifying the responsibilities of the government, local authorities and food-related businesses and the role of the consumer as well as establishing the basic policy of promoting risk assessment, the assessment of the effects to food and health, risk management, the formation of policies based on risk assessment, and risk communication, the exchange of information and opinions between the concerned parties.

In line with the establishment of the Food Safety Basic Law, on the same day a Food Safety Commission was set up in the Cabinet Office, which is independent from the Ministry of Health, Labor, and Welfare and the Ministry of Agriculture, Forestry, and Fisheries, the risk management authorities, to execute neutral risk assessment based on scientific findings. The Food Safety Commission has conducted risk assessment based on assessment requests from the risk management authorities or by selecting items that should be assessed. This is the main role that this commission should be playing.

Moreover, the Food Safety Commission can give advice to the ministers of the related risk management authorities through the prime minister regarding the policies that should be implemented for food safety based on the results of the risk assessments.

Features in the Food Safety Basic Law

1. Basic Philosophy
   (1) Enact necessary measures under the basic awareness that the protection of public health is most important
   (2) Secure safety in each stage of the food supply
   (3) Enact necessary measures based on scientific findings but placing full consideration on international trends and public opinion

2. Responsibility and Roles of Concerned Parties
   (1) Government responsibilities and responsibilities of local authorities
      • Enact and execute policies to secure food safety under an appropriate division of labor
   (2) Responsibilities of food-related businesses
      • Execute necessary and appropriate measures by being aware that securing food safety is their main responsibility
      • Endeavor to provide accurate and appropriate information
      • Cooperate in policies that are enacted by the government and local authorities
   (3) Roles of the Consumer
      • Endeavor to have deeper understanding and knowledge as well as express their opinions on the policies

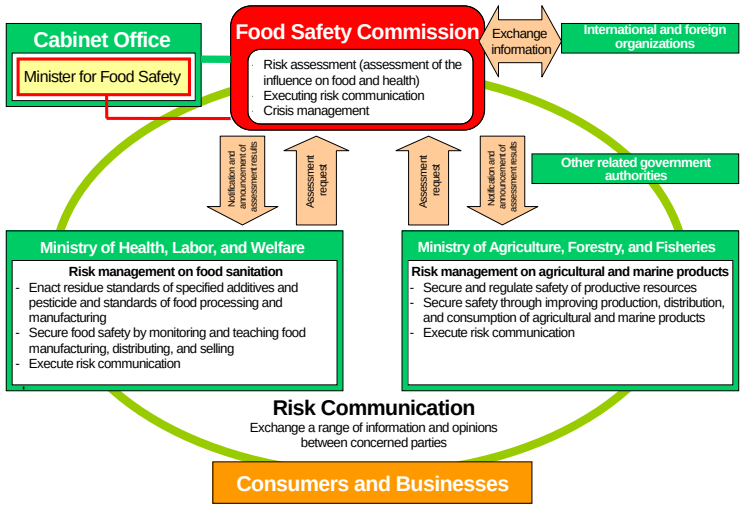
3. Basic Strategies on Enacting Policies
   ○ Implementing risk analysis methods
      • Execute risk assessment (assessment that will influence food and health)
      • Enact policies based on the results of the risk assessment
      • Promote risk communication

3.1.2 Risk Management Structure in Japan

The Food Safety Commission is in charge of risk evaluation, risk communication, and measures during emergencies.

The Ministry of Agriculture, Forestry, and Fisheries has realized a safe provision of feed by regulating agricultural and marine products in the production stage and by improving the food manufacturing technologies. The Ministry of Health, Labor, and Welfare set up food safety criterions and improved public sanitation by controlling sales activities.

Figure 3.1 Food Safety Administration in Japan



Chapter 4 Examples in Hazardous Factors in Food

4.1 Biological Hazardous Factors

4.1.1 BSE

BSE is a disease, which is yet to be understood, where sponge-like holes are made in the brain of the cattle. It was discovered in the UK in 1986 and a BSE infected cow was confirmed in Japan in 2001. There are no causative factors in BSE but is thought to be caused by an abnormal prion that mutated from a protein called prion. The consumption of nervous systems on brains and such from infected cows is thought to be the cause of vCJD.

