Administrative approach to seafood HACCP in Japan

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SUMMARY: Since lots of foods are imported from various parts of world to Japan, guarantees of their safety and compliance to the Japanese requirements are essential in term of public health in Japan. Every year about three million tons of fresh and processed seafood are imported and 350 thousands of notifications in accordance with the provisions of the Japanese Food Sanitation Law are received by the Quarantine Offices. As origins, kinds and processes of the imported seafood are varied, various food safety issues related to imported foods are experienced.

HACCP has been an internationally recognized approach for food safety since its adoption in the Codex Alimentarius. Applications of HACCP throughout food chain are encouraged. Voluntary application of HACCP in Japan was regulated in 1995. The Ministry of Health, Labour and Welfare currently approves eighteen processing establishments of Fish-Paste products.

KEY WORDS: Seafood, HACCP, Food Safety

Food safety is one of the priories in public health concerns and it has been global challenges in private sectors as well as government. Application of HACCP throughout food chain is essential to promote food safety assurance and consumer confidence.

Incidence of Foodborne Diseases

Every year several incidences of foodborne diseases are experienced. In total 35,214 cases and 7 deaths in 2,697 incidences of foodborne diseases were reported in 1999 to the Ministry of Health, Labour and Welfare. Pathogenic Escherichia coli such as O157, Salmonellosis and Vibrio parahaemolyticus infections are the major leading microbiological foodborne diseases.

In response to the reports, the MHLW has carried out investigations to identify the cause and taken the following measures:

1. Establishment on new standards for hygiene handling in meat plants.
2. Establishment on guidelines for hygiene management in mass catering and inspection by food safety inspectors.
3. Distribution of leaflets for consumers with information as to how to prevent food poisoning.
5. Monitoring programme on microbiological contamination in foods.
6. Development of sensitive detection methods on EHEC.

In total, 9,396 cases and 1 death in 664 incidences of Vibrio parahaemolyticus infection are reported in 1999. This figure counts 1/4 of the total incidence of the Japanese Foodborne Diseases Statistics. The incidences of Vibrio parahaemolyticus infections have been increasing since 1996. This increase is seemed
to be due to the prevalence of the new serotype O3K6 which is currently a major serotype of *Vibrio parahaemolyticus* in Asia.

The incidences of the *Vibrio parahaemolyticus* infections are reported during summer. The infections are mainly caused by consumption of raw fishes and shellfishes such as “SUSHI” and “SASHIMI”.

Following the above measures new requirements on fresh fish and shellfish products for raw consumption were enforced in July 2001.

**HACCP Regulations in Japan**

HACCP system is quite different from the previous food safety management that weighs on inspection of final products. HACCP system is focused on preventing the occurrence of hazards and ensuring food safety throughout all food production process—from its raw state through finished products. Under the system, hazards on individual food or its process are first analyzed and processes to control these hazards are identified as critical control points.

Manufacturers have to prepare an operating plan for food safety control based on seven principles and 12 tasks for HACCP system established by the Joint FAO/WHO Food Standards Programme of Codex Alimentarius Commission.

The “Comprehensive sanitation controlled manufacturing process”, provisional translation of Japanese legal term on HACCP application, is a legal framework established
when the amendment of the Food Sanitation Law was amended in 1995. This is the first legal framework for food safety assurance based on the HACCP system.

In accordance with this legal framework food manufacturers or processors in certain food groups may apply to the Minister of Health, Labour and Welfare its approval. The Minister of Health, Labour and Welfare can provide his/her approval to individual manufacturing/processing facilities in certain food groups if HACCP based hygiene and food safety control applied in the facilities is confirmed satisfactory through inspection on documentations and operations.

As of the end of the year 2000, processors in the following food categories are applied in the HACCP framework on voluntary approval:

1. Milk (cow's milk, processed milk, and similar products)
2. Dairy products (cream, ice cream and similar products, fermented milk, lactic acid bacterial beverages, milk drinks, and similar products)
3. Soft drinks and Nonalcoholic beverages
4. Meat products (ham, sausages, and similar products)
5. Fish-paste products (KAMABOKO and fish ham/ sausages)
6. Foods packed into a container/package and pasteurized under pressure (canned foods and retort foods)

In the legal framework, food manufacturers and/or processors establish HACCP based manufacturing and/or processing plans on their products and sanitary controls on their facilities. And the Ministry of Health, Labour and Welfare confirms whether these established plans comply with the requirements for their approvals.

The manufacturing and/or processing methods approved under the system are considered to meet the uniform standards for manufacturing and/or processing under Article 7 Paragraph 1 of the Food Sanitation Law. The legal framework on HACCP application enables the application of a wide variety of food manufacturing and/or processing, even though the process is not followed the uniform standards in the Food Sanitation Law.

Export Certifications on Seafoods to the US and EU

Those who wish to export marine products to the EU must obtain recognition by the Ministry of Health. Labour and Welfare (MHLW). The MHLW and the corresponding local governments on the applying facilities conduct inspections. When the inspection is satisfactory there facilities are recognized as "facilities processing marine products exported to the EU." Requirements for the recognition are based upon the safety requirements in the EU, namely Council Directive 91/493/EEC.

Food safety inspectors designated by the MHLW regularly inspect the recognized facilities. On this bases health certificates on export consignments to the EU are issued to the applicant processors.

The Director of the Inspection and Safety Division, Department of Food Safety, Ministry of Health, Labour and Welfare (MHLW), Japan issues "Directive for US Export Seafood processors" to the local Governments such as Prefectures. It regulates that when a processor wishes to be certified to export seafood to the United States under the MHLW certification, a processor shall comply with FDA Seafood HACCP regulation and Good Manufacturing Practice regulation (21 CFR part 123 and part110). The Directive requires designated food safety inspectors in prefecture
governments to inspect for those regulations in addition to ordinary food safety inspection based on the Japanese Food Sanitation Law. The designated inspectors are trained with knowledge relevant to the 21 CFR 110 and 123.

The Japanese recognition framework was confirmed satisfactory, as a result of an inspection conducted by the U.S. FDA in September 1999.

Seventy three establishments of seafood processors are certified to be in compliance to 21 CFR part 123 and part 110 as noted in 21 CFR Part 123.12(a)(2)(ii)(B).

Food Trade

The number of import notifications for 1999 was 1,404,110, up 10% from previous year. 28.9 million tons of food products are notified to import in the same year. In order to assure safety of imported foods official inspections and tests were conducted for 108,515 instances (7.7%) among the 1,404,110, and violations were found for 948. Substances in violation were destroyed, reshipped, or otherwise treated.

Notifications of seafood imports to Japan are shares about 25 percents of total notifications. In the weight base the portion of seafood imports counts 10 percents of total food imports. In the last two decades the number of notifications and total weight of imported seafood have been dramatically increased.

Promotion of Food Safety throughout Food Chain

Since seafood are known to have a nutritional advantage comparing other animal origin foods and their presence is essential in our Japanese society, the food safety issues related to fish and fishery products have to be well managed with sound risk analysis which is consisted of risk assessment, risk management and risk communication.

In addition an integrated food safety management system from fishery including aquaculture to consumption of seafood should be considered. Application of HACCP would provide assurance on the management. Sharing responsibilities on food safety among society members is essential to promote food safety.