Chapter 7.
Promotion of Measures for Safety and Security of People

Section 1. Reflections on Damage to Health by Drugs/Medical Devices

1. Measures for Hepatitis C Lawsuit

(1) Relief of Suffers based on the "Act concerning Special Measures for Relief from Hepatitis C Infection"

Compensation Lawsuits were filed in 5 district courts (Tokyo, Osaka, Fukuoka, Sendai, and Nagoya) against the government and drug manufacturers over Hepatitis C virus infections caused by fibrinogen or coagulation factor IX products tainted with Hepatitis C virus, blood products to stop hemorrhaging in the deliveries, over the period of 1971 to 1990. The judgments of 5 district courts were rendered over the period of June 2006 to September 2007.

Each district court judgment differed in the period for which drug manufacturers and the government were liable and the type of drug products. The defendants and the plaintiff then discussed the compromise recommended by the Osaka High Court. As the final result, "Act concerning Special Measures to the Payment of Benefits to Relief Sufferers from Hepatitis C Infection caused by Specific Fibrinogen Products and Specific Coagulation Factor IX Blood Products" was enacted on January 11, 2008 to provide uniform relief regardless of the period of administration.

In accordance with the law, the government recognized its liability for that it caused great damage to the sufferers and could not prevent its spread, and offered sincere apologies to them and their bereaved families, and made a promise to make the maximum effort to prevent any recurrence of suffering to people's health caused by drugs by a basic agreement signed by the Minister of Health, Labour and Welfare, the plaintiff, and the counsel on January 15, 2008.

The Ministry of Health, Labour and Welfare is making an effort to publicize the concept of the law as well as calling for people to take Hepatitis virus examinations who were possibly administered fibrinogen products or Coagulation Factor IX blood products through disclosing the names of the medical institutions that the products

were supplied to. Efforts are also being made to facilitate compromise with the sufferers of the Hepatitis C virus infection caused by administration of specific products in accordance with a payment system based on the said law after that the actual administration was proved by courts. (As of March 31, 2009, compromises have been concluded with 905 people.)

(2) "Study Group on Examination of Hepatitis C virus infection caused by use of Hepatitis C virus-tainted blood products and Prevention of the Recurrence"

1) Purpose of the Study Group on Examination

Having made aforementioned basic agreement and discussions among the Minister of Health, Labour and Welfare, the plaintiff, and the counsel, the Ministry of Health, Labour and Welfare established a "Study Group on Examination of Hepatitis C virus infection caused by using of Hepatitis C virus-tainted blood products and Prevention of the Recurrence" (hereinafter referred to as the Study Group on Examination) on May 23, 2008 with the aim of conducting multidimensional examination of actual situations including an incidence of Hepatitis C virus infection, the process of spreading damages, and the causes, and making suggestions about considering pharmaceutical administration for preventing recurrence.

2) Interim Summary

The Study Group on Examination had a total of 4 discussions intensively from May to July 2008 particularly on enhancing post-marketing safety measures as an urgent issue, and then, compiled an interim summary on July 31, 2008.

The interim summary incorporated following measures which require prompt implementation: a) improving and enhancing collection, analysis and evaluation of safety information; b) introducing new analysis/evaluation methods along with risk management methods; and c) urgently and substantially increasing the number of personnel in charge of safety measures. Concerning pharmaceutical administrative organization, the discussions were conducted based on two plans: one is that the Ministry of Health, Labour and Welfare handles approval review, safety measures, and relief service for adverse effects; and the other plan is that Pharmaceuticals and Medical Devices Agency deals all these tasks. Discussion will be made further after

raising the issues related to each plan.

In consideration of the Interim Summary, the Pharmaceuticals and Medical Devices Agency will add 100 safety measure personnel by spending the FY 2009 budget and contributions from enterprises.

3) The First Proposal

Since October 2008, the Study Group on Examination discussed on prevention of any recurrence of suffering to people's health caused by drugs in consideration of the issues extracted from the incidence of Hepatitis C virus infection, and submitted "The First Proposal" on April 30, 2009 summarizing 12 discussions held in FY 2008.

The Proposal made concrete proposals concerning pharmaceutical administration as a whole including issues related to the use of pharmaceuticals and medical devices at medical practice sites as well as proposal for each stage such as 1) clinical tests/trials, 2) approval reviews, 3) post-marketing safety measures, 4) relief system for health damage, 5) safety measures at medical institutions, and 6) measures to utilize specialized knowledge. With regard to pharmaceutical administrative organization, the proposal suggested the establishment of an independent organization to supervise and evaluate pharmaceutical administration. Discussions will continuously made on pharmaceutical administrative organization in cooperation with pharmaceutical administrative organization.

4) Measures in Future

Based on the First Proposal, the Ministry of Health, Labour and Welfare will promptly undertake a concrete reform. In addition, the Study Group on Examination will continue to make further proposals on measures to prevent recurrence in consideration of the examination on the incidence of Hepatitis C virus infection.

(3) Issue of Fibrinogen Data

Data, including a table of 418 cases related to the administration of fibrinogen products, submitted by Mitsubishi Pharma Corporation (at the time) in response to an order to submit a report was published with masking (private information painted black) in 2002. The Ministry of Health, Labour and Welfare, however, discovered

data with the names of 2 patients that had not been masked in basement storage on October 19, 2007.

The Minister of Health, Labour and Welfare ordered an investigation of this issue and its background. The “Project Team for Investigation on the Fibrinogen Data Issue and its Background” (hereinafter referred to as the “Investigation Team”) conducted investigations and published the results on November 30, 2007.

The data with no masking consists of cases in which adverse drug reactions had taken place and were collected from medical institutions by Mitsubishi Pharma Corporation (at the time). The investigation revealed that after the data had been submitted by Mitsubishi Pharma in 2002, it was stored in a basement without having been appropriately transferred to successors. The transfer/management of the data was quite inappropriate in such that acceptance of the data had not even been recorded in the relevant document registration book. In addition, no discussions were made within the Ministry on notifying the 418 patients by identifying the individuals using the data. The Investigation Team reported that since the Ministry failed to think about notify the patients, “as an organization in charge of issues concerning people’s lives and health, the Ministry should accept the serious criticism in its entirety, that the Ministry should realize what should be done for people suffering with Hepatitis from the viewpoint of the patients”.

In response to this report, the Ministry of Health, Labour and Welfare is making the effort to appropriately manage documents within the Ministry that includes thorough directions on appropriate storage/management of administrative documents. In addition, the Ministry is making their best effort with measures where people can take examination/treatment for Hepatitis as early as possible through disclosing the names of the medical institutions that fibrinogen products and Coagulation Factor IX blood products were supplied to, as described earlier.

2. HIV/CJD Problems

(1) Compromises and Confirming letters Concerning Lawsuits Regarding HIV Problem and CJD Problem

Hemophiliacs had filed compensation lawsuits for damages arising from HIV

infections caused by blood products against the government, drug manufacturers and these compromises were concluded on March 29, 1996. And sufferers who had infected by CJD through human dry dura known as “Lyodura” had filed compensation lawsuits for damages against the government, drug manufacturers. A compromise of these lawsuits was concluded on March 25, 2002.

In confirming letters concerning these compromises, the Ministry of Health, Labour and Welfare had stated that it would sincerely and seriously accept the views of the court. Furthermore, it realized the serious responsibility of the Ministry for the spread of HIV infection among hemophiliacs and the CJD infection that resulted from the transplantation of the human dry dura of “Lyodura”, as well as for the terrible harm that resulted, which was pointed out in the letters. It also stated that the Ministry wholeheartedly apologized to the sufferers, including the plaintiffs having serious mental and physical damage, and the fact that they had been forced into an extremely serious situation.

The Ministry of Health, Labour and Welfare then made a firm promise to make an effort to investigate the cause of these incidents and to confirm what improvements had been made. It also made a promise that Ministry of Health, Labour and Welfare would make the best efforts to prevent any recurrence of suffering to people’s health caused by drugs, based on the recognition of their great responsibility to provide safe and effective drugs to the people and to protect people’s lives and health from adverse drug effects and adulterated drugs.

(2) Promotion of Various Permanent Measures

The Ministry of Health, Labour and Welfare is taking the following permanent measures that were based upon compromises reached in the HIV and CJD lawsuits.