4.1.2 Microoganisims and Bacteria

There are pathogenetic bacteria (food poisoning bacteria) found in food poisoning, viruses, worm infections, and toxins that are produced in the body. The most well known food poisoning bacteria are: salmonella bacterium found in eggs, enteritis vibrio found in seafood and fish; entrohemorrhagic Escherichia coli 0157 that live in animal intestines and pollute food and drinking water with feces and urine; staphylococcus aureus that live in humans and animals and are the source of food poisoning as it creates toxin when proliferating; and bacillus cereus that can be found in widely in nature such as in soil and are the source of food poisoning as it creates toxin when proliferating.

Viruses are norovirus and hepatitis virus that are thought to be caused by eating raw shellfish.

Parasites are protozoans, and anisakis that are mainly found in fresh fish, and lung fluke that originate in eating raw meat.

4.2 Chemical Hazardous Factors

There are many chemical substances in food. Other than components and nutrients such as carbohydrates and proteins, there are substances that are used in the production, manufacturing, and processing of food and substances that are transmitted to the food from the environment, tools and wrappings. (Refer to Table 4.1)

In general, there apparently is a concept where “natural substances are safe but synthetic substances are dangerous.” It is possible to cause adverse effects to human health when a substance is consumed in excess regardless whether it is natural or synthetic. Therefore, other than the substances that is known to be safe to human health with the accumulated knowledge from a long historical human perspective, it is necessary to make assessments whether the natural or synthetic substance is safe or not.

According to the agreement regarding the hygiene in WTO and the plant protection measures, the CODEX Alimentarus Commission, the only organization that is acknowledged to enact food safety standards, is establishing criterions on chemical substances and other announcements based on the framework of risk analysis.

Table 4.1 Chemical Substances in Food

Type	Example
Substances are that added in the final product intentionally	➢ Food additives (artificial coloring, sweetener, preservatives, antitoxidant agent, flavoring agents and such) ➢ Nutrients (calcium, vitamins and such) ➢ Functional substances
Substances that are found in the final product as it is used in producing the basic ingredient	➢ Food additives ➢ Processing aids ➢ Pesticides ➢ Drugs for animals ➢ Dietary additives
Substances that are found naturally in small amounts in natural basic ingredients and food	➢ Tetrodotoxin, a natural toxin which is produced by shellfish ➢ Solanine, a natural toxin that is produced by plants ➢ Various allergen
Substances that are found in fungus during storage	➢ Mold (aflatoxin and ochratoxin A and such)
Substances that generate while cooking and processing	➢ Acrylamide ➢ Polycyclic aromatic hydrocarbon such as benzpyreme ➢ Ethyl carbamate
Substances that are found in the final product due to contact or being in the environment	➢ Heavy metal (lead, mercury, and such) ➢ Dioxin ➢ Substances transferred from wrappings such as vinyl chlorid monomer, acetonitrile and such)

4.3 Physical Hazardous Factors

Physical hazardous factors are nuclear radiation and foreign substances mixed into the food during the distribution and processing process. Normally these foreign substances are not found in the food but can produce adverse effects to human health from its physical effects. For example, mixtures of foreign substances can be glass fragments from damages in glass containers and lighting equipment, metal fragments found in basic ingredients and combined from machinery, or hard plastic fragments.

Chapter 5 Examples of Measures taken for Confidence in Food Safety and Security in Japan

5.1 Securing Food Safety

5.1.1 Good Agricultural Practice

Good Agricultural Practice (GAP) is a guide on how to minimize the harm that can occur during the agricultural production process. These include the insertion of hazardous elements such as pathogenic microorganisms, contaminated substances, and foreign objects, and its countermeasures to secure food safety. This measure is also being promoted internationally in countries and areas such as the US and EU.

It has been proved that the cause that jeopardizes food safety can be found even in the process prior to manufacturing and it has been recognized that it is important to implement measures during the production stage of the agricultural products. In other words, it is important for the producers of agricultural products to subjectively implement risk management from the time the crops are cultivated, harvested, and shipped.

In Japan, GAP policies are being promoted for food safety during the production of agricultural products as the government has top priority in protecting public health.

Topics to Enforce GAP for Food Safety

1. Maintain a clean agricultural production environment
   - Try to keep the agricultural production site clean
   - Grasp the harmful substances in the soil and try to remove then if the soil is contaminated
   - Do not bring in objects that may contaminate agricultural produce
2. Thorough sanitary control of agricultural produce during and after harvest
   - Handle the agricultural produce particularly in a hygienic way prior to shipping
   - Clean the machinery and agricultural tools used for harvest
   - Try to prevent deterioration, decay, and decomposition during storage with rapid drying, adjustment and precooling
   - Prevent intrusion of rats, small animals, and insects and arrange and organize the operation environment.

