

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

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Agenda Item 7(a)

**CX/ASIA 99/8
October 1999**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COORDINATING COMMITTEE FOR ASIA

Twelfth Session

Chiang Mai, Thailand, 23 - 26 November 1999

INFORMATION AND REPORTS ON FOOD CONTROL AND FOOD SAFETY ISSUES INCLUDING ACCEPTANCE OF CODEX STANDARDS

REPORTS BY MEMBER COUNTRIES

In response to CL 1999/12-ASIA, Japan provided the following information.

JAPAN

In order to facilitate information exchange, we would inform those Member countries in the Region of the activities in the area of food safety issues.

A. CURRENT ISSUES RELATED TO DIOXINS IN JAPAN¹

Many public attentions have been currently paid to Dioxins issues in Japan. For instance some concerns are pollution of environment by exhaust gas from incinerators, contamination in foods and their adverse health affects. During last several months the Japanese Government has established various strategies and measures tackling with this big issue in social security.

Re-Evaluation of Tolerable Daily Intake (TDI) on Dioxins

The Ministry of Health and Welfare (MHW), the Government of Japan established the Tolerable Daily Intake (TDI) of 10 pgTEQ/kg body weight (bw) in 1996 with reference to the evaluation and conclusion of the WHO expert consultation in 1990.

In May 1998 the WHO European Centre for Environment and Health and the International Programme on Chemical Safety (IPCS) organized an expert consultation on assessment of the health risk of Dioxins to re-evaluate the TDI with updated scientific information. The consultation has concluded TDI of 1-4 pgTEQ/kg bw is established for Dioxins which includes PCDDs, PCDFs and Co-PCBs.

Since the WHO experts consultation in May 1998 concluded the revised TDI as 1-4 pgTEQ/kg bw, the Ministry of Health and Welfare, jointly with the Agency for Environment, has requested the Joint meeting of the Living Environment Council and the Food Sanitation Investigation Council, which are advisory groups for the Minister of Health and Welfare, and the Central Environment Council which is an advisory group for the Minister of Environment to review the current scientific knowledge on human health risks of Dioxin. In June 1999 the meeting concluded the TDI of 4 pgTEQ/kg bw.

¹ Secretariat's Note: This subject is also relevant to Agenda Item 8 on the implementation of Risk Analysis.

Other Control Measures for Dioxins

In March 1999 a meeting with Cabinet members responsible for various issues related to Dioxins was established and the essential guideline for the government to promote control measures against Dioxins issues. The guideline declares the government commitments which try to decrease about 90% of total emission of Dioxins in 1998 within next four years as well as to provide directions on various control measures like establishment of TDI.

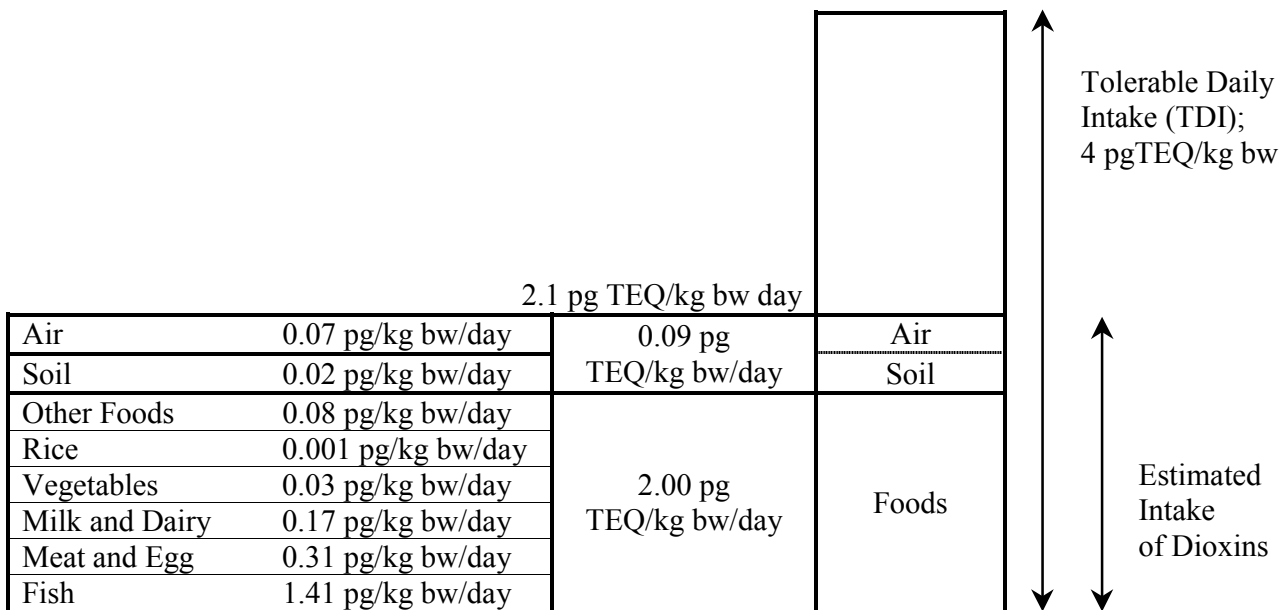
In addition the Law concerning Special Measures against Dioxin Issues was enforced in July 1999. This law has provided legislative background to the government which is trying to achieve their commitments in the guideline this March.