1) Upgrading of medical care system

The Center for AIDS treatment, Research and Development was founded at the International Medical Center of Japan with the aim of improving medical care standards for AIDS in respective regions and to correct any regional differences. In addition, regional-block core hospitals were established in 8 districts, which are there to secure the appropriate medical treatment, along with model hospitals for

AIDS treatment. In the mean time, a system to send at-home medical care support teams consisting of specialized doctors stationed in respective prefectures was established to secure the stable recuperation of CJD and other patients, as well as a system of technical support for doctors treating CJD patients.

2) Support for patients and the bereaved

Counseling activities for the bereaved are conducted with the aim of relieving the mental distress of bereaved whose children, spouses, etc. was lost to HIV infection caused by blood products. In the meantime, support is being offered through support network activities, particularly through telephone counseling conducted by families whose patients was lost to CJD, with the aim of improving the welfare of patients and their families. Efforts are also being made to eliminate any prejudice and discrimination against the people that are infected with HIV and so on.

3) Condolence activities

As a measure of consoling the spirit of the sufferers, an “Oath Monument” was set up in the front garden of the Ministry of Health, Labour and Welfare (August 1999), in declaring the determination to do its best efforts to secure the safety and efficacy of drugs and to prevent any recurrence of miserable incidents like the HIV infections caused by drugs.

Section 2. Promotion of safety measures and establishment of systems for early provision of pharmaceuticals and medical devices.

1. Safety Measures for Pharmaceuticals and Medical Devices

Since pharmaceuticals and medical devices basically provide medication for patients by having some effect on human bodies, they do cure diseases as expected, while on the other hand, it is unavoidable to cause unexpected adverse drug reactions or medical device adverse effects. Pharmaceuticals and medical devices are allowed on the market after they are evaluated on both their effectiveness and safety based on the data including clinical trials for obtaining approval from the Minister of Health, Labour and Welfare, as it is important to balance effectiveness and safety. However, safety information obtained through clinical trials before approval is limited. So, it is necessary to accurately collect information on adverse drug reactions and medical devices adverse effects after marketing, then to analyze and evaluate that information, and to take safety measures for pharmaceuticals and medical devices promptly based on that analysis and evaluation.

(1) Report System for Adverse Drug Reactions

In accordance with the “Pharmaceuticals and Medical Devices Safety Information Report System”, information on post-marketing adverse drug reactions and medical device adverse events is reported from marketing authorization holders and medical professionals to the Minister of Health, Labour and Welfare. When the marketing authorization holders of pharmaceuticals and medical devices find out the occurrence of diseases that are suspected of being induced by adverse drug reactions and medical device adverse effects, they must report that information to the Minister of Health, Labour and Welfare and also to medical institutions. Medical professionals such as physicians, dentists, and pharmacists are also required to report any such information to the Minister of Health, Labour and Welfare in accordance with the “Pharmaceuticals and Medical Devices Safety Information Report System”. In FY 2007, approximately 32,000 cases of adverse drug reaction and around 17,000 cases of medical device adverse effects, based on the

Pharmaceutical Affairs Act, were reported annually.

In addition, marketing authorization holders of pharmaceuticals and medical devices are obliged to conduct early-phase post-marketing surveillance on those products that require careful verification of safety such as newly approved products. They must also provide information of rational use of pharmaceuticals and medical devices and promptly detect occurrence of serious drug adverse reactions and medical device adverse effects by, for example, periodically visiting medical facilities.

(2) Evaluation and Provision of Information on Adverse Drug Reactions and Medical Device Adverse Effects

The Ministry of Health, Labour and Welfare conducts immediate and appropriate evaluations of information on adverse drug reactions and medical devices adverse effects reported by marketing authorization holder and related medical professionals in cooperation with the Pharmaceuticals and Medical Devices Agency, and implements safety measures based on the results of the evaluations. In particular for urgent and important information, the Ministry orders marketing authorization holders to distribute emergency safety alert information (so-called a doctor letter) in order to promptly inform to medical institutions. In addition, information such as revision of instruction for use is provided through the monthly publication of “Pharmaceuticals and Medical Devices Safety Information”.

(3) Prediction- and Prevention-Oriented Active Safety Measures

In addition to these passive safety measures, i prediction- and prevention-oriented active safety measures are being enhanced and strengthened in cooperation with related academic societies, medical facilities, and marketing authorization holders. In order to detect and deal with patients suffered from serious adverse reactions in early phase, the Ministry have edited and provided “Manual for Detection and Treatment of Serious Adverse Reactions by Symptom” that summarizes early symptom, detection and medication in collaboration with related academia since FY2005.

In addition, “Japan Drug Information Institution in Pregnancy” established the

National Center for Child Health and Development collects information of effect of drugs on pregnant women and fetus through consultations with pregnant women who are worried about effects of medicines taken during pregnancy.

Furthermore, the Pharmaceuticals and Medical Devices Agency has provided information for medical professionals, patients and their families by providing reports on adverse drug reactions reported from marketing authorization holders and “Patient Medication Guide” about drugs with information required special attention for patients prepared by drug marketing authorization holders since January 2006 through its website (http://www.info.pmda.go.jp). In addition, “Information Distribution Service for Pharmaceuticals and Medical Devices” is provided on this website so that information and notification on safety measures for pharmaceuticals, etc. can be promptly and accurately obtained.

2. Speeding up Approval Review of Pharmaceuticals and Medical Devices

(1) Measures to Promptly Provide Pharmaceuticals and Medical Devices

While the development of pharmaceuticals and medical devices is making rapid progress, it has been pointed out that pharmaceuticals and medical devices used abroad are not being made promptly available in Japan. It is expected to provide safe and effective drugs and medical devices to people in a timely manner.

Under this circumstance, measures for faster and better review will be implemented aiming for reducing the time period before marketing of new drugs by 2.5 years based on the “5-Year Strategy for Creation of Innovative Pharmaceuticals and Medical Devices” formulated jointly by the Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and Industry, and the Ministry of Education, Culture, Sports, Science and Technology in April 2007 (and revised on May 2008 and February 2009). Concerning medical devices, measures will be taken to speed up and improve the quality of reviews by reducing the period required to grant approval by 19 months based on the “Action Program for Speeding Up Approval Review of Medical Devices” (formulated in December 2008).

More concretely, the following measures will be implemented: a) doubling the

number of pharmaceutical reviewers and quality improvement (increase of 236 staff members over 3 years from FY 2007), b) clarifying the review processes and standards and improvement in the operation of GCP (Good Clinical Practice), c) establishing a guidance on global clinical trials, d) discussions on the possible introduction of parallel scientific advice program for global clinical trials between regulators of Japan, the United States, and Europe, e) tripling the number and quality improvement of reviewers of medical devices (increase of 69 staff members over 5 years from FY 2009), f) clarifying the review standards of medical devices, and g) improvement in the operation of medical device GCP .

(2) Discussion on the Issues of Using Unapproved Drugs

With regard to domestically unapproved drugs that have been approved in the United States and Europe, the status of approval in the United States and Europe as well as requests from academic societies and patients have been regularly identified by a “Study Group on Unapproved Drugs” made up of experts since January 2005. The study group has been securing safety and opportunity for use of unapproved drugs by scientifically evaluating the clinical necessity and appropriateness of use and by leading them to domestic execution of clinical trials. The study group had a total of 21 meetings by the end of June 2009. So far the study group has reached conclusions on 45 cases where clinical trials should be started early and requested related enterprises to promptly conduct clinical trials on them.

(3) Discussion on Early Introduction of Medical Devices of High Medical Need

The “Study Group on Early Introduction of Medical Devices etc. of High Medical Need” (hereinafter referred to as the “Study Group on Need”) is held to discuss the early introduction of domestically unapproved or off-label use of medical devices and in-vitro diagnostics (IVDs) . The study group has met 11 times to date and selected 25 types of prioritized medical devices. Discussions are being made on concrete measures for early introduction of these products. Among them, 9 types of medical devices were approved and provided to the medical practice sites. Early introduction of medical devices and IVDs of high medical needs will be promoted in the future and will include making additional selection of products to be discussed by the Study

Group.

3. Revision of Sales System for Over-The-Counter Drugs

(1) Summary of Revision of Sales System for Over-The-Counter Drugs

To cope with the changing environments surrounding over-the-counter drugs in recent years including changes in people's consciousness and progress being made in separating dispensing from medical practice, the "Act to Amend the Pharmaceutical Affairs Act" (hereinafter referred to as the "Revised Pharmaceutical Affairs Act") was promulgated on June 14, 2006 to revise the entire over-the-counter drug sales system.

The revision can be summarized as follows: a) categorize over-the-counter drugs into 3 classes according to the degree of risk, b) establish a system of new type of professionals (registered sales persons) that differ from pharmacists to take a role in sales of over-the-counter drugs, and c) arrange an environment regarding sales of over-the-counter drugs to enforce on notifications at pharmacy/drug stores and labeling of the degree of risk so that purchasers can make the appropriate choice.

Regarding the Revised Pharmaceutical Affairs Act, the designations of the risk categories were executed on April 1, 2007 and an examination system regarding registered sales persons was implemented in April 1, 2008, and the law was entirely enforced in June 1, 2009.

(2) Measures for Enforcement

1) Designation of Risk Categories

Concerning designation of risk categories, a notification was promulgated on March 30, 2007 to designate First-class OTC drugs and Second-class OTC drugs. This classification of over-the-counter drugs calls for efforts to be made in the collection/evaluation of the up-to-date information on their appropriate use and will be revised as required.

2) Examination System regarding Registered Sales Persons

With regard to examinations for registered sales persons, a "Study Group on

Formulation of Guideline to execute Registered Sales Person Examination" was held to discuss the scope of test papers and execution schemes for the examination and compiled a report in June 2007. [1] [2] In consideration of this, the "Ordinance to Amend Enforcement Regulations of the Pharmaceutical Affairs Act was promulgated on January 31, 2008, and has been enforced in each prefecture starting in FY 2008.

3) Establishment of System and Environment Related to Sales of Over-the-Counter Drugs

Concerning the establishment of a system and environment related to sales of over-the-counter drugs, a "Study Group on Establishment of System and Environment Related to Sales of Drugs" was held, and a report was compiled in July 2008. In consideration of this, the "Ordinance to Amend Enforcement Regulations of the Pharmaceutical Affairs Act" (hereinafter referred to as the "Amended Ordinance" was promulgated on February 6, 2009, which stipulated that a) OTC drugs should be sold face to face by specialists, or by general sales persons under the supervision/instruction by the specialists ; b) Information on First-class and Second-class OTC drugs are provided face to face by specialists; c) Mail-order sales is only available for Third-class OTC drugs; d) OTC drugs should be displayed by risk category; [3] and e) Standards for buildings and facilities as well as a sales system to properly supply information should be observed.

In consideration that various opinions were gathered through the public comment for the aforementioned ordnance, a "Study Group on Smooth Implementation of a New Sales System for Pharmaceuticals" was held (7 meeting by May 2009). Taking into account the discussions made at this Study Group and aiming at taking provisional measures for the cases that purchasing drugs at pharmacies/drug stores is difficult, the "Ordinance to Amend the Ordinance to Amend Enforcement Regulations of the Pharmaceutical Affairs Act" was promulgated on May 29, 2009. More specifically, the amended ordinance stipulates that mail-order sales of Second-class OTC drugs are available until May 31, 2009: a) when they are sold to the residents of isolated islands without any pharmacies/drug stores; and b) when the same pharmacy/drug store sells the same drugs to those who had purchased

the drug before the enforcement of the amended Ordinance (June 1, 2009) and were recognized as having continuously used the drug at the time of enforcement.

4) Others

Efforts will be made to publicize the new system and make it well known among related people and the general public as well as to enlighten people on the appropriate use and promote knowledge on drugs and medical devices in cooperation with prefectures and related agencies/ organizations.

---

[1] "First-class OTC drugs" refer to: ① drugs whose adverse effects could cause health damage to the degree that might disturb daily life and have been designated by the Minister of Health, Labour and Welfare as the ones that require special attention for the usage ; and ② drugs whose active ingredients are distinctly different from those of the drugs whose production and sales have been approved but not passed a certain period of time after obtaining an approval.

[2] "Second-class" OTC drugs refer to those whose adverse effects could cause health damage to the degree that might disturb daily life (excluding First-class OTC drugs) and have been designated by the Minister of Health, Labour and Welfare.

[3] Third-class OTC drugs refer to OTC drugs other than First-class and Second-class OTC drugs.

4. Measures for Preventing Drug Abuse

(1) Measures against Narcotics and Stimulants

The number of drug offenders arrested reached approximately 14,000 in 2008. And the number of methanphetamine offenders was 11,000, and decreased over the previous year. The number of cannabis offenders, however, was a record high, and the situation of drug abuse in young generation especially those in their twenties appeared rampant and continued grave situation.

With regard to measures to prevent drug abuse taken by the government, the "Headquarters for the Promotion of Countermeasures to Drug Abuse" (changed the

name to the “Promotion Council for Countermeasures to Drug Abuse” in December 2008 as a subordinate organization of a Cabinet meeting on Crime Countermeasures) formulated “The 3rd 5-Year Strategy to Prevent Drug Abuse”, and comprehensive measures have been promoted in close cooperation with related ministries and agencies.

The control of drug offences has been implemented at the Narcotics Control Departments in Regional Bureaus of Health and Welfare (8 departments, 1 branch office and 3 annexes nationwide). The recent drug offences have become complicated and shrewd ranging from organized smuggling and illicit sales by organized crime group and drug trafficking organizations made up of foreigners including the Iranians, to trafficking over the cell phone or the Internet. In order to take countermeasures against them and to strengthen control of drug offences, the structure for investigation has been enhanced by increasing narcotic control agents and cooperation with related organizations has been promoted. Furthermore, marijuana abuse has recently become a social issue, and hence, control has been implemented in cooperation with related organizations and making the most of regulations of the existing laws.

As measures to prevent drug re-abuse, consultation programs for drug abusers themselves and their families are provided in health centers and local mental and welfare centers. In addition, national campaigns like the “’No, Absolutely No!’ public awareness Promotion Campaign” has been taken place, enlightenment materials are distributed as enlightenment activities in accordance with developmental stage, and “caravan cars for drug abuse prevention” are used as effective public awareness activities in schools all over Japan.

Regarding the promotion of proper use on narcotics in medical field, efforts are being made to establish a system where narcotics used for pain relief are properly and smoothly made available and guidance and supervision given to narcotic handlers.

(2) Measures against Substances of Abuse not-controlled under the Narcotic Control Act and other legislation for drug control

Substances of abuse not-controlled under the Narcotic Control Act and other

legislation for drug control not only damage the health of abusers but also cause harm to public health as they can lead to narcotics or other illicit drugs being abused. Thus, they are designated as designated substances controlled by the Pharmaceutical Affairs Act. Furthermore, enlightenment campaigns on preventing any substance abuse are being conducted through distributing leaflets on the harmful effects and danger of such substances in addition to procurement investigations. Moreover, efforts are being made to impose further rigorous controls under the Narcotic Control Act, designating substances of narcotic as soon as they have been scientifically validated to have dependency and other psychotoxicity .

5. Improving the Quality of Pharmacists and Enhancing the Role of Pharmacy

(1) Improving the Quality of Pharmacists

It has become necessary to foster high-quality pharmacists in order to meet social demands being made in recent years such as promoting appropriate use of drugs in terms of the advance of medical technologies and the progress in separation of dispensing from medical practice. It is critical to enhance the quality of pharmacists through improving pharmaceutical education at universities and life-long learning after graduation.

Aiming at developing high-quality pharmacists, the education course at universities fostering pharmacists was extended from 4 years to 6 years so that they can foster practical abilities related to clinical affairs. As a result, graduates that have completed the 6-year school education course are qualified to take the National Examination for Pharmacists in 2006.

In FY 2007, the “Study Group on the System for the National Examination for Pharmacists” commenced discussions on the National Examination for Pharmacists in response to the revision of the educational curriculum due to the introduction of the 6-year pharmacy education system and compiled a report of the study group in July 2008. Through the discussions at the Committee on Pharmacists within the Medical Ethics Council, question standards for the new National Examination for Pharmacists and a whole examination system will be established.

In addition, discussions have also been conducted on the future trends in the

supply and demand of pharmacists in estimating the effect of an increase in the number of pharmacy students, which may arise from the increase in the number of Schools of Pharmacy and Faculties of Pharmaceutical Sciences in addition to the further specialization of pharmacy students and changes in workplaces due to the introduction of the 6-year course. Furthermore, the pharmacists who are imposed administrative sanctions discussed at the Medical Ethics Council have been obliged to take reeducation program since April 2008.

New training focused on the fields of medical pharmacy and practical training that had not been taken in the 4-year course has been conducted. It has been started to improve the quality of pharmacists that had completed the 4-year course before introduction of the 6 year-course since FY2007. In addition, specific field training on cancer drug therapy has been conducted since FY2006 in order to train pharmacists specialized in cancer with advanced knowledge and skills.

(2) Enhancement of Roles of Pharmacies and Promotion of Separation of Dispensing from Medical Practice

The “Act to Amend the Medical Care Act for Establishment of the System to Provide High Quality Medical Care” was enacted in 2006 to enhance the functions of pharmacies so that pharmacies can further contribute to community medical care. Based on this law, pharmacies were positioned as medical care provision facilities in April 2007, and are now expected to make contribution as bases for supplying pharmaceuticals under the regional medical care plan.

In addition, efforts are being made to promote the separation of dispensing from medical practice with aim of ensuring the appropriate use of drugs. In FY 2007, the number of prescriptions issued by external pharmacies was approximately 680 million. The rate of separation was estimated at 57.2%, of which increase of 1.4% from the previous year (according to the Japan Pharmaceutical Association).

It is necessary to continuously promote a high quality system based on the medical care plan, etc. in accordance with the actualities of respective regions. Therefore efforts will be made to improve the quality of separation of dispensing from medical practice through enlightenment that enables to realize the appropriate use of

pharmaceuticals, and the project to collect “hiyari-hatto cases” to secure medical safety at pharmacies.

6. Recent Development in Blood Business

(1) Promotion of Blood Donations

In recent years, the number of blood donors has been decreasing with remarkable decrease especially among young donors. Accordingly, various measures have been taken to promote blood donations through the Reform of Blood Donation Structure, which set up following goals to be achieved in about 5 years from 2005: a) increasing the number of young donors, b) securing stable group blood donations, and c) increasing multiple donation givers.

As a result, in 2008, total number of donors rose to 5.08 million (an increase of about 140,000 people or 2.8% up from the previous year), and the amount of donated blood reached 1.97 million liters (an increase of about 80,000 liters or 4.2% up over the year before). Both the number of donors and the amount of donated showed a sign of recovery.

Looking at changes in the number of blood donors by age group, however, the number of donor in their 20’s has leveled off and that of teen donors has been shrinking, showing ongoing downward trend of young blood donors. Accordingly, the “Study Group on Blood Donation Promotion” was established in September 2008 to hold discussions from various angles on measures to promote blood donation in the future including revision of blood collecting standards, and compiled their proposal in February 2009.

(2) About the Restrictions on Blood Donation from People who have been to Europe

A vCJD (variant Creutfeldt-Jakob disease) patient was discovered in Japan for the first time in February 2005. In order to prevent any outbreaks of vCJD through blood transfusions, it was agreed in March 2005 that blood donations from people who had been in the United Kingdom for one day or longer anytime between 1980 and 1996 would be temporarily restricted from giving blood, and was put into effect in June.

Best efforts are being made for secure blood donations and promote their appropriate use in cooperation with related institutions to avoid any confusion in medical practices caused by a shortage of blood products due to this restriction.

(3) System to Provide Vaccines

Vaccines contribute to public health as a means of preventing infectious diseases in Japan. It has become necessary, however, to establish a system for developing and providing vaccines that includes risk management to cope with the new threats to public health which have emerged in recent years, such as the new types influenza and re-emerging infectious diseases. In the meantime, internationalization has progressed as seen in vaccines produced abroad also being used in addition to those made in Japan in response to medical demands. Under such circumstances it is necessary to secure a stable supply of vaccines while maintaining their quality, in consideration of the fact that it is difficult to increase production of vaccines in response to demands in a short period of time, unlike general chemical drugs.

In light of this various issues with developing and securing the stable supply of vaccines required in Japan were published in March 2007 as the “Vision for Vaccine Industry”. The “Vision of the Vaccine Industry Promotion Committee” has also met with discussions being made on promoting the measures provided in the vision.

7. Sefety Measures for Chemicals

(1) Acquisition of Safety Information on Chemicals

Under the “Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.” (hereinafter referred to the “Chemical Substances Control Act”), the government regulatesmanufacture, import, etc. of new chemicals, which have not been manufactured or imported before. The regulation is based on toxicity of a new chemical, and the toxicity is reviewed before the chemical is manufactured or imported. Regarding the safety of existing chemicals, the government conducts toxicity tests of those chemicals. In addition, information on the safety of chemicals at high production volume has been collected internationally by Organization for Economic Co-operation and Development (OECD) and also througha joint program

among the private and the public sectors for collecting and releasing safety information of Japan HPV existing chemicals (named "Japan HPV Challenge Program").

In recent years, the international environment regarding the management of chemicals has been drastically changing; for instance, a new regulation on chemicals has been established in Europe. In consideration of these circumstances, the Ministry of Health, Labour and Welfare started discussions to revise the “Chemical Substances Control Act” with the Ministry of Economy, Trade and Industry and the Ministry of the Environment in January 2008, and the report of the related councils was compiled in December 2008. In consideration of the report, the amendment bill was approved by the cabinet council in February 2009, and the revised law was promulgated in May 2009 after having deliberated at the Diet. The revised law stipulates that manufacturers/importers which manufacture/import more than a certain amount of chemicals including the existing ones are obliged to report the amount, etc. every year in order to implement the risk assessmentsteadily and also to promote rigid management of chemicals in Japan. Concerning chemicals which will be regulated under the international treaty, the regulation will be revised to approve their exceptional uses under rigid control, which are allowed by the international treaty, for the purpose of global harmonization of chemical regulations .

(2) Safety Measures for Household Products

In order to prevent health damages caused by chemical substances used in household products, regulatory standards have been set for textile products, cleaning agents, and timber for gardening in accordance with the “Act for the Control of Household Products Containing Harmful Substances” (as of the end of FY2008, standards had been set for 20 substances). In addition, health damage report system in relation to household products has been implemented.

(3) Safety Measures for Poisonous and Deleterious Substances

With regard to chemical substances, which are strongly poisonous or deleterious, necessary control has been implemented from a viewpoint of public health and hygiene through revising designation of poisonous or deleterious substances under

the “Poisonous and Deleterious Substances Control Act” and regulations for handlers. As of the end of FY2008, 104 items had been designated as poisonous substances and 364 items as deleterious substances in accordance with the law.

Section 3. Promotion of Safety Measures with Food to Secure Public Health

1. Measures for Securing Safety of Food Required of the Ministry of Health, Labour and Welfare

The situation with dietary habits in Japan has drastically changed over recent years due to advances in production technologies and an increase in imported foods. And as a result is that people's interest in food has grown day by day.

In the mean time, due to the issues of BSE and pesticide residues as well as cases of drug-poisoning cases involving Chinese frozen 'gyoza' dumplings that took place in 2008, requests for securing the safety of food are also increasing.

Because of this the establishment of the Food Safety Basic Act in 2003 and revision of the Food Sanitation Act clarified the roles of risk evaluation institutes in evaluating the health effects of food and risk management institutions in formulating specifications and standards as well as carrying out the relevant managerial work. In consideration of new established framework, the Ministry of Health, Labour and Welfare is making the effort to promote food safety in cooperation with local governments and related ministries and agencies, and with support from the public.

2. Current Situation with Safety Measures for Food

Some of the key food safety measures are described below.

(1) Revision of Specifications and Standards

1) Confirmation of the usage/distribution and the safety on existing food additives

Since the establishment of the Food Sanitation Law in 1947, chemically synthesized food additives can be used or marketed only when those are designated as safe by the Minister of Health and Welfare (at the time). Subsequently, at the revision of the law in 1995, the application of designation system was extended to so-called "natural additives" (except fo natural flavoring agents and substances that are both generally provided for eating or drinking and used as food

additives) to respond to the possibility of food additives derived from plants and animals without experience of consuming as food being used as food additives.

However, 489 items of “natural additives” already in the marketd at 1995 were permitted to be used as “existing additives” continuously because they have been experientially used as food additives without any health effect occasions.

The Ministry of Health, Labour and Welfare has promoted confirmation of their safety systematically. In addition, existing food additives that are determined to be no longer marketed are withdrawn from the List of Existing Food Additives. To date, one item with safety problem and 70 items not in use have been withdrawn. As of July 2009, 418 existing additives had been permitted for use/distribution.

2) Revision of Japan's specifications and standards for food additives

The Minister of Health, Labour and Welfare established the standards and specifications for food additives, and prepares “Japan’s specifications and standards for food additives” to clarify the regulations on food additives and to promote the appropriate usage of food additives. The updating of the publication is conducted to provide new information on specification and standards, and to accommodate the progress of manufacturing technology, quality control and testing methodology, approximately every 5 years. The latest edition was published in 2007.

On revision of Japan's specifications and standards for food additives, a study group consisting of professional and academic people makes discussions on reviewing the general evaluation methods and standards of ingredients and improving the descriptions of specifications for existing additives. In consideration of the results of discussions, the”Specifications and Standards for Foods, Food Additives, etc” that lists specifications and standards related to food additives is also revised.

The 9th revision of Japan's specifications and standards for food additives will be prepared after setting up a study group.

3) Positive list system for agricultural chemical residues in foods

On May 29, 2006 the Ministry of Health, Labour and Welfare (MHLW) introduced the positive list system for agricultural chemicals remaining in foods — the 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 agricultural chemicals include pesticides, feed additives and veterinary drugs.

After enforcement of this system, a case arose in which unintentional pesticide residue was found in aquatic animals. Methods for establishing MRLs for such cases are being developed in Health and Labour Science Research Grants Programs, and discussion is being made on setting Pesticide Residue Standards for aquatic animals as required.

MRLs have been established for 817 agricultural chemicals by July 2009, including MRLs set after enforcement of the system.

Since the year 2006, the MHLW has formulated plans annually and asked the Food Safety Commission to conduct safety evaluation for agricultural chemicals that were newly established at the introduction of the system. Based on the Commission's assessment, the Pharmaceutical Affairs and Food Sanitation Council have reviewed the MRLs.

The MHLW will continue to strive to make the system known in and around Japan and to develop analytical methods in order to ensure the appropriate and smooth implementation of the system.

4) Measures for Apparatus, Containers / Packaging, and Toys

Concerning apparatus and containers/packaging, specifications and standards are being formulated in order to prevent sanitation hazards caused by drinking/eating. On July 31, 2008, the specifications and standards for lead were enhanced for glass, ceramic, and enameled equipments and containers, metal apparatus and containers/packaging, and raw materials, of metal products. In view of global harmonization, discussions are being made on introducing the positive list system for chemicals used for plastic apparatus and containers/packaging and on revising the specifications and standards for phthalates used for polyvinyl chloride apparatus and containers/packaging. With regard to bisphenol A used for containers, necessary measures will be taken based on the results of evaluations by the Food Safety Commission.

In addition, the Minister of Health, Labour and Welfare designates toys, which may

pose health hazards to infant through contact therewith, and establishes the specifications and standards. On March 31, 2008, the scope of the toys designated by he Minister of Health, Labour and Welfare was expanded, and specifications and standards were established for lead contained in coatings of toys. Concerning polyvinyl chloride used for toys, use of two types of phthalates has been restricted since 2002. Taking into account the global consistency, discussions are being made on revising the current specifications and standards.

(2) Establishment of monitoring and Inspection System

1) Plan-based monitorning and guidance

For the purpose of securing food safety, it is critical to implement monitoring and guidance in cooperation between the Ministry of Health, Labour and Welfare and related administrative organizations such as prefectural governments. In order to carry out their intensive, efficient, and effective implementation, "The Guideline for Implementation of the Monitoring and Guidance regarding Food Sanitation" was established. In addition, the Ministry of Health, Labour and Welfare is to formulate, announce and implement a supervision and instruction plan every year for imported food, while prefectural governments will be in charge of making domestically-traded food plans with consideration given to the actualities of their respective regions.

2) Securing Safety of Imported Foods

(Situation with imported foods)

The reported number of cases and volume of imported food have been increasing every year, reflecting the decline in the Self-Sufficiency Ratio of Food and diversity of consumer needs.

(Efforts for securing safety of imported foods)

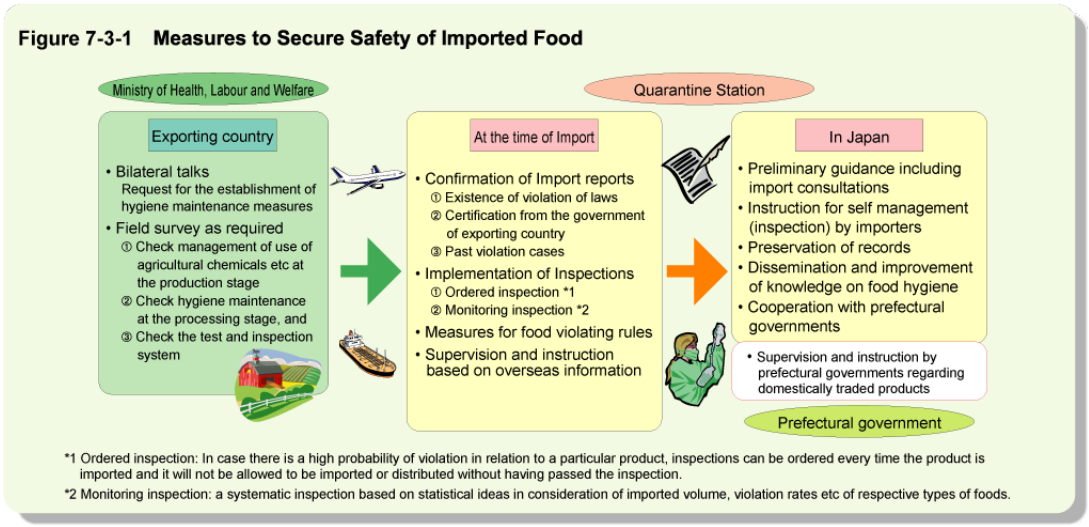
To secure the safety of imported foods, the Ministry of Health, Labour and Welfare formulates a "Monitoring and Guidance Plan for Imported Foods" every year in implementing intensive, effective, and efficient supervision and inspections. In this plan governmental organizations take measures at three stages: in export countries, at the time of import (shoreline), and during the process of domestic distribution (see

Figure 7-3-1). If any violations are repeatedly detected in the system, bilateral talks or on-site inspections as required are conducted in consideration of prohibiting the export of the relevant food stuffs, while requesting the relevant exporting countries to take measures at the production/manufacturing stage.

In addition, in order to prevent the occurrence of incidents, the number of inspectors at quarantine stations has been substantially increased; sophisticated inspection equipments were installed to be used for inspecting organo—phosphoric pesticide contained in processed food in the FY 2008 first supplementary budget; and in FY 2009, information collection and evaluations related to sanitation maintenance measures to be taken by exporting countries are being promoted in addition to conventional bilateral cooperation and on-site inspections conducted when a problem occurs.

According to the “Statistics of Imported Food Monitoring” (2007) prepared by the Department of Food Safety, Pharmaceuticals and Food bureau of the Ministry of Health, Labour and Welfare, inspections at the time of import were conducted for 200,000 cases, or 11.0% of the total reported number of import cases of 1.8 million. Violations were detected in 1,150 cases (0.1% of the reported number) of the inspected cases. Standards on the ingredients of frozen foods, standards of additives use, and standards of pesticide residues in vegetables are violated often. The food involved in violations was disposed of or returned.

Figure 7-3-1 Measures to Secure Safety of Imported Food



*1 Ordered inspection: In case there is a high probability of violation in relation to a particular product, inspections can be ordered every time the product is imported and it will not be allowed to be imported or distributed without having passed the inspection.

*2 Monitoring inspection: a systematic inspection based on statistical ideas in consideration of imported volume, violation rates etc of respective types of foods.

3) Measures against food poisoning

As a result of the development of a distribution system in recent years there is a growing concern that food poisoning outbreaks could spread throughout wide areas. In 2007, prefectural governments reported 1,289 cases of food poisoning, with the number of patients being 33,477 and with 7 having died (Note). The number of case has been declining since 1998, when it reached a peak, and the number of patients in 2007 decreased by 5,500 from that in 2006 (39,026 patients).

Although the major cause of food poisoning has traditionally been bacteria such as Campylobacter and Salmonella, increases in viruses such as the Norovirus have also been reported in recent years. Food poisoning cases caused by the Norovirus, in particular, resulted in more than 20,000 patients being reported in 2006, a large increase from 2005 and earlier in which the number of patients was around 10,000 annually. As there are many genotype of Norovirus, it is impossible to increase their number for use in cultured cells or in experimental animals, and it is often difficult to clear up the cause or identify the route of infection because patients have been infected through contact with other people in many cases, and hence problems remain unsolved for taking measures against it.

The Ministry of Health, Labour and Welfare is promoting basic research that will contribute to measures against bacterial food poisoning and viral food poisoning. In addition, a Q&A on Campylobacter and Norovirus is being disclosed through the website of the Ministry of Health, Labour and Welfare so that people can extend their understanding of the correct knowledge on food poisoning and thus take preventive measures.

In consideration of drug-poisoning cases involving Chinese frozen ‘gyoza’ dumpling which occurred in January 2008, the Management Office of Foodborne Disease Surveillance was established in April 2009 within the Inspection and Safety Division, Food Safety Department, Pharmaceuticals and Food bureau of the Ministry of Health, Labour and Welfare in order to aggregate/centralize information on food poisoning from prefectures. In addition, an Information Corner for Health Damage Caused by Foods was launched on the website of the Ministry of Health, Labour and Welfare for the purpose of extensively collecting and identifying information on health damages caused by eating/drinking.

(Note) Cause of death (including estimates): animal natural poison (3 person from fugu poison), vegetative natural poison (2 person from mushroom, 1 person from colchicum, 1 person from a bulb of Gloriosa rothschildiana)

4) BSE measures

(Measures against outbreak of BSE in Japan (Note))

In response to the increase in European nations where BSE (Bovine Spongiform Encephalopathy) has broken out, the Ministry of Agriculture, Forestry and Fisheries and the Ministry of Health, Labour and Welfare have been promoting the establishment of an inspection system for BSE. The first BSE case in Japan was detected in September 2001. And in response, elimination and incineration of specified parts (heads excluding tongues and cheeks, the spinal cord, and the distal ileum) were made compulsory on October 18, 2001, covering all cattle processed and used for food. At the same time BSE inspections were introduced at all slaughterhouses in Japan. And hence a system to stop the distribution of beef etc from BSE-infected cattle has been established.

On September 9, 2004, assessments and inspections related to domestic measures against BSE were summarized by the Food Safety Commission. The Ministry of Health, Labour and Welfare, together with the Ministry of Agriculture, Forestry and Fisheries, questioned the Food Safety Commission on revision of domestic BSE measures (so-called risk management measures) on October 15, 2004 and the commission submitted a report on May 6, 2005. In response to this report, the system was amended so that only cattle 21 months old or older will have to undergo BSE inspections.

As of March 2009, and as a result of BSE inspections conducted at slaughterhouses, 21 BSE infected cattle had been identified. In Japan, 36 cattle have been confirmed as infected with BSE, including the 21 cattle mentioned above,

the first cow being discovered in 2001, and 14 dead cattle. As a measure for BSE, cease of pishing had been promoted because it could contaminate dressed carcass through blood circulation and enhance the risk of BSE to meat, while paying attention to the balance of securing safety for both meat and workers. In consideration that pishing was ceased at all slaughterhouses in April 2009, the Ordinance for Enforcement of the Slaughterhouse Act was revised to prohibit pishing also in the system.

(Measures against outbreak of BSE in the United States etc)

Beef and beef products imported from countries where BSE has broken out, including EU nations, are not allowed to be imported until having had confirmed an equivalent safety level to Japan, in making it absolutely certain that the safety of these products traded in Japan is secure.

In response to the BSE outbreak in Canada in May 2003 and in the United States in December 2003, importation of beef produced in Canada and the United States was prohibited. Since then, however, discussions have been held with the United States etc. on resuming the beef trade. Taking into consideration the results of evaluations on the impact of food on health by the Food Safety Commission, importation of beef produced in the United States and Canada was then resumed on December 12, 2005. However, veal including spinal columns did arrive from the United States on January 20, 2006, and hence importation of all beef produced in the United States was then ceased.

Subsequently, taking into consideration a report from the US government that clarified the cause and recurrence preventive measures against it and the results of exchanging opinions with consumers, field surveys of qualified facilities exporting beef to Japan were conducted by Japan, and the importation of US-produced beef was then resumed on July 27, 2006.

Japan is verifying the compliance status of the US import program to Japan through conducting regular field surveys that include accompanied surprise inspections in the United States and import inspections at quarantine stations. Efforts will continue to be made to ensure that the import program to Japan is being observed by the United States and that the appropriate information is being provided

to consumers.

In addition, a request was made by the United States to review the import conditions in following standards laid down by the World Organisation for Animal Health (OIE) in June 2007. In response to this, technical discussions were held between executives in Japan and the United States in June and August 2007. A report on the discussions is being jointly compiled by these two countries. It will be handled utilizing scientific knowledge in cooperation with the Ministry of Agriculture, Forestry and Fisheries with the provision that the safety of food and consumers' trust is the major premise.

(Note) Division of Roles between Related Offices and Ministries with BSE Measures

The Ministry of Health, Labour and Welfare promotes measures to secure the safety of meat in compliance with the Act on Slaughterhouses and Food Sanitation Act. The Ministry of Agriculture,

Forestry and Fisheries promotes measures to prevent infectious livestock diseases and secure the safety of livestock feed at the production stage in compliance with the Act on Domestic Animal Infectious Diseases Control and the Act on Securing the Safety of Livestock Feed and Improving Quality. These two ministries are in charge of managing the risk (the probability of emergence and degree of adverse impacts harmful substances in foods could cause on health as a result of being eaten).

On the other hand, a Food Safety commission within the Cabinet Office, which was organized in 2003,

evaluates risks (evaluations on the impact of food on health) independently of other related administrative organizations managing risk. These related office and ministries closely cooperate in taking measures.

5) Measures for individual problems related to foods made in China

(Measures for drug-poisoning cases involving Chinese frozen 'gyoza' dumplings)

Ten cases of suspected organophosphorus poisoning from people eating Chinese frozen 'gyoza' dumplings imported from China in Chiba and Hyogo prefectures have

occurred since December 2007. Later, as a result of inspections by related organizations, it was reported that methamidophos, an organophosphate insecticide, had been detected, in amounts exceeding standard values from packaging of the products and Chinese-style dumplings, in vomit.

In response to this, the Ministry of Health, Labour and Welfare made the public announcement that people should avoid eating the product and ordered an immediate recall after receiving the information from the viewpoint of preventing any further damages. In addition, the government compiled “Preventive Measures against Recurrence of Drug Poisoning Cases through Food” (related ministers’ agreement on drug poisoning cases through food) on February 22, 2008.

In accordance with this, Article 73 of the Ordinance for Enforcement of the Food Sanitation Act was revised in April 2008 to expand the scope of food poisoning cases that prefectural governors are required to report to the Minister of Health, Labour and Welfare immediately as part of improving the system of collecting/centralizing information. In addition, the “Guidelines for Managerial/Operating Standards to be implemented by Business Operators of Foods” for establishing a Prefectural Ordinance was revised so that rules for business operators of foods to promptly make reports to health centers were established. Furthermore, the scope of the processed foods which are subject to pesticide residue inspections at quarantine stations has been expanded, starting from the one those inspection has become technologically available. In addition, the “Guideline on Hygiene Control of import Processed Foods” was compiled in June 2008 with the aim of increasing hygiene maintenance in importing countries.

(Measures against the Cases of Milk and Dairy Products laced with melamine made in China)

In response to the confirmation in China of melamine contaminated milk and dairy products laced with melamine made in China, the Ministry demanded the Chinese government to investigate details and provide information.

In consideration of this, importers of processed foods made with milk or dairy products imported from China were instructed through quarantine stations to conduct melamine-related self inspection of the products having been imported in

the previous year. For the products imported after that, the importers were ordered to carry out melamine-related inspection. As a result, prefectures were asked to order a recall to related importers when melamine is detected

In October 2008, on the heel of the case that melamine was detected in eggs contaminated through feed, it was decided that a prefecture orders voluntary recall to the concerned business operators when more than 2.5 ppm of melamine residue, which is an regulated amount of melamine residue set by various foreign countries, is detected in foods which were contaminated through feed. In addition, importers were instructed through quarantine stations to conduct melamine-related self inspection of eggs and egg products from China.

In November 2008, following the case that melamine was detected in the processed foods that contain the addictives made by the specific Chinese companies, melamine-related inspections were ordered through quarantine stations to the importers of the concerned additives and the foods containing them.

Efforts will be continuously made to strengthen measures for imported food safety through increasing the number of food sanitation inspectors at quarantine stations and providing inspection equipments.

6) Securing safety of health foods

Because of people's growing interest in their health, various health foods are now being sold as health food. Some of them never before generally served for human consumption and others are in a peculiar form. In July 2008, the 'Study Group for Securing Safety of "Health Food"' compiled a report aiming at supplying safe and secure products to consumers.

The report stated that "concrete measures to secure safety of "health foods" at production stage" need to be enhanced, including Raw Materials Safety Self-Inspection Guidelines and Proper Management of Production Process Guidelines. In addition, it is appropriate to pay attention to securing safety of raw materials and securing safety as well as effectiveness through management of production process in order that consumers can understand those measures. At the same time, the report suggested that "enhancement of a system to collect and process information on health damage" and "dissemination and enlightenment for

consumers" need to be promoted. In consideration of this, it was decided that an independent organization, which is voluntary managed by an organization of business operators, authorizes each food for its securing of raw materials safety, and securing of safety of management of production process following the guidelines established by the Ministry of Health, Labour and Welfare. Guidance will be continuously provided to business operators of foods in order to enhance a system to collect and process information on health damage.

3. Providing Accurate and Clear Information

(1) Promotion of Risk Communication

1) Risk communication

Provision for risk communication (exchanging information and opinions on risk) was included in the Food Safety Basic Act of 2003 as an important factor in risk analysis. More concrete provisions for listening to citizens and residents (so-called risk communication provision) were also included in the Food Sanitation Act that provides measures for securing individual food safety (risk management measures).

2) Current situation with measures and future plans

The Ministry of Health, Labour and Welfare is taking measures on risk communication in cooperation with the Food Safety commission within the Cabinet Office, the Ministry of Agriculture, Forestry and Fisheries, and local governments.

Taking into consideration the results of discussions made at the "Study Group on Risk Communication on Food Safety", operating plans for programs were formulated in March 2005, and opinion exchange meetings on safety measures for imported foods, a positive list system of pesticide residues, the BSE issue, health foods, and food additives have been regularly held since FY 2005. In order to promote risk communication in the future, it is important that the public are accurately acknowledged of the risks of foods, select the information, and make a judgment based on the information they selected. Hence, the "Discussion Group on Information Provision related to Food Safety" was established in July 2008 and had a total of 4 opinion exchange meetings with the parties concerned by March 2009

aiming at extensively listening to the opinions concerning information provision by the governments and mass media and those on risks of foods.

In addition, efforts are being made including distribution of various pamphlets, improving the content of websites, and promoting cooperation between related organizations and consumer organizations.

Opinion exchange meetings with related entities, including consumers, will be continued to be actively held. In addition, improvements will be repeatedly made to make the system better by taking into consideration the “Improvement of Risk Communication on Food Safety” compiled by the Food Safety Commission in 2006.

(2) Food Labelling

1) Revision of food labelling

The food labelling system was established to secure the safety of food and offer information that helps consumers to select food products. It has been pointed out, however, that the system is difficult for both consumers and business operators of food to understand, because there are different regulations based on multiple laws such as the “Food Sanitation Act” and the “Act Concerning Standardization and Proper Labelling of Agricultural and Forestry Products” known as the “Japanese Agricultural Standards (JAS)Act”).

In consideration of this, since December 2002, the Ministry of Health, Labour and Welfare and the Ministry of Agriculture, Forestry and Fisheries have jointly held “Study Group on Food Labelling” meetings with the aim of establishing a more easily understandable food labelling system.

Based on discussions held in the joint meetings it was agreed that the expiration date of food which quality deteriorates rapidly, within about five days including the production date, shall be labelled uniformly as “use-by dates" while the expiration dates of foods whose quality does not deteriorate for a relatively long time shall be labelled as freshness dates.

In addition, discussions on the system of allergy labelling introduced in 2001 have been made. And as a result bananas were added to the list of materials which labelling is recommended in 2004, and in 2008, shrimps and crabs were added to the list of materials which labeling is obligated. In 2005 and 2006, additions to the

subjects of labelling of genetically modified foods were also made.

In order to strengthen the supervision of inappropriate food labelling in cooperation with the Cabinet Office, Fair Trade Commission, National Police Agency, and the Ministry of Agriculture and Forestry in response to the “Safety Life Project - Emergency Concrete Measures” (related cabinet members meeting agreement on “Safety Life Project” on December 27, 2007) of the government, “Food Labelling Supervision Councils” have been established at related prefectureal governments and local agencies of the government to share and exchange information on food labelling. In addition, a “Food Labelling Conference” was established for the above related ministries and agencies to share related information so that required measures, including disposition of violating business operators, in accordance with the laws related to food labeling can be taken promptly and smoothly.

Three legislations related to the Consumer Affairs Agency (the “Consumer Affairs Agency and Consumer Commission Establishment Act”, the “Act on the Arrangement of Related Acts that Accompany the Enforcement of the Consumer Affairs Agency and Consumer Commission Establishment Act”, and the “Consumer Safety Act”) were approved on May 29, and promulgated on June 5, 2009. They are to be enforced on the day specified by Cabinet Order within a period not exceeding one year from the date of promulgation. Based on them, the food labeling system will be implemented by the Consumer Affairs Agency.

2) Prohibition of false/exaggerated advertisements

With the recent growth in health consciousness in a health boom, food is being advertised on various media, including the Internet, as healthy to promote sales. Some of the advertisements make people expect certain health maintenance / promoting effects, although they have not always been proved. Without sufficient controls on such advertisements, they can seriously harm the appropriate health maintenance/promotion of people who have believed them, who may lose their opportunity for proper treatment. Because of this advertisements that “remarkably differ from the facts” or are “particularly misleading” (false/exaggerated advertisements) about the health maintenance/promotion effects of substances sold as food are being prohibited under the Health Promotion Act.

(3) Information Collection and Research for Securing Food Safety

As dietary habits have diversified, the risks to health caused by eating/drinking are also becoming more diverse. Hence it is necessary to collect variety of information both domestically and from abroad, have related institutions share it, and then implement risk management measures based on science in securing food safety.

With the system used to collect information, information on food safety both domestically and from abroad is collected, analyzed, and distributed to related entities by Division of Safety Information on Drug, Food and Chemicals of the National Institute of Health Sciences. The Drug, Food and Chemicals of the National Institute of Health sciences Reseach collects, analyzes and distributed information to national and local government organization. Research on securing food safety is also being conducted at national research institutions. In addition, a broad range of research is being conducted through Health and Labour Science Research Grants that includes investigation/research on formulating specifications and standards, research/development on establishing official inspection methods, and research on safety.

(4) Revising a System of Food for Special Dietary Uses

A system of food for special dietary uses (excluding specified health food) is a system based on the regulations of the Health Promotion Act, which makes it mandatory to obtain approval from the Minister of Health, Labour and Welfare in order to display that the food for sale is appropriate for a specified purpose including foods for infants, children, pregnant/lactating women, or for the ill.

With the recent expanding medical expenses resulted from aging of society and growth of patients of lifestyle related diseases, the environments surrounding a system of food for special dietary uses have been significantly changing such as remarkable progress of medical science and dietetics, and establishment of a system for nutrient function claims. In consideration of such a situation, the “Study Group for Improving the System of Food for Special Dietary Uses” compiled a report in July 2008, which revised the scope of the subject foods, for instance by including general nutritive food in medical foods for the ill. In response to this, the Ministry of

Health, Labour and Welfare revised the ordinances and notices and put them into effect in FY 2009. Efforts will be continuously made to publicize the contents of the revisions.

4. International Efforts for Securing Food Safety

(1) Designation of Additives which Safety Evaluations have Internationally Confirmed

Efforts have been made since 2002 to achieve international consistency with regard to widely-used food additives for which safety evaluations have been internationally established.

More concretely, with additives a) which safety has been confirmed by the Joint FAO (Food and Agriculture Organization)/WHO (World Health Organization) Expert Committee for Food Additives (JECFA) to a certain extent and b) which usage is freely permitted in countries such as the United States, EU countries and which necessity is deemed high internationally, discussions will be made on the safety and necessity of the respective aim of designating them without being petitioned to do so by enterprises.

Food additives that satisfy the above selection criteria have their order of priority fixed, with information being collected in that order of priority. By July 2009, the Food Safety Commission has been requested to conduct evaluations of the impact on health of 36 food additives and 29 flavoring agents. Of them, 26 food additives and 20 flavoring agents have already been designated after being evaluated by the Food Safety Commission and through consultations with the Pharmaceutical Affairs and Food Sanitation Council.

(2) Activities related to Codex

The Codex Alimentarius Commission (Codex) is an international intergovernmental organization jointly established by Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO) in 1963 to develop food safety and quality standards. The mandate of Codex is to protect the health of the consumers and to ensure fair practices in the food trade. Codex standards and

related texts are referred to as international standards in the SPS Agreement, which encourages to harmonise national regulations with the international standards under the multilateral trade agreement of the World Trade Organization (WTO). Japan has become a member of Codex as of the year 1966. The constituency of Codex comprises 182 countries and one member organization the European Union as of July 2009.

As the Codex standards, guidelines and other related text for food safety greatly affects risk management measures in Japan. The Ministry of Health, Labour and Welfare (MHLW), in collaboration with the Ministry of Agriculture, Forestry and Fisheries (MAFF) and relevant research institutes, actively participates in activities of Codex work. At national level, consultative meetings on Codex, organized by MHLW/MAFF are held to exchange views and information related to Codex work between the government and stakeholders including consumers.

Section 4. Promotion of Preventive Measures against Suicide

As the number of people who have committed suicide remains high at around 30,000 annually since 1998, measures against suicide have become an urgent issue. Considering this, and in response to the Basic Act on Suicide Prevention approved in 2006, the “General Policies of Comprehensive Measures against Suicide” (hereinafter referred to as the “General Policies”) was formulated in June 2007 as guidelines for measures to be promoted by the government. The General Policies provided for measures against suicide to be strongly promoted in close cooperation between the government, local governments, medical institutions, and public organizations, and the goal set of reducing the death rates from suicide by 20% or more from that of 2005 by 2016. The General Policies were revised in October 2008 to strengthen measures for people with high risk of suicide except patients suffered from depression.

The Ministry of Health, Labour and Welfare has been making efforts, including providing information at the Suicide Prevention Comprehensive Measure Center established in the National Institute of Mental Health of the National Center of Neurology and Psychiatry (established in October 2006), promoting effective measures against suicide and supporting measures of business operators in communities, improving the consultation system and human resource development for preventing suicide, and promoting/disseminating/enlightening the results of comprehensive investigations and research of suicide issues.

In addition, discussions on another important point with suicide measures, that of caring for families of people who have attempted/committed suicide, have been held since December 2006 and a report was compiled in March 2008. Based on the report, the guideline for consultation and support has been formulated, and training for workers in this field has been provided.

Section 5. Enhancement of Health Risk Management System

The Ministry of Health, Labour and Welfare has been promoting health risk management through establishing the required systems in accordance with the "Basic Guidelines for the Management of Health Risk" that was revised in January 2001 following restructuring of the ministries and other governmental agencies to ensure prompt and appropriate responses to health risks that threaten people's health and lives.

More concretely, the Ministry collects information from related departments and facilities as well as national research institutions. In addition, the related bureaus and offices of the Ministry work together to exchange information on health risks such as infectious diseases, food poisoning, drug related risks, and pollution of drinking water twice a month, including an executive meeting at the "Health Risk Management Coordination Conference", so that they can promptly implement proper health risk management measures. Furthermore, the Ministry has established 24/7 communication system. In the case of a serious health emergency occurring the Conference will be immediately convened to take the necessary measures, including establishing a headquarters, dispatching officials and experts to the place of concern, and providing health risk-related information to people. In order to establish regional health risk management systems, annual seminars are being held for prefectural officials.

Major examples of activities conducted by the Conference include measures against biochemical terrorism taken in view of the anthrax case that occurred in the United States in 2001, measures against biochemical terrorism taken after the occurrence of the Iraq issue in 2003, responding to the occurrence of the highly pathogenic bird flu appearing in Japan in 2004, responding to the health damage cases that are suspected as being caused by frozen Chinese-style dumplings produced in China and responding to non-edible rice in 2008, and responding to novel influenza in 2009.

Section 6. Stable Supply of Safe and High Quality Water

As water is essential to people's lives, it is necessary to ensure a safe stable supply of it. The total volume of water needed is approximately 16 billion cubic meters per year and Japan has the high level of water supply coverage of 97.4% (as of the end of March 2008). In order to supply safe water to all citizens, however, it is an urgent issue to supply it to those uncovered areas. In addition, efforts are being made to realize the "Waterworks Vision", which was formulated in June 2004 and revised in July 2008, so that safe, high quality water can be stably supplied in the future. In addition, water suppliers are being recommended to formulate a "Local Waterworks Vision".

1. Quality Management of Water Supply

In order to secure safe, high quality water that conforms to water quality standards, it is important to fully implement water quality management from the source of the water through to taps. Water quality standards had been set for 51 items as of the end of FY 2008 and are reviewed repeatedly taking into consideration the latest scientific knowledge through collecting knowledge and conducting research as required. As there is a concern that insufficient management of water tanks in buildings and apartment houses could cause contamination to water, complete management and switching to direct connection to the water supply system are being promoted. In addition, as measures against Cryptosporidium, which is an infectious protozoan that is resistant to chlorine, new treatment with ultraviolet light was approved for water treatment and a "Guidelines for Cryptosporidium Treatment in Waterworks" were formulated in March 2007.

2. Measures against Disasters including Earthquakes and Risk Management Measures

In order to secure a stable water supply for people, even in times of natural disasters including earthquakes or in emergency cases such as water quality

accidents, water suppliers are expected to secure the safety of core water supply facilities and have a prompt recovery system ready. Considering that water supply facilities were also suffered great damage in the Noto-Hanto Earthquake of March 2007 and Niigata Chuetsu-oki Earthquake of July 2007, an Ordinance of the Ministry on technical standards for water supply facilities was revised to clarify the earthquake-resistant functions that water supply facilities should provide in promoting measures against earthquakes (and enforced on October 1, 2008). The water supply facilities were suffered significant damage also in the Iwate Miyagi Nairiku Earthquake in June 2008. Efforts are continuously being made to promote measures to systematically improve the earthquake-resistance of existing water supply facilities. In addition, in response to the great damages to people's lives and the economy caused by the water supply being cut off for a long time because of excessive processing capacity caused by increased turbidity of raw water in Kitami City of Hokkaido in June 2007, the recurrence of such accidents was ensured not to happen through training for water service technological managers and national directors meetings at health, labour and welfare bureaus. Regarding risk management measures, guidance is being given to individual water suppliers in establishing a risk management system that includes measures against natural disasters and terrorism using a "Guidelines for Formulating Risk Management Measures Manual". To ensure a stable water supply is in place in the case of an outbreak of novel influenza, measures to be taken by water suppliers have been compiled in the "Guideline for Pandemic Influenza Preparedness at Waterworks" in October 2007 and revised as well as disseminated in February 2009.

3. Appropriate Maintenance/Management of Water Supply Facilities

Considering that the level required of water services is getting very high including advances in water quality management, aging facilities and their renewal, environmental measures, and measures against disasters and terrorism, on-site investigations have been conducted at water suppliers to identify whether appropriate management is being implemented or not. In FY 2008 on-site investigations were conducted at 58 water suppliers and written administrative

guidance made in 42 cases, according to consistency with the law, for which reports were submitted on the status with improvement.

4. Improvement of Managerial Bases

In order to improve the managerial bases of small-scale water suppliers, it is important to integrate/expand their services. Hence in FY 2008 subsidies were created for water suppliers to establish remote monitoring systems that integrate the small-scale water supply system to promote integration.

Section 7. Promotion of Environmental Health Measures

1. Development of Environmental Health Industries

"Environmental health industries" are industries that are closely related to people's lives and include barber shops, beauty salons, laundries, hotels and inns, public bath houses, places of entertainment, restaurants, cafes, butchers, and ice and snow shops. To facilitate the development of these industries and maintain/improve their health level, and thereby contributing to improved/enhanced public health and stabilization of people's life, various measures are being taken including consideration in budget, financing, and taxation.

For the purpose of promoting energy conservation in the environmental health industries, the FY 2009 budget included the programs for 4 groups with existing guidelines including restaurants/hotels and inns, barber shops/beauty salons, laundries, and places of entertainment/bath houses to stabilize their management with cost reduction brought about by energy conservation through the activities to formulate the guidelines for energy conservation. Through these programs, efforts are to be made to promote environment health industries.

In addition, the National Life Finance Corporation founded to make loans to environmental health business operators in order to maintain/improve the health level of environmental health industries, was integrated with other governmental financial institutions to establish the Japan Finance Corporation (JFC) in October 2008. Loans being made to environmental health business operators are succeeded by JFC. From April 2009, Loans for Business Promotion have been expanded in order to provide financial support for environmental health business operators.

2. Promotion of Health Measures in Buildings

Buildings of a certain scale used as places of entertainment, department stores, shops, offices, and schools (specific buildings) are obligated to be maintained/managed in accordance with the building sanitation management standards in securing health in buildings.

As buildings are becoming larger in scale and used in more complicated ways, advanced level maintenance/management of buildings is being required. In addition, there are issues such as the so-called “Sick House Syndrome”, which involves various health problems being caused by chemical substances in buildings. And hence a standard amount of formaldehyde in the air inside rooms was added in building sanitation management standards in 2003 to prevent such health damage from occurring.