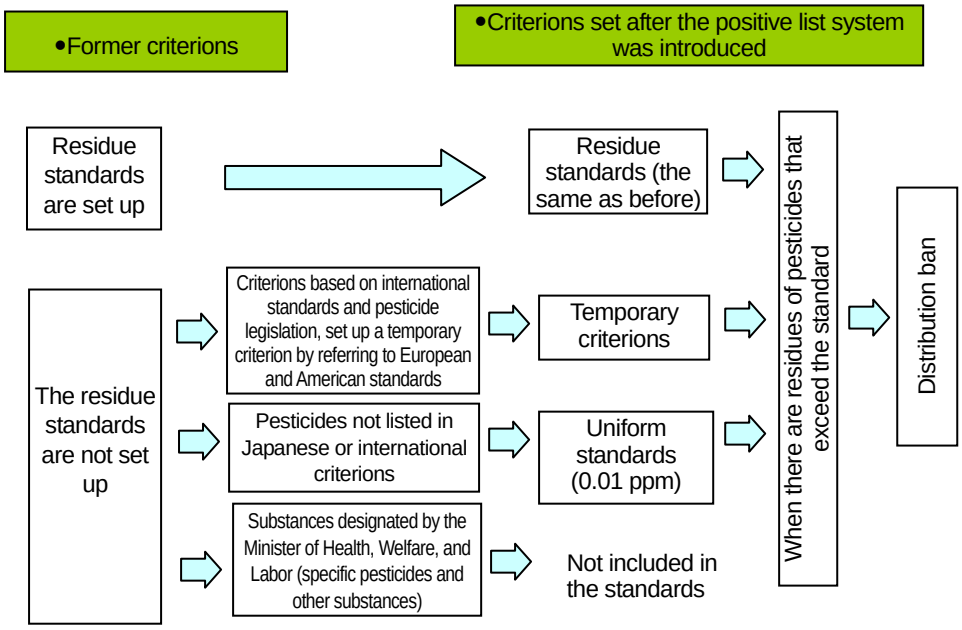
5.1.2 Positive List System for Pesticides Found in Food

Pesticides found in agriculture and livestock products, dietary additives, and drugs for animals had residue standards in the Food Sanitation Law. Agriculture and livestock products that exceeded this standard were, in principle, prohibited to be distributed but pesticides that were not subject to the residue standards were not included. Therefore in 2003 the revised Food Sanitation Law, which was enacted in 2006, stipulates that if the pesticide is found to exceed a certain amount even if the pesticide is not included in the residue standards, the agriculture and livestock product are primarily be banned from being distributed (The introduction of a Positive List System).

A provisional standard with reference to international standards, and a uniform standard for those not stated in domestic or international standards were set up for pesticides that are not stated

in the residue standards. The uniform standard sets a strict amount of 0.01ppm as the amount that will incur harm to human health. It is possible that cases will occur where the product will exceed this standard. For example, pesticides may disperse from neighboring farms and attach to the farm products or soil containing residue pesticides may be absorbed by the second harvest. A strict control in the dispersal of pesticides will need to be taken.

Table 5.1 The Positive List System for Pesticides and Other Chemicals



5.1.3 Hazard Analysis and Critical Control Point (HACCP)

HACCP is a method of hygiene control developed for food to secure safety in food prepared for astronauts in the US in the 1960s. This method was reported by CODEX and is an internationally recognized method and is recommended to be adopted in each country. The concept of food safety until now was based on the idea that food could be manufactured safely if the factory environment was kept clean. Emphasis was placed on the hygiene and the maintenance of the manufacturing environment. The safety of the manufactured food was confirmed by carrying out random inspections (for cultivation surveys of microorganisms) on the final product. (Thus all the products were not inspected.)

In addition to this concept, the HACCP method speculates hazards in all processes from the delivery of the ingredients, manufacturing, to shipment and specifies important management issues to prevent that hazard (reduces to prevention, extinction, and the tolerance level). It is a system that can prevent shipment of defective goods beforehand as it troubleshoots and solves the problem immediately after abnormality is detected as it monitors and records the specific issue continuously. In the food industry, there are an increasing number of companies that are importing this HACCP manufacturing management to secure consumer confidence and food safety for their manufactured products.