National Monitoring Activities on Dioxins Contamination in Foods

It is generally recognized that food is major route of dioxin in take to human. In order to estimate human intake of Dioxins, which includes PCDDs, PCDFs and Co-PCBs, from foods the MHW has been conducting a research activities on dioxin contamination in individual foods since 1992 and total diet study which is designed to estimate dioxin intakes from foods with normal diet in Japan since 1996.

The result of the monitoring activities in 1998 (Fig1) estimates 2.0 pgTEQ/kg bw/day from foods through normal diet in Japan. Accompanying with average levels of Dioxins inhalations to human from air and soil, total Dioxins intakes to human in Japan estimates 2.1 pgTEQ/kg bw/day.

Fig.1 Result of Total Diet Study on Dioxins Intake in Japan (1998)



Source; Report of National Monitoring Activities on Dioxins Contamination in Foods, MHW, 1998

The monitoring results on individual foods (Table 1) shows fish are major source of Dioxins and Co-PCBs are major parts of Dioxins in fish. It is understood that this is due to past releases of PCBs to natural environment before prohibiting its usage and enforcing control measures against PCBs in 1974. However MHW studies shows the level of Dioxins intakes from diets in an area of Japan (Fig 2) has been dramatically decreased since 1977.

Concerning health risks with these monitoring results on Dioxins contamination in foods the MHW is advised by the Food Sanitation Investigation Council notably,

- 1) the present level of human Dioxins intakes from normal diets in Japan is lower than the Japanese Tolerable Daily Intake (TDI) of 4 pgTEQ/kg bw which was established in June 1999.
- 2) however the consumers has to be advised to have variety of foods in their diet, and
- 3) the MHW should promote further research activities on human dioxin intakes from food and risk assessment on Dioxins with updated scientific information.

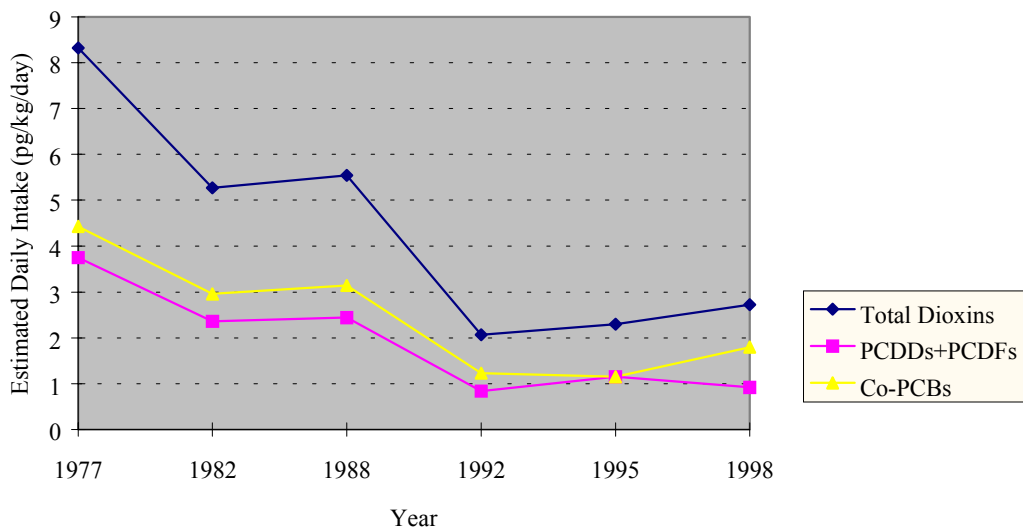
Since laboratory practices to analyze Dioxins in foods are technically very difficult and the data from the analysis should be acceptable in their quality, the MHW has produced a guideline on the laboratory practices which indicate standardized methodology on laboratory tests and quality assurance mechanism in laboratory.

Table 1 Average Level of Dioxins Contamination in Foods (pgTEQ/g)

Foods	PCDDs+PCDFs	Co-PCBs	Total Dioxins
Horse Mackerel	0.597	0.671	1.267
Sea Eel	0.921	2.736	3.657
Flatfish (KAREI)	0.181	0.224	0.404
Flatfish (HIRAME)	0.159	0.445	0.604
Mackerel	0.312	0.681	0.992
Sea Bass	2.642	7.755	10.397
Sea Bream	0.274	0.422	0.696
HOKKE	0.204	0.228	0.433
Beef (Domestic)	0.227	0.111	0.338
Beef (Imported)	0.201	0.021	0.221
Pork (Domestic)	0.033	0.018	0.051
Pork (Imported)	0.009	0.011	0.020
Chicken (Domestic)	0.088	0.101	0.189
Chicken (Imported)	0.046	0.061	0.107
Milk	0.031	0.019	0.050
Cheese	0.103	0.077	0.179
Rice	0.002	0.005	0.007
Sweet Potato	0.013	0.002	0.015
Beans	0.009	0.005	0.014
Apple	<0.001	0.006	0.007
Cucumber	0.017	0.004	0.021
Welsh Onion	0.004	0.004	0.008
Chinese Cabbage	<0.001	0.003	0.003
KOMATSUNA	0.115	0.029	0.144
Spinach	0.158	0.028	0.187
SHIITAKE Mushroom	0.001	0.002	0.003

Source; Report of National Monitoring Activities on Dioxins Contamination in Foods, MHW, 1997

Fig.2 Trends of Estimated Dioxins Intake from Foods from 1977 to 1998 in Japan



Source; Report of National Monitoring Activities on Dioxins Contamination in Foods, MHW, 1998

Response to the Belgian Dioxin Issues

Since 1 June 1999 the Ministry of Health and Welfare(MHW) has directed:

- the quarantine stations to hold the Belgian products such as chicken, egg, pork, beef, milk, mutton and their products in accordance with the provisions of the Food Sanitation Law, and
- the importers of the suspected Belgian products not to sell and/or withdraw the products produced since 15 January 1999 from market.

The Ministry of Health and Welfare have been consulting with the Belgian Government through diplomatic channels and asking the government to provide information on this issue in order to lift the above measures.

B. STATE OF HACCP IMPLEMENTATION IN JAPAN

Introduction

In Japan, HACCP was introduced into national legislation in 1995 by amendment of the Food Sanitation Law. This amendment results in the introduction of a voluntary approval system entitled “The approval system of Comprehensive Sanitation Controlled Manufacturing Process (CSCMP)”. This system applies to food products that have established manufacturing and processing standards and to which the HACCP system has been determined to be applicable.

Following scientific evaluation by the Food Sanitation Council, which advises the Minister of Health and Welfare, approval standards have been established for milk and dairy products, meat products, high-pressure/high-temperature packed products, fish paste products and soft-drinks.

Regulatory systems and control in Japan

In order to prevent the occurrence of public health hazards, manufacturing standards for a number of foods have been established under Article 7 of the Food Sanitation Law. In accordance with the provisions of Article 7 of the Food Sanitation Law, some high risk foods, particularly foods of animal origin for which potential hazards have been identified, are regulated under uniform, precise standards which specify certain time-temperature combination. For example, manufacturing standards for heated meat products requires sterilization with a core temperature at 63 degrees centigrade for 30 minutes.

The combination of progress in modern food manufacturing technology and market demand for new foods in Japan, together with international recognition of HACCP as an effective sanitation control tool, led to the revision of food safety regulations. The CSCMP approval system provides flexibility in determining standards for diverse and variable manufacturing methods, as long as products are guaranteed safe with documented HACCP system and appropriate general sanitation control system.

The CSCMP is applied to food products for which manufacturing standards have been established. A manufacturer(including a foreign manufacturer exporting to Japan) who wishes to apply HACCP system in manufacturing their products to produce foods under the CSCMP system, may obtain an approval from the Minister of Health and Welfare when their HACCP system meets the approval standards prescribed by Ministerial Ordinance under the Food Sanitation Law, Article 7-3. This approval applies to individual foods from individual facilities.

Before HACCP

1. The consolidated hazards list

When developing criteria for the CSCMP, MHW had needed to show the most significant food safety hazards for each products. MHW reviewed various food manufacturing operations, in co-operated with individual food industries and identified food safety hazards that needed to be prevented to ensure food safety. Implementation of HACCP system was based on the review of epidemiological data, including related food-borne disease outbreaks in the past.

Thus, hazards that needed to be controlled which could affect the safety of products had to be identified, clarified and developed into a consolidated hazards list for each products (e.g. meat products; table 1). This list helps industries to conduct hazards analysis.

2. Generic Model

After a number of specific CSCMP had been established, MHW developed a generic model that could be applied to individual foods. MHW recognized that many industries faced a lack of reference information with which to produce detailed HACCP approaches. This generic model now helps industries who wish to introduce HACCP.

3. HACCP training and education program

MHW has developed a HACCP training and education program to conduct appropriate HACCP for local government officials (Food-inspector) at various levels, because the inspection methods has need completely changed, required extensive and in-depth inspection. MHW has also established HACCP training program for companies managers and QC personnel in the food industry, as we recognized we must provide extra technical assistance to industries who is able to implement HACCP.

- A three-day HACCP training course (basic)
- A two-day training for those inspecting facilities authorized to process fish and fishery products for export to the U.S. and EU
- A one-month food sanitation control course

CSCMP inspection procedures

1. Consulting and advice

In order to smoothly introduce the HACCP system into food manufacturing and processing facilities, it is necessary that food sanitation inspectors in local government provide proper technical advice and guidance to manufacturing of facilities and check that appropriate controls (including general sanitation control) are employed in production processes.

2. Application of documents

Before submitting the application, manufacturing shall receive training for and endeavor to acquire knowledge about the HACCP system so that they can implement a plan. Each applicant shall then prepare and give documents including a full description of their HACCP plan based on HACCP 7 principles and 12 processes and protocol of general sanitation control such as sanitation for facilities and equipment, personnel hygiene education, water quality control, pest control etc..

3. Review submission

MHW will review documents submitting to conform to the HACCP approval standards and notify the applicant of its evaluation and whether go forward to the next step.

4. Onsite inspection

MHW in co-operated with the local governments that have jurisdiction over facilities, will conduct an onsite inspection to verify that the HACCP system under consideration is working as intended.

HACCP based inspection:

Plants are inspected in accordance with procedures describes in the CODEX Committee draft guideline for conducting an assessment and verification as follows;

- 1) Opening meeting
- 2) Examination
 - a.Document review
 - b.Onsite inspection (verification)
 - c.Follow up audit (if necessary)
- 3) Working documents
- 4) Closing meeting

5. Judging committee

After onsite inspection, a MHW inspector in charge of a facility must report to the judging committee, which is organized with the MHW evaluator other than inspector in charge and a local government inspector who is working with an inspector in charge. The judging committee may ask for an opinion on technical matters related to the approval, from a panel comprised of people with experience or academic standing. By reporting all HACCP verification to the judging committee, it is intended that all facilities must be evaluated objectively and consistently.

6. Report

Final reports and recommendations of evaluation including determining objectionable conditions elaborated by the judging committee will be provided to the manufacturer and local government with jurisdiction over the facility.

7. Follow up onsite inspection

MHW may commission the local government to conduct an onsite inspection to verify that the corrective measures against the objectionable conditions identified at the first onsite inspection have been done.

8. Approval

When corrective actions for all objectionable items has been taken in the facility, MHW approves food manufacturing and processing control methods for production processes under a special HACCP system entitled CSCMP. The successful applicant is granted a Letter of approval.

Current Situation

As of 1st October 1999, total of 863 commodities from 377 facilities have had HACCP programs approved. A Letter of approval of CSCMP has been granted to these facilities. Since May 1996, approximately 10% of total milk and dairy product manufactures, 4% of total meat product manufactures, 0.3% HPHT packed product manufactures and 0.1% fish-paste product manufactures have had HACCP programs approved.(Table 2)

The Future of HACCP implementation

Items covered by CSCMP are currently limited to milk and dairy products, meat products, HPHT packed products, fish-paste products and soft-drinks. MHW is now investigating the applicability of CSCMP system to other items, for example, frozen sliced and/or processed seafood for raw consumption.

And also, as small manufactures require more official support to implement CSCMP, MHW is now studying data-base system for analysis its hazards of food safety in their process.

Table 1 Hazards list for meat products

1	Afratoxin (exclusively for such cases where the spice is used as a raw materials)	10	Salmonella bacteria
2	Foreign materials	11	<i>Bacillus cereus</i>
3	<i>Staphylococcus aureus</i>	12	Detergent
4	<i>Campylobacter jejuni</i>	13	<i>Trichinella spiralis</i>
5	<i>Campylobacter coli</i>	14	<i>Vibrio paraphaemolyticus</i> (exclusively for such cases where fishery product or its processed goods are used as a raw materials)
6	<i>Clostridium bacteria</i>	15	Additives (exclusively for those for which the usage requirements are specified in accordance with paragraph 1, Article 7 of the Law)
7	Antibacterial substances which are chemical synthetic compounds (exclusively for those for which are included in law materials, milk, meat, eggs, fish and their products)		
8	Antibiotics		
9	Disinfectant		