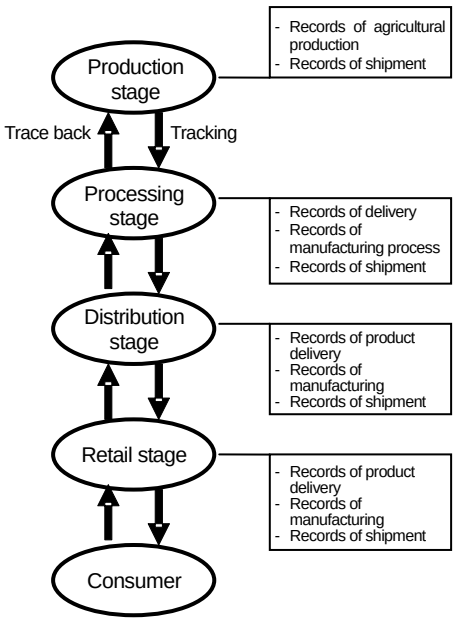
However, implementing this HACCP system in the food manufacturing process will increase food safety compared to the conventional manufacturing methods, but it will not assure complete safety in the manufactured products. It will be indispensable to have employees trained and educated in the HACCP system to monitor the HACCP facility daily and check that the specified procedure and manufacturing process is being followed.

5.2 Securing Food Reliability (Safety)

5.2.1 Food Traceability

When the outbreak of BSE became a social problem in Europe, a system was configured to specify the origin when the outbreak occurred using a unified management of information on the breeding, slaughtering, and distribution of each cow as a countermeasure for this problem. This was the beginning of traceability in Japan. Traceability is to trace and to track the food and its information from production, processing, distribution and sales in each stage of the food chain. In other words, with traceability it can trace and track the food and its information by recording, keeping a log book, and storing the origins of the basic ingredient. It will be easier to trace and track the said food and to clarify the cause of unexpected problems regarding food safety using the explanation of the process between the farms to the dining table.

Figure 5.2 Food Traceability System



5.2.2 Sales Activity of Producers

Producers traditionally shipped their agricultural produce to Japan Agriculture (JA) but recently they are carrying out their own sales activities to positively appeal food safety in their produce. By having the producer sell the produce directly from the fields in stores, consumers can discover who produced the food and where it came from. There are many instances where the producer is securing consumer confidence by clearly labeling the producer's name on the product.

This sales activity is permeating through out Japan. It not only secures consumer confidence but it also has advantages as it promotes the sales of agricultural products, and gives vigor to regional agricultural products.

5.2.3 Safety Control of the Food Ingredients and Providing Information

In the food service industry such as restaurants and food manufacturing industry, there are more companies that are actively disclosing information to consumers regarding the safety

management of fresh food used by the companies and about the fresh food itself.

For example, regarding vegetables, there are companies that are actively disclosing information in restaurants and on the Internet by concluding contracts with the farmland that is interested in improving and eliminating the use of pesticides and chemical fertilizers and by grasping the how the vegetable is being cultivated. When the consumer cooks at home, they can choose and purchase the food stuff that they want, however, as this is a response by the food industry to the consumer demands in checking whether the food stuff used in restaurants is safe or not, this will secure consumer confidence in the industry itself.

5.2.4. Disclosing Easy to Understand Information to Consumers

It is necessary to secure transparency when disclosing information. Generally, reliability and the amount of information are proportionate and it is effective to disclose information periodically to heighten reliability. However, information is not communication. Difficulties and inconveniences must be described. Information should not be a one-way communication. Information and opinions should be exchanged and by understanding the needs of other concerned parties, these needs should be reflected in policies and measures. Also the information must be understood by the receiver. To do so, the message must be thought out before it is communicated such as the terminology used and how it should be transmitted. The response of the receivers must be considered as well.

Presently, there is a social demand to disclose information. Information should be disclosed but the scientific and social repercussions should be considered as well. From a scientific point of view, examinations should be made on whether the data is reflecting the parent population, if the sampling is accurate, what is the goal of the analysis (for example the assumption of the intake or the amount of environmental contamination), the reliability of the analysis value, and whether correct statistical processing has been made. Furthermore, the information should be provided knowing the meaning of the data.

5.3 The Role of Administration, Companies, and Consumers in Food Safety

It is obvious that producers and manufacturers must produce safe food but the government must also implement necessary regulations periodically. In addition, the food that was safely produced and manufactured must be stored, distributed and sold in a way that it is safe. On the other hand, it is necessary to produce and manufacture safe food by utilizing the consumer purchasing power to produce and manufacture selling products. It is important for consumers to take an active role in securing food safety by deepening their understanding and knowledge on food safety as well as endeavor to express their opinions in policies on securing food safety.